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Geetanjali

Geethanjali College of Pharmacy

Approved By AICTE, PCI New Delhi, Permanently Affiliated to JNTUH & Accredited by NBA (B. Pharmacy)
Recognized Under UGC Section 2F & 12B of UGC Act, 1956, by DSIR-SIRO & HI/BI of MSME Certified by ISO 9001:2015
Cheeryal (V), Keesara (M), Medchal-Malkajgiri District, Telangana State - 501 301.

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Syllabus Copies of B. Pharmacy, Pharm D, Pharm D (PB), and M. Pharmacy Programs for the Academic Year 2016-17

S.No.	Program	Year of Study	Academic Year	University Regulation followed for Syllabus
1.	B. Pharmacy	I Year	2016-17	R16
		II Year		R15
		III Year		R13
		IV Year		R13
2.	Pharm D	I Year	2016-17	R08
		II Year		R08
		III Year		R08
		IV Year		R08
3.	Pharm D (PB)	I Year	2016-17	R08
		II Year		R08
		III Year		R08
4.	M. Pharmacy (Pharmaceutics)	I Year	2016-17	R15
		II Year		R15
5.	M. Pharmacy (Pharmaceutical Analysis & Quality Assurance)	I Year	2016-17	R15
		II Year		R15
6.	M. Pharmacy (Pharmaceutical Management & Regulatory Affairs)	I Year	2016-17	R15
		II Year		R15

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With effect from 02/08/2016

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

B. PHARMACY COURSE STRUCTURE (2016-17)

I YEAR I SEMESTER

S. No	Course Code	Subject	L	T	P	Credits
1	BS101/ BS102	Remedial Mathematics / Remedial Biology - I	4/ 2	1/ 1	0	4/ 2
2	PS103	Dispensing and General Pharmacy	4	1	0	4
3	PS104	Anatomy, Physiology and Health Education – I	3	1	0	3
4	BS105	Pharmaceutical Organic Chemistry – I	4	1	0	4
5	HS106	Professional Communication in English	3	0	0	3
6	PS107	Dispensing and General Pharmacy Lab	0	0	3	2
7	PS108	Anatomy, Physiology and Health Education – I Lab	0	0	3	2
8	BS109	Pharmaceutical Organic Chemistry – I Lab	0	0	3	2
9	BS110	Remedial Biology - I Lab	0	0	3	2
10	*MC111	NSS	0	0	0	0
		Total Credits	18/16	4/4	12	24/24

I YEAR II SEMESTER

S. No	Course Code	Subject	L	T	P	Credits
1	BS201	Pharmaceutical lnorganic Chemistry	3	1	0	3
2	BS202	Pharmaceutical Organic Chemistry – II	4	1	0	4
3	PS203	Physical Pharmacy - I	4	1	0	4
4	BS204	Statistical Methods and Computer Applications	3	1	0	3
5	PS205	Anatomy, Physiology and Health Education – II	4	1	0	4
6	BS206	Pharmaceutical lnorganic Chemistry Lab	0	0	3	2
7	BS207	Statistical Methods and Computer applications Lab	0	0	3	2
8	PS208	Physical Pharmacy – I Lab	0	0	3	2
9	*MC209	Physical Education	0	0	0	0
		Total Credits	18	5	9	24

Note: For Bi.P.C Students to choose Remedial Mathematics (Theory).
For M.P.C Students to choose Remedial Biology (Theory: 2-1-0-2, Lab: 0-0-3-2)

***Mandatory Course**

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REMEDIAL MATHEMATICS

B.Pharm. I Year I Sem.	**L**	**T/P/D**	**C**
Course Code: **BS101**	**4**	**1/0/0**	**4**

Course Objectives: This is an introductory course in mathematics, the subject deals with introduction to algebra, trigonometry, differential calculus, integral calculus etc.

Course Outcome: The student will learn the basics of mathematics which will be helpful in pharmaceutical calculation in the higher classes

UNIT I

Algebra: Permutations and combinations - Binomial theorem –Partial fractions (addition, subtraction and multiplication) –Matrices –Determinants -Application of determinants to solve simultaneous equations (Cramer's Rule).

UNIT II

Trigonometry: measurement of angles, trigonometry functions, compound angles, trigonometry ratios of multiple angles (sin 2θ, cos 2θ, tan 2 θ), Heights and distances (All simple problems only).
Co-ordinate Geometry: Distances between two points, Area of a triangle, division of line segment, locus.

UNIT III

Differential Calculus: Continuity and limit: Differentiation, derivative of product, derivative of function, derivation of a fraction of functions
Derivatives of trigonometric functions (excluding inverse trigonometric and hyperbolic functions). Derivatives of Logarithmic and exponential functional, partial dedifferentiation, maxima and minima (all simple problems)

UNIT IV

Integral Calculus: integration of algebraic and exponential functions, Integration of trigonometric functions, integration by parts, integration by the method of substitution, definite integrals, areas and curves (all simple problems)

UNIT V

Differential Equations: Formation of a differential equation, equation of 1^{st} order and 1^{st} degree, Homogenous, exact differential equation

Text Books

1) Intermediate first Year mathematics and Intermediate Second year mathematics, printed and published by Telugu Academy, Himayath nagar, Hyderabad
2) Remedial Mathematics by Shahnaz Bathul
3) Text book of Pharmaceutical Mathematics with Application to Pharmacy-Panchaksharappa Gowda. D. H.

References

1) Pharmaceutical Arithmetic's by Mohd. Ali CBS publishers and distributor, New Delhi.
2) Higher Engineering Mathematics by Grewal.

REMEDIAL BIOLOGY - I

	L	T/P/D	C
B.Pharm. I Year I Sem.			
Course Code: **BS102**	**2**	**1/0/0**	**2**

Course Objectives: This is an introductory course in biology which gives detailed study on natural sources such as plant and animal origin. This subject deals with the plant cell, animal cell classifications plant kingdom and study of animal issues and study about frogs and some animals.

Course Outcome: The student will learn details about plant and animal cells plant taxonomy classification and some aspects of physiology of frogs and animals.

UNIT I

Plant cell and tissues: ultra structure of plant cell and its inclusions. Cell division-mitosis and meiosis. Types of tissues and their functions, tissue systems.

UNIT II

Morphology and histology of root, stem, bark, wood, leaf, flower, fruit and seed. Modifications of root and stem.

UNIT III

Taxonomy: Systemic position and classification of following families: umbelliferae, apocyanaceae and liliaceae.

UNIT IV

Animal cells and tissues: ultra structure of animal cell, cell division, types of cells and tissues and their functions

Study of anatomy of frog; Basic study of digestive system, CVS, nervous system, genito-urinary system, musculoskeletal system.

UNIT V

Structure and life history of parasites illustrated by Amoeba, Entamoeba, Trypanosome, Plasmodium, Taenia, Ascaris,

Suggested Text Books

1) Intermediate First Year and Second Year Botany / Zoology Text Books printed and published by Telugu Academy, Himayath nagar and Hyderabad.
2) A.C. Dutta, Text Book of Botany
3) Botany for Degree students Vol I and II by B. P. Pandey
4) Enger- Concepts biology

DISPENSING AND GENERAL PHARMACY

B.Pharm. I Year I Sem.	L	T/P/D	C
Course Code: **PS103**	4	1/0/0	4

Course Objectives: The student shall be given orientations to know the origin of pharmacopoeias on dispensing procedure of medicines, pharmaceutical calculation, and interpretations of incompatibilities.

Course Outcome: Student will be familiar with the Hospital pharmacy organization, drug distribution procedures, dispensing, storage, incompatibilities and patient related factors.

UNIT I

a. Genesis and Evolution of Pharmacy: History of Pharmacy, origin and development of the Pharmacopoeias, History of Ayurveda, salient features of IP, USP and BP.

Pharmacy Education – D. Pharm, B Pharm, M.Pharm, Pharma-D, Qualification for getting license.

b. Dispensing Pharmacy: Principles of dispensing, form of prescription, handling of prescription, source of errors in prescription, care required in dispensing procedures including labelling of dispensed products.

UNIT II

Calculations:

Weights and Measures, introduction to Latin terms, Percentage calculations, alligation method, proof spirit calculations, displacement value and calculations of isotonicity adjustment. General dispensing procedure- posology-calculations of doses.

UNIT III

Principles involved and procedures adopted in dispensing of the following classes of preparations.

(i) Mixtures (ii) Solutions (iii) Emulsions (iv) Powders
(v) Lotions and liniments (vi) Ointments (vii) Suspensions (viii) Syrups
(ix) Suppositories.

Definition of the following preparations like creams, capsules, pastes, jellies, suppositories, ophthalmics, lozenges, pills, inhalations, paints, sprays and tablet triturates .

UNIT IV

Pharmaceutical ethics

Introduction to Pharmaceutical ethics, ethical guidelines for retail pharmacist / community Pharmacist, manufacturing Pharmacist and pharmaceutical researcher

UNIT V

a. Fundamental operations: Weighing, measurement of liquids, procedure of dispensing solution.

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b. Colours: Reasons for colouring pharmaceutical preparations, colouring of tablets, capsules and non-injectable fluids, Desirable properties of colouring agent, different types of colouring agents.

c. Excipients: Types of flavouring agents, preservatives and stabilisers

Text Books

1) Cooper and Gunns Dispensing Pharmacy, CBS, Publ. and Distributors New Delhi.
2) R.M Metha, Dispensing Pharmacy.
3) JS Quadry, Hospital Pharmacy.

References

1) Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
2) William Hassan, Hospital Pharmacy.

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ANATOMY PHYSIOLOGY AND HEALTH EDUCATION - I

B.Pharm. I Year I Sem.	**L**	**T/P/D**	**C**
Course Code: **PS104**	**3**	**1/0/0**	**3**

Course Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the human body .The overall anatomy and physiology of organ systems and their coordination are being dealt.

Course Outcome: Describes the structure and functions of various organs of the human body and mechanisms in the maintenance of normal functioning and disease state are knows.

UNIT I

Scope of Anatomy and Physiology and basic terminology used in these subjects. Structure of cell, its components and their function. Elementary tissues of the human body: epithelial, connective, muscular and nervous tissues, their sub- types and characteristics. Body fluids, Homeostasis

Skeletal system: Structure, composition and functions of skeleton, classification of joints, types of movements at joints,

Skeletal muscles: Gross anatomy, physiology of muscle contraction, physiological properties of skeletal muscles and their disorders. Rheumatoid arthritis, Gout.

UNIT II

Haemopoietic system and Lymphatic System: Composition and functions of blood and its elements, their disorders, blood groups and their significance, mechanism of coagulation, Anemias and its types, lymph organs.

UNIT III

Cardiovascular system: Basic anatomy, physiology and conduction system of heart, blood vessels and circulation. Basic pulmonary, coronary, hepatic, system, understanding of cardiac cycle, heart sounds and electrocardiogram. Blood pressure and its regulation. Brief outline of cardiovascular disorders like hypertension, myocardial infarction, congestive heart failure and cardiac arrhythmias.

UNIT IV

Digestive System: Gross anatomy of the gastro-intestinal tract, functions of its different parts, various gastrointestinal secretions and their role in the absorption and digestion of food, peptis ulcer, ulcerative colitis, hepatic disorder.

UNIT V

Demography and Family Planning: population problem, family planning and various contraceptive methods. Medical termination of pregnancy.

Brief outline of communicable diseases, causative agents, modes of transmission and prevention (chicken pox, influenza, diphtheria, whooping cough, tuberculosis, poliomyelitis, hepatitis, cholera, typhoid, malaria, rabies, tetanus, leprosy, syphilis and Aids).

Text Books

1) Tortora, G.J and Anagnodokas, Principles of Anatomy and Physiology, N.P Harper and Row Publishers N.Y
2) Ross and Willson, Text Book of Human Anatomy, M. J. Mycek S. B Gerther and MMPER
3) Human Anatomy and Physiology with health education by Padma B Sanghani

References

1) Guyton, Textbook of Medical Physiology, AC Guyton WB Sannders Company, 1995.
2) K. Sembulingam and Prema Sembulingam, Essentials of Medical Physiology, 3rd Edition, Jaypee Bros., New Delhi.

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PHARMACEUTICAL ORGANIC CHEMISTRY - I

B.Pharm. I Year I Sem.
Course Code: **BS105**

L	T/P/D	C
4	1/0/0	4

Course Objectives: The organic compounds are classified based on their functional groups and character. The basic principles and mechanisms of different types of organic reactions are explained in an elaborative manner.

Course Outcome: The detailed study on the mechanisms involved in various reactions would help the students to understand the synthesis of higher organic compounds which would be dealt in future classes.

UNIT I

a. Structure and Activity of Organic Molecules: Shapes of organic molecules, bond lengths, bond angles and bond dissociation energies. Electronic effects in organic molecules: inductive effect, electromeric or mesomeric effect, hyperconjugation, concept of resonance; types of organic reagents and reactions.

b. Aliphatic/Alicyclic Hydrocarbons: Nomenclature, isomerism (chain, conformational and geometrical) relative stabilities (heats of combustion and hydrogenation), ring stabilities of cyclohexane, chair-boat conformation, Bayer's strain theory and sachse-mohr theory. Free radical substitution reactions (halogenation) of alkanes.

UNIT II

a. Alkenes: Electrophilic addition reactions of alkenes, Markovnikov's rule, Kharasch effect, Bayer's oxidation (cis-hydroxylation, polymerisation).

b. Alkadienes: Stability and 1,4 addition reactions of conjugated alkadienes.

c. Alkynes: Acidity of 1-alkynes, formation of metal acetylides. Stereo specific reduction of alkynes. Addition of hydrogen halide (HCl) addition of water and keto-enol tautomerism.

UNIT III

Aromatic Hydrocarbons: Kekule's structure of benzene, bond lengths, heats of hydrogenation and stability, molecular orbital picture of benzene, aromaticity, Huckel's rule, nomenclature of benzene derivatives, electrophilic reactions of benzene, theory of reactivity and orientation in mono substituted benzenes.

UNIT IV

a. Halogen Compounds-Aromatic: Nomenclature, low reactivity of halo benzenes towards nucleophilic substitution, arenes.

b. Halogen Compounds-Aliphatic: Nomenclature, general methods of preparation, characteristic nucleophilic substitution reactions, factors that play role in SN^1 and SN^2, Walden inversion, elimination reaction and Saytzeff's rule.

UNIT V

Alcohols: Nomenclature, classification, general methods of preparation, physical properties, hydrogen bonding, characteristic nucleophilic substitution reactions (replacement of -OH by -

Cl), elimination reactions, and relative reactivities of 1°, 2° and 3° alcohols, Meerwein Pondorff Verley reduction.

Text Books

1) T. R. Morrison and R. N. Boyd, Organic chemistry, prentice hall of India private Limited, New Delhi.
2) I.L. Finar Vol. I and Vol. II, the Fundamentals Principles of Organic Chemistry, ELBS/Longman.
3) Ball and Ball Advanced pharmaceutical organic chemistry.

References

1) Jerry March, Reactions and Mechanism 4th ed.
2) Jerry March, Advanced Organic Chemistry

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PROFESSIONAL COMMUNICATION IN ENGLISH

	L	T/P/D	C
B.Pharm. I Year I Sem.			
Course Code: **HS106**	**3**	**0/0/0**	**3**

INTRODUCTION

In view of the growing importance of English as a tool for global communication and the consequent emphasis on training students to acquire language skills, the syllabus of English has been designed to develop linguistic and communicative competencies of Engineering students.

In English classes, the focus should be on the skills development in the areas of vocabulary, grammar, reading and writing. For this, the teachers should use the prescribed text book for detailed study. The students should be encouraged to read the texts/poems silently leading to reading comprehension. Reading comprehension passages are given for practice in the class. The time should be utilized for working out the exercises given after each excerpt, and also for supplementing the exercises with authentic materials of a similar kind, for example, from newspaper articles, advertisements, promotional material, etc. *The focus in this syllabus is on skill development, fostering ideas and practice of language skills.*

Course Objectives:

The course will help students to:

a. Improve the language proficiency of students in English with an emphasis on Vocabulary, Grammar, Reading and Writing skills.

b. Equip students to study academic subjects more effectively using the theoretical and Practical components of English syllabus.

c. Develop study skills and communication skills in formal and informal situations.

Course Outcomes:

Students will be able to:

1. Use English Language effectively in spoken and written forms.
2. Comprehend the given texts and respond appropriately.
3. Communicate confidently in formal and informal contexts.

SYLLABUS

Reading Skills:

Objectives:

1. To develop an awareness in students about the significance of silent reading and comprehension.
2. To develop students' ability to guess meanings of words from the context and grasp the overall message of the text, draw inferences, etc., by way of:

- Skimming and Scanning the text
- Intensive and Extensive Reading
- Reading for Pleasure

- Identifying the topic sentence
- Inferring lexical and contextual meaning
- Recognizing Coherence/Sequencing of Sentences

NOTE: The students will be trained in reading skills using the prescribed texts for detailed study. They will be tested in reading comprehension of different 'unseen' passages which may be taken from authentic texts, such as magazines/newspaper articles.

Writing Skills:

Objectives:

1. To develop an awareness in the students about writing as an exact and formal skill
2. To create an awareness in students about the components of different forms of writing, beginning with the lower order ones through;

- Writing of sentences
- Use of appropriate vocabulary
- Paragraph writing
- Coherence and cohesiveness
- Narration / description
- Note Making
- Formal and informal letter writing
- Describing graphs using expressions of comparison

In order to improve the proficiency of the students in the acquisition of language skills mentioned above, the following text and course contents, divided into Five Units, are prescribed:

Text Books:

1. ***"Fluency in English – A Course book for Engineering Students"*** by Board of Editors: **Hyderabad: Orient BlackSwan Pvt. Ltd. 2016. Print.**
2. Raman, Meenakshi and Sharma, Sangeeta. ***"Technical Communication- Principles and Practice".*** **Third Edition. New Delhi: Oxford University Press. 2015. Print.**

The course content / study material is divided into **Five Units.**

Note: ***Listening and speaking skills are covered in the syllabus of ELCS Lab.***

UNIT –I:

Chapter entitled '***Presidential Address' by Dr. A.P.J. Kalam*** from ***"Fluency in English– A Course book for Engineering Students"*** published by Orient BlackSwan, Hyderabad.

Vocabulary: Word Formation -- Root Words --The Use of Prefixes and Suffixes– Collocations– Exercises for Practice.

Grammar: Punctuation – Parts of Speech- Articles -Exercises for Practice.

Reading: ***Double Angels*** by David Scott-Reading and Its Importance- Techniques for Effective Reading- Signal Words- Exercises for Practice

Writing: Writing Sentences- Techniques for Effective Writing-- Paragraph Writing- Types, Structure and Features of a Paragraph-Coherence and Cohesiveness: Logical, Lexical and Grammatical Devices - Exercises for Practice

UNIT –II:

Chapter entitled ***Satya Nadella: Email to Employees on his First Day as CEO*** from ***"Fluency in English– A Course book for Engineering Students"*** Published by Orient BlackSwan, Hyderabad.

Vocabulary: Synonyms and Antonyms – Homonyms, Homophones, Homographs- Exercises for Practice (Chapter 17 ***'Technical Communication- Principles and Practice'. Third Edition*** published by Oxford University Press may also be followed.)

Grammar: Verbs-Transitive, Intransitive and Non-finite Verbs – Mood and Tense—Gerund – Words with Appropriate Prepositions – Phrasal Verbs - Exercises for Practice

Reading: Sub-skills of Reading- Skimming, Scanning, Extensive Reading and Intensive Reading - ***The Road Not Taken*** by **Robert Frost** -- Exercises for Practice

Writing: Letter Writing –Format, Styles, Parts, Language to be used in Formal Letters- Letter of Apology – Letter of Complaint-Letter of Inquiry with Reply – Letter of Requisition –- Exercises for Practice

UNIT –III:

From the book entitled ***'Technical Communication- Principles and Practice'. Third Edition*** published by Oxford University Press.

Vocabulary: Introduction- A Brief History of Words – Using the Dictionary and Thesaurus– Changing Words from One Form to Another – Confusables (From Chapter 17 entitled '*Grammar and Vocabulary Development*')

Grammar: Tenses: Present Tense- Past Tense- Future Tense- Active Voice – Passive Voice- Conditional Sentences – Adjective and Degrees of Comparison. (From Chapter 17 entitled '*Grammar and Vocabulary Development*')

Reading: Improving Comprehension Skills – Techniques for Good Comprehension- Skimming and Scanning- Non-verbal Signals – Structure of the Text – Structure of Paragraphs – Punctuation – Author's viewpoint (Inference) – Reader Anticipation: Determining the Meaning of Words – Summarizing- Typical Reading Comprehension Questions. (From Chapter 10 entitled '*Reading Comprehension*')

Writing: Introduction- Letter Writing-Writing the Cover Letter- Cover Letters Accompanying Resumes- Emails. (From Chapter 15 entitled '*Formal Letters, Memos, and Email*')

UNIT –IV:

Chapter entitled ***'Good Manners' by J.C. Hill*** from ***Fluency in English – A Course book for Engineering Students"*** published by Orient Blackswan, Hyderabad.

Vocabulary: Idiomatic Expressions –One- word Substitutes --- Exercises for Practice (Chapter 17 ***'Technical Communication- Principles and Practice'. Third Edition*** published by Oxford University Press may also be followed.)

Grammar: Sequence of Tenses- Concord (Subject in Agreement with the Verb) – Exercises for Practice

Reading: ***'If'*** poem by **Rudyard Kipling**--Tips for Writing a Review --- Author's Viewpoint – Reader's Anticipation-- Herein the Students will be required to Read and Submit a Review of a Book (Literary or Non-literary) of their choice – Exercises for Practice.

Writing: Information Transfer-Bar Charts-Flow Charts-Tree Diagrams etc., -- Exercises for Practice.

Introduction - Steps to Effective Precis Writing – Guidelines- Samples (Chapter 12 entitled '*The Art of Condensation*' from ***Technical Communication- Principles and Practice. Third Edition*** published by Oxford University Press)

UNIT –V:

Chapter entitled ***'Father Dear Father'*** **by Raj Kinger** from ***Fluency in English – A Course book for Engineering Students"*** Published by Orient BlackSwan, Hyderabad

Vocabulary: Foreign Words—Words borrowed from other Languages- Exercises for Practice

Grammar: Direct and Indirect Speech- Question Tags- Exercises for Practice

Reading: Predicting the Content- Understanding the Gist – SQ3R Reading Technique- Study Skills – Note Making - Understanding Discourse Coherence – Sequencing Sentences. (From Chapter 10 entitled **'Reading Comprehension'** - ***Technical Communication- Principles and Practice. Third Edition*** published by Oxford University Press.)

Writing: Technical Reports- Introduction – Characteristics of a Report – Categories of Reports –Formats- Prewriting – Structure of Reports (Manuscript Format) - Types of Reports - Writing the Report. (From Chapter 13 entitled **'Technical Reports'** - ***Technical Communication- Principles and Practice. Third Edition*** published by Oxford University Press.)

- **Exercises from both the texts not prescribed shall be used for classroom tasks.**

References

1 Green, David. *Contemporary English Grammar –Structures and Composition.* MacMillan India. 2014 (Print)

2. Rizvi, M. Ashraf. *Effective Technical Communication*. Tata Mc Graw –Hill. 2015 (Print).

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DISPENSING AND GENERAL PHARMACY LAB

B.Pharm. I Year I Sem.	**L**	**T/P/D**	**C**
Course Code: **PS107**	**0**	**0/3/0**	**2**

1) Dispensing of prescriptions falling under the categories; Mixtures, solutions, emulsions, creams, ointments, powders, pastes, lotions, liniments, inhalations, paints, syrups, Suppositories etc.

2) Dispensing procedures involving pharmaceutical calculations, pricing of prescriptions and dosage calculations for paediatric and geriatric patients.

3) Dispensing of prescriptions involving adjustment of tonicity.

4) Categorization and storage of pharmaceutical products based on legal requirements of labelling and storage.

5) Project report on visit to the community pharmacy for Counselling on the rational use of drugs and aspects of health care.

References:

1. Pharmaceutics –I, Practical manual by N. K. Jain, Vijay Mishra
2. Dispensing pharmacy practical manual by B. S. Sanmethi, K. Mehta and Anshu Gupta

ANATOMY, PHYSIOLOGY AND HELATH EDUCATION - I LAB

B.Pharm. I Year I Sem. | **L T/P/D C**
Course Code: **PS108** | **0 0/3/0 2**

(21 Experiments)

1. Study of human skeleton
2. Study of different systems with the help of charts and models
3. Microscopic study of different tissues
4. Estimation of Haemoglobin in blood, Determination of bleeding time, clotting time – 3 Experiments.
5. Estimation of R.B.C. count – 2 Experiments.
6. Estimation of W.B.C count – 2 Experiments.
7. Estimation of D.L.C.
8. Recording of body temperature, pulse rate and blood pressure, basic understanding of Electrocardiogram-PQRST waves and their significance
9. Determination of vital capacity, experiments on spirometry
10. Study of reproductive system with the help of charts and models
11. Various devices used in Family planning like Copper T, Lippers loop, Pills, Diaphragm and Condom.
12. Microscopic studies of abnormal tissue sections
13. Simple experiments involved in the analysis of normal and abnormal urine; collection of specimen, appearance, determination of pH, sugars, proteins, urea and creatinine
14. Study of special senses with the help of charts and models

References

1. Plummer, Practical Biochemistry
2. Chatterjee, Human Physiology
3. C. L. Ghai, Pratical Physiology
4. Elaine N. Marieb, Human Anatomy and Physiology.

PHARMACEUTICAL ORGANIC CHEMISTRY-I LAB

B.Pharm. I Year I Sem. | **L T/P/D C**
Course Code: **BS109** | **0 0/3/0 2**

I. Introduction to Equipment and Glassware

1. Determination of melting point/boiling point by Thiels method.
2. Determination of Mixed melting point for organic compounds.
3. Recrystallization (Purification including decolourization) of two organic compounds.
4. Purification and drying of organic solvents.

II. Preparation of organic compounds (each involving a specific organic reaction covered in theory)

1.	N-Acetylation	:	Preparation of Acetanilide from Aniline
2.	O-Acetylation	:	Preparation of Aspirin from Salicylic acid
3.	Nuclear Bromination	:	Preparation of p-Bromoacetanilide from Acetanilide
4.	Hydrolysis	:	Preparation of p-Bromoaniline from p-Bromoacetanilide
5.	Nuclear Nitration	:	Preparation of m-Dinitrobenzene from nitrobenzene
6.	Oxidation	:	Preparation of Benzoic acid from Benzyl chloride
7.	Esterification	:	Preparation of n-Butylacetate from n-Butylalcohol
8.	Etherification	:	Preparation of β-Naphthyl methyl ether from β-Naphthol
9.	α-Halogenation	:	Preparation of Iodoform from Oxidation of Acetone
10.	Extensive Nuclear Substitution	:	Preparation of Tribromophenol or Bromination Tribromoaniline from Phenol or Aniline

III. Systematic qualitative Analysis (Identification) of Monofunctional Organic Compounds:

Avoid water-soluble compounds, and compounds containing more than one functional group; at least six individual compounds to be analyzed.

References

1. Vogel's Text Book of Practical Organic Chemistry, 5th Edition.
2. R. K. Bansal, Laboratory Manual of Organic Chemistry.
3. O. P. Agarwal Advanced Practical Organic Chemistry.
4. F. G. Mann and B.C. Saunders, Practical Organic Chemistry.
5. Organic Chemistry a lab manual, Cengage learning India Pvt. Ltd. By Pavia
6. Advanced Practical Organic Chemistry, Vishoi-Vikas Publications.

REMEDIAL BIOLOGY LAB

B.Pharm. I Year I Sem. | **L T/P/D C**
Course Code: **BS110** | **0 0/3/0 2**

1) Introduction to simple and compound microscope and their handling
2) Morphological study of various plant parts
3) Study of histology of monocot root, stem, leaf and dicot root, stem and leaf
4) Systemic study of representatives of following families: apocyanaceae, solanaceae, three sub families of leguminaceae and liliaceae
5) Demonstration of various systems of frog
6) Study of structure of human parasites and insects mentioned in theory with the help of specimen.
7) Microscopic examination of specimens slides related to plant and animal tissues.

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w. e. f. AY 2016-17

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B. PHARMACY COURSE STRUCTURE (2016-17)

I YEAR II SEMESTER

S. No	Course Code	Subject	L	T	P	Credits
1	BS201	Pharmaceutical Inorganic Chemistry	3	1	0	3
2	BS202	Pharmaceutical Organic Chemistry – II	4	1	0	4
3	PS203	Physical Pharmacy - I	4	1	0	4
4	BS204	Statistical Methods and Computer Applications	3	1	0	3
5	PS205	Anatomy, Physiology and Health Education – II	4	1	0	4
6	BS206	Pharmaceutical Inorganic Chemistry Lab	0	0	3	2
7	BS207	Statistical Methods and Computer applications Lab	0	0	3	2
8	PS208	Physical Pharmacy – I Lab	0	0	3	2
9	*MC209	NCC/NSO	0	0	0	0
		Total Credits	**18**	**5**	**9**	**24**

***MC – Mandatory Course**

PRINCIPAL
Geethanjali College of Pharmacy
Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

BS201: PHARMACEUTICAL INORGANIC CHEMISTRY

B. Pharm. I Year II Sem

L	T	P	C
3	1	0	3

Course Objectives: The subject has been designed to make the students understand different categories of inorganic drugs/ compounds which are used as medicinal agents

Course Outcome: The knowledge gained by the student after studying the subject in detailed manner will be applicable to study and understand the concepts for higher classes.

UNIT - I

1. Classification of Inorganic Pharmaceuticals based on their applications and therapeutic uses.
2. Sources of impurities in pharmaceutical substances.
3. Test for purity
   a) Setting property of plaster of paris
   b) Ammonium compounds in sodium bicarbonate
   c) Oxalate in sodium citrate.
   d) Barium and thiocynate in Ammonium chloride
4. Qualitative tests for anion and cations
5. Limit tests for arsenic, heavy metals, lead, iron, chloride and sulphate.

Note: Definition, Preparation, Assay principle, Limit tests and Uses of the compounds mentioned in Unit II to Unit V

UNIT - II

1. **Electrolytes**:
   a) **Sodium and Potassium replenishers**: Sodium chloride, compound sodium chloride solution (Ringer solution), potassium chloride, ORS.
   b) **Calcium replenishers**: Calcium gluconate, dibasic calcium phosphate, calcium chloride.
2. **Acid base regulators:** Sodium bicarbonate, sodium lactate, sodium citrate/potassium citrate, sodium acetate, and ammonium chloride
3. **Dialysis fluids:** Haemodialysis fluids.

UNIT - III

Gastro-intestinal agents.

1. **Acidifiers and Antacids:** Dilute hydrochloric acid, sodium acid phosphate, sodium bicarbonate, aluminium hydroxide gel, dried aluminium hydroxide gel, magnesium oxide (Magnesia), magnesium hydroxide mixture, magnesium trisilicate.
2. **Adsorbents and related drugs**: Light kaolin, heavy kaolin, and activated charcoal.
3. **Laxatives:** Magnesium sulphate, sodium phosphate.
4. **Mineral Nutrients / Supplements**

a) **Haematinics** – Ferrous sulphate, ferrous fumarate, ferrous gluconate, ferric ammonium citrate, iron and dextrose injection.
b) **Halogens:** Iodine, Iodides.

5. **Pharmaceutical aids:**
   a) **Excipients**: Dicalcium phosphate, magnesium stearate, talc and calcium carbonate (Precipitated chalk).
   b) **Suspending agents**: Bentonite, colloidal silica.
   c) **Colorants:** Titanium oxide, Ferric oxide

UNIT - IV

a) **Expectorants**: Ammonium chloride, potassium iodide.
b) **Emetics**: Potassium antimony tartarate, copper sulphate.
c) **Antidotes:** Sodium thiosulphate, sodium nitrite.

Topical agents:

1. **Astringents:** Zinc sulphate, calcium hydroxide, Bismuth sub carbonate.
2. **Topical protectants:** Zinc oxide, calamine, zinc stearate, talc, titanium-dioxide, heavy kaolin and light kaolin (only uses).
3. **Silicone polymers:** Activated dimethicone.
4. **Anti-Infectives:** Hydrogen peroxide solution, potassium permanganate, silver nitrate (silver protein), iodine, (solutions of iodine, povidone iodine), boric acid, zinc undecylenate, mercury compounds (yellow mercuric chloride)

UNIT - V

Dental products:

1. **Fluorides**: Sodium fluoride, sodium monofluorophosphate and stannous fluoride.
2. **Oral antiseptics and Astringents**: Hydrogen peroxide, magnesium, peroxide, zinc peroxide and mouth washes.
3. **Dentifrices**: Calcium carbonate, dibasic calcium phosphate, calcium phosphate, sodium
   metaphosphate and strontium chloride.
4. **Cements & fillers** : Zinc oxide (only uses).

Miscellaneous Medicinal Agents

a)	Antineoplastics	:	Cisplatin
b)	Antidepressants	:	Lithium carbonate
c)	Diagnostic agents	:	Barium sulphate
d)	Surgical Aids	:	Plaster of Paris
e)	Antirheumatic agents	:	Sodium aurothiomalate
f)	Internal parasiticid	:	Sodium antimony gluconate
g)	Anti thyroid agents	:	Potassium perchlorate

TEXT BOOKS

1. A. H. Beckett and J. B. Stenlake, Practical pharmaceutical chemistry, Part-I. The Athtone press,
2. University of London, London.
3. P. Gundu Rao, Inorganic pharmaceutical chemistry; Vallabh Prakashan, Delhi.
4. Advanced Inorganic Chemistry by Satya Prakash, G. D. Tuli

REFERENCES

1. L.M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry Oxford University Press, London.
2. Indian Pharmacopoeia 1996, 2006.

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BS202: PHARMACEUTICAL ORGANIC CHEMISTRY - II

B. Pharm. I Year II Sem

L	T	P	C
4	1	0	4

Course Objectives: The organic compounds are classified based on their functional groups and character. The basic principles and mechanisms of different types of organic reactions are explained in an elaborative manner.

Course Outcome: The detailed study on the mechanisms involved in various reactions would help the students to understand the synthesis of higher organic compounds which would be dealt in future classes.

UNIT - I

Carbonyl Compounds: Nomenclature, two important methods of preparation, polarity of carbonyl group, relative reactivities of carbonyl compounds, nucleophilic addition and addition-elimination reactions, oxidation-reduction reactions, aldol condensation, Cannizzaro reaction, benzoin condensation, Perkins reactions, Reformatsky reaction, Oppenauer oxidation.

UNIT - II

a. Ethers: Nomenclature, Williamson's synthesis, action of hydro iodic acid on ethers (Ziesel's method).

b. Phenols: Nomenclature, general methods of preparation, physical properties, acidity of phenols, stability of phenoxide ion, reactions of phenols, Kolbe-schmidt reaction stability of conjugated dienes, and Fries rearrangement, Reamer-Tiemann Reaction.

UNIT - III

a. Carboxylic acids and their derivatives:

Carboxylic acids: Nomenclature, intermolecular association, stability of carboxylate anion, two important methods of preparation, decarboxylation, functional groups reactions, reduction of carboxylic acids. a note on dicarboxylic acids.

b. Acid derivatives: (acid chlorides, anhydrides, esters and amides). Nomenclature, reactions like hydrolysis, reduction of esters and amides, Hofmann's degradation of amides.Brief account of preparation and properties of malonic and acetoacetic esters, their importance in organic syntheses.

UNIT - IV

a. Nitro compounds: Nomenclature, acidity of nitro compounds containing α- hydrogens, reductive reactions of aromatic nitro compounds.

b. Nitriles and isonitriles: Nomenclature, two methods of synthesis, reactivity and functional reactions.

UNIT - V

a. Amines: Nomenclature, basicity of amines, classification, relative reactivity, hinsberg method of separation, acylation reactions.Diazotisation and reactions of diazonium salts.

b. Organo metallic compounds: Synthetic applications of Grignard reagent

TEXT BOOKS:

1. T. R. Morrison and R. N. Boyd, Organic chemistry, prentice hall of India private Limited, New Delhi.
2. I.L. Finar Vol.I. & Vol. II., the Fundamentals Principles of Organic Chemistry, ELBS/Longman.
3. Ball & Ball, Advanced pharmaceutical organic chemistry.

REFERENCES:

1. Jerry March, Advanced Organic Chemistry
2. Bruce, Organic chemistry

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PS203: PHYSICAL PHARMACY – I

B. Pharm. I Year II Sem

L	T	P	C
4	1	0	4

Course Objectives: The student shall know important physical properties of drug molecules, phase value & its importance. Different law of thermodynamics, electrolyte and non-electrolyte solutions, importance of p^H and drug research.

Course Outcome: Student will know about physical properties of molecules, three laws of thermodynamics, properties of electrolytes and non electrolytes, p^H and buffers. They also understand the importance of these studies in the physical pharmaceutics & Formulation development.

UNIT - I

Physical properties of Drug Molecules: Dielectric constant induced polarization, dipole moment, refractive index and molar refraction and optical rotatory dispersion.

UNIT - II

a. Phase equilibria and the phase rule:- System containing single component, System containing two component, two component system containing solid and liquid phases, three component systems

b. Thermodynamics: The first law of thermodynamics. The second law of thermodynamics. The third law of thermodynamics, Free energy functions and applications.

UNIT - III

a. Solutions of Electrolytes: Properties of solutions of electrolytes. The Arrhenius theory of electrolyte dissociation. The modern theory of strong electrolytes and other coefficients for expressing colligative properties.

b. Solutions of Non electrolytes: Concentration expressions, ideal and real solutions, colligative properties, molecular weight determinations.

UNIT - IV

Ionic equilibria: Modern theories of acids, bases and salts, Sorensen's pH scale, species concentration as a function of pH, calculation of pH and acidity constants.

UNIT - V

Buffers and buffered isotonic systems: The buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions, methods of adjusting tonicity and pH (relevant numerical problems).

TEXT BOOKS:

1. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences Fifth Edition.
2. C. V. S. Subramanyam, Essentials of Physical Pharmacy, Vallabh Prakashan.
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.

REFERENCES:

1. Pharmacopoeias, (I.P., B.P., U.S.P. and European.)
2. Martindale, The Extra Pharmacopoeia; latest edition, the Royal Pharmaceutical Society.

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BS204: STATISTICAL METHODS AND COMPUTER APPLICATIONS

B. Pharm. I Year II Sem

L	T	P	C
3	1	0	3

Course Objectives: The objective of the course, centered around various techniques, collection of data and its treatment; Probability and distribution, correlation, regression and statistical inferences, besides computer application.

Course Outcome: At the end of the course the expected outcomes are thorough knowledge of statistical techniques and application of computer in pharmacy

Section - A: Bio-statistics

UNIT - I

Data collection and treatment: Data Collection and organization, diagrammatic representation of data(bar, pie, 2-D and 3-D diagrams), standard deviation and standard error of means, co-efficient of variation, Correlation and regression analysis.

Probability and Distributions: Bayer's theorem, probability theorem, elements of binomial and Poisson distribution, normal distribution curve and properties.

UNIT - II

Statistical inference: Common parametric and non-parametric tests (t-test, F-test, X^2-test employed in testing of significance in biological/pharmaceutical experiments and elements of ANOVA (One way and two way).

UNIT - III

Design of experiments: Basic concepts of CRD, RBD and Latin square designs.

Sampling and Quality Control: Concept of random sampling, statistical QC charts. Applications of statistical concepts in pharmaceutical sciences.

Section - B: Computer Applications

UNIT - IV

MS-Excel: Basics, spreadsheets, data types, formulas, formatting, charts, graphs. Calculation of statistical parameters using excel.

MS-Power Point: Power point Basics, views, slide controls, applied design, page setup, templates, back ground control, colour screens, transitions, and animations, working with texts, and working with graphics.

UNIT - V

Database Management: Concepts and Objectives of database management systems, advantages of the database management systems and examples of DBMS packes (like DBASE III)

Introduction to structured Query language (SQL): over view of SQL, Reserved words, SQL Commands. **Computer Applications** in pharmaceutical and clinical studies.

TEXT BOOKS:

1. Sanford Boltan, Pharmaceutical statistics, Practical and clinical applications
2. Pranab Kumar Benarjee, Introduction to Biostatistics
3. Khan and Khanum, Fundamentals of Biostatistics

REFERENCES:

1. Roger E. Kirk, Statistics an introduction, Thomson Wadsworth
2. Walter T. Ambrosius, Topics in Biostatistics, Humana Press

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PS205: ANATOMY, PHYSIOLOGY AND HEALTH EDUCATION - II

B. Pharm. I Year II Sem

L	T	P	C
4	1	0	4

Course Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the human body. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

Course Outcomes: Knowledge on structure and functions of various organs of the human body and the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body and the pathological states

UNIT - I

Central Nervous System: Functions of different parts of brain and spinal cord, reflex action, electroencephalogram, cranial nerves and their functions. Epilepsy, psychosis, depression, mania, Parkinsonism, Alzheimer's disease.

Autonomic Nervous System: Physiology and functions of autonomic nervous system. Mechanism of neurohumoral transmission in the A.N.S.

UNIT - II

Respiratory System: Anatomy of respiratory organs. Functions of respiration, mechanism and regulation of respiration, respiratory volumes and vital capacity. Asthma, tuberculosis.

Urinary System: Various parts, structures and functions of the kidney and urinary tract. Physiology of urine formation and acid base balance, acute and chronic renal failure.

UNIT - III

Endocrine System: Basic anatomy and physiology of pituitary, thyroid, parathyroid, adrenals, pancreas their hormones and functions. Diabetes, Hyperthyroidism, and Hypothyroidism.

UNIT - IV

Reproductive Systems: Male and Female reproductive systems and their hormones, physiology of menstruation, Sex differentiation, Pregnancy its maintenance and parturition.

UNIT - V

Basic Principles of Cell Injury, Adaptation & process of inflammation: Causes of cellular injury, pathogenesis, morphology of cell injury. Cellular adaptations, atrophy, hypertrophy. Acute and chronic inflammation, mediators of inflammation.

TEXT BOOKS:

1. Tortora, G.J and Anagnodokas, Principles of Anatomy and Physiology, N.P Harper & Row Publishers N.Y

2. Ross & Wilson, Text Book of Human Anatomy, M. J. Mycek, S.B Gerther and MMPER
3. Robbins, SL & Kumar, Basic Pathology.

REFERENCES:

1. Guyton, Textbook of Medical Physiology, AC Guyton WB Sannders Company, 1995.
2. K. Sembulingam and Prema Sembulingam, Essentials of Medical Physiology, 3rd Edition, Jaypee Bros, New Delhi.

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BS206: PHARMACEUTICAL INORGANIC CHEMISTRY LAB

B. Pharm. I Year II Sem

L	T	P	C
0	0	3	2

List of experiments:

A) Limit tests for the following as per the procedure given in Indian Pharmacopoeia (1996 – Including the latest addenda)

1. Chlorides
2. Sulphates
3. Heavy metals
4. Iron
5. Arsenic (demonstration)

B) Balances and Weighing; Calibration of weights, Pipette and Burette.

1. Preparation and standardization of Hydrochloric acid solution (0.1N).
2. Preparation and standardization of Potassium permanganate solution (0.1N & 0.1M).
3. Preparation of a primary standard solution of 0.1N Potassium hydrogen-phthalate.
4. Preparation and standardization of 0.1N EDTA solution.
5. Preparation and purification of Boric acid.
6. Preparation and purification of Sodium citrate.
7. Preparation and purification of Potash alum.
8. Preparation and purification of Magnesium stearate.
9. Assay of sodium bicarbonate and assay of Boric acid (Neutralization).
10. Assay of Calcium gluconate (or) any calcium compounds (Complexometry).
11. Assay of Copper sulphate (Redox titration).
12. Assay of Sodium acetate (Non-aqueous titration).
13. Assay of Ferrous sulphate (Oxidation-reduction / Redox titration).
14. Exercises related to assay by Gravimetric method.

NOTE: Minimum 15 experiments must be performed.

REFERENCES:

1. Indian Pharmacopoeia - 2010.
2. Vogel's Qualitative Analysis

BS207: STATISTICAL METHODS AND COMPUTER APPLICATIONS LAB

B. Pharm. I Year II Sem

L	T	P	C
0	0	3	2

1. **Solving biostatistics problems** related to inference, sampling, graphical representation of data etc., with the help of calculators & software programs like Graph-pad.

2. **Sample programs in C**: Program to calculate simple and complex arithmetic expressions, program using structures, program using loops and nested loops, program using functions and simple programs using arrays.

3. **Operating systems** like WINDOWS, UNIX, etc.

4. **Software packages** like MS-WORD, EXCEL, ACCESS, and POWER POINT.

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PS208: PHYSICAL PHARMACY – I LAB

B. Pharm. I Year II Sem

L	T	P	C
0	0	3	2

List of experiments:

1. Percent composition determination by Capillary Flow method
2. Percent composition determination by polarimeter & refractometer
3. Molecular weight determination by Landsberger method.
4. Molecular weight determination by Rast camphor method.
5. Calibration of pH Meter
6. pH Estimation – pH meter
7. pH Estimation – colourimetric method.
8. pH Estimation by Half Neturalization Method
9. Refractive index of liquids.
10. Molar refraction determination
11. Effect of dielectric constant on the solubility of the drug.
12. Phenol water system – CST
13. Lower consolute temperature – Tirethanol amine and Water
14. Heat of neutralization
15. Phase diagram - Phenol – Water, Effect of Impurities.
16. Ternary phase diagram.
17. Preparation of Buffers and Buffer Capacity Determination.

NOTE: Minimum 15 experiments must be performed.

REFERENCES:

1. Physical pharmacy practical book by C.V.S. Subramanyam
2. Physical pharmacy practical text by Guru Prasa Mohanta, Prabal Kumar Maitie

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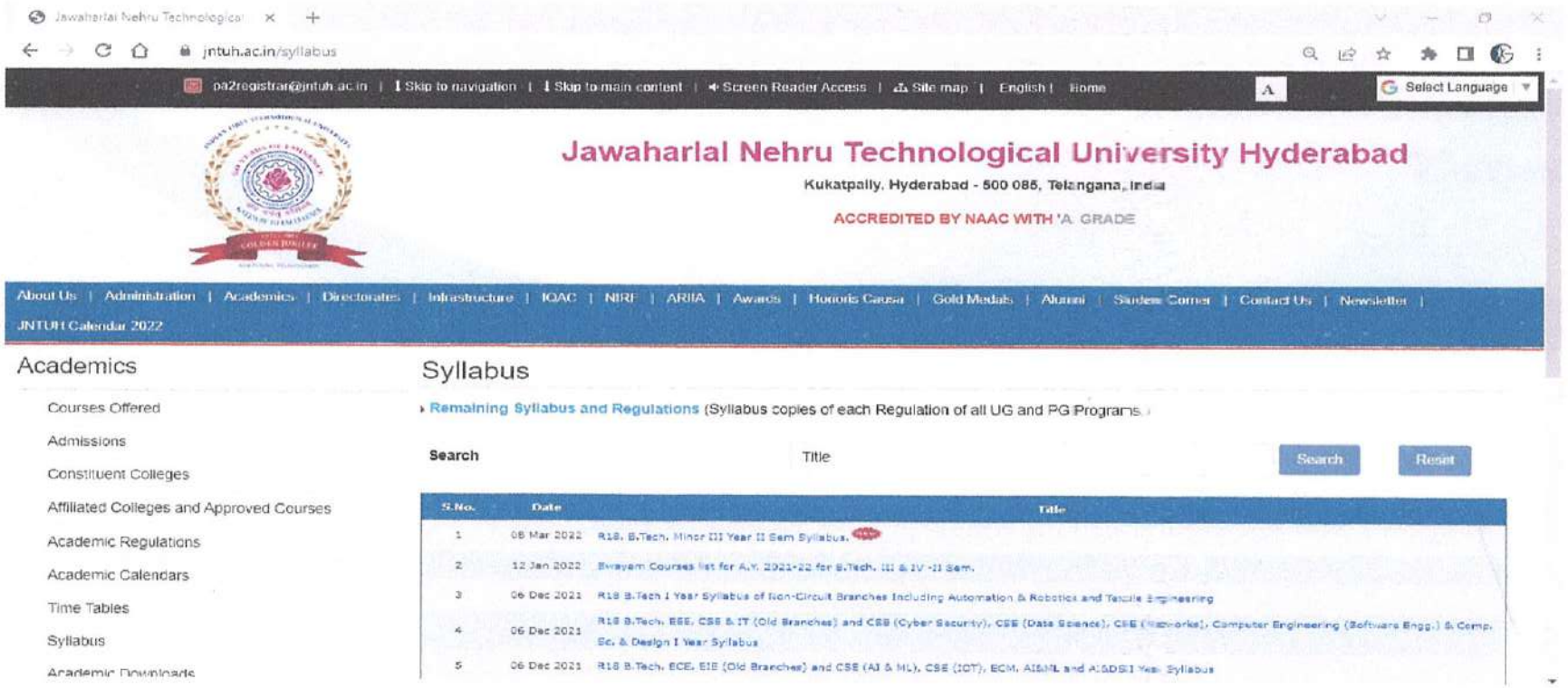
JNTUH Syllabus Links in JNTUH Sites

1. https://jntuh.ac.in/syllabus
2. https://studentservices.jntuh.ac.in/oss/syllabus.html?type=syllabus



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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

(Established by Andhra Pradesh Act No.30 of 2008)
Kukatpally, Hyderabad 500 085, Telangana State, India

IMPORTANT POINTS ON R 15 REGULATIONS:

- The candidate shall pursue a course of study for not less than four academic years and not more than eight academic years.
- After eight academic years of course of study, the candidate is permitted to write the examinations for two more years.
- The candidate shall register for 226 (224+2 credits for Gender Sensitization) and secure 218 (216+2) credits and all practical subjects, Industry oriented mini project, Comprehensive Viva-Voce, Seminar and Project work are compulsory subjects.
- The student can avail exemption of two subjects upto 8 credits, that is, one open elective and one elective subject OR two elective subjects.

ACADEMIC REQUIREMENTS:

- A student is eligible to write the University examinations only if he/she acquires a minimum of 75% of attendance in aggregate of all the subjects.
- Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester or first year may be granted by the College Academic Committee
- Shortage of Attendance below 65% in aggregate shall not be condoned.
- If any candidate fulfills the attendance requirement in the present semester or first year, he/she shall not be eligible for readmission into the same class.

MINIMUM ACADEMIC REQUIREMENTS:

- A student is deemed to have satisfied the minimum academic requirements if he/she has earned the credits allotted to each theory/practical design/drawing subject/project and secures not less than 35% of marks in the end semester exam, and minimum 40% of marks in the sum total of the mid-term and end semester exams.

PROMOTION POLICY: No. of Credits required:

First to Second Year	From Second to Third Year upto II Year I Sem.	From Third to Fourth Year upto III Year I Sem.
28 credits out of 56 credits of I year from all the examinations (50%)	50 credits out of 84 credits from one regular and one supplementary examinations of I year, and one regular and one supplementary examination of II year I semester irrespective of whether or not the candidate takes the examination, and secures prescribed minimum attendance in II Year II Semester (60%)	84 credits out of 140 credits up to III year I semester or 100 credits from the following examinations, whether the candidate takes the examinations or not, and secures prescribed minimum attendance in III Year II Semester. a.Two regular and two supplementary examinations of I year. b.Two regular and two supplementary examinations of II year I semester. c.Two regular and one supplementary examinations of II year II semester. One regular and one supplementation examination of III year I semester (60%)

- A student shall register and put up minimum attendance in all 226 credits and earn 218 credits. Marks obtained in the best 216 credits shall be considered for the calculation of percentage of marks.

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II Year B. Pharm I-Sem	L	P	C
	4+1	-	4

(R13201) PHARMACEUTICAL UNIT OPERATIONS- I

Objective: The student shall be exposed to various aspects of handling of fluids, application of filtration, centrifugation, crystallization and humidification in pharmaceutical industry.

UNIT I

a. Fluid Flow: Types of flow, Reynold's number, viscosity, concept of boundary layer, basic equations of fluid flow, valves, flow meters, manometers and measurement of flow and pressure.

b. Dehumidification and Humidity control

Basic concepts and definition, wet bulb and adiabatic saturation temperature. Psychrometric chart and measurement of humidity, application of humidity measurement in pharmacy, equipments for dehumidification operations.

UNIT II

Filtration and Centrifugation: Theory of filtration, filter aids, filter media, industrial filters including filter press, rotary filter, edge filter, etc. Factors affecting filtration, mathematical problems of filtration, optimum-cleaning cycle in batch filters.

Principles of centrifugation, industrial centrifugal filters, centrifugal filters, and centrifugal sedimeters.

UNIT III

Crystalization: Characteristics of crystals like; purity, size, shape, geometry, habit, forms, size and factors affecting it. Solubility curves and calculation of yields. Supersaturation theory and its limitations. Nucleation mechanisms, crystal growth. Study of various types of crystallizers such as Swenson walker crystalizer, vacuum crystalizer, crystal crystallizer. Caking of crystals and its prevention. Numerical problems on yields.

UNIT IV

Distillation: Raoult's law, phase diagrams, volatility, simple steam and flash distillations, principles of rectification, Azeotropic and extractive distillation

UNIT V

Industrial hazards and safety precautions: Mechanical, Chemical, Electrical, fire and dust hazards. Industrial dermatities, accident records etc.

Outcomes: Student will understand the concepts of fluid flow, parameter of filtration, centrifugation, crystallization and humidification. They also understand the safety factors and posses a sound knowledge on the above aspects.

TEXT BOOKS

1. S.J. Carter, Cooper and Gunn's Tutorial Pharmacy 6th ed CBS publisher, Delhi.
2. G.V.S. Subramanyam, Pharmaceutial Unit Operation, Vallabh Prakashan
3. Prof. K. Samba Murthy, Pharmaceutical Engineering.
4. Badzer & Banchero, Introduction to Chemical Engineering

REFERENCES

1. Perry's Handbook of Chemical Engineering.
2. Unit Operations by Mc Cabe & Smith.
3. Mc Cabe & Smith, Elements of Chemical Engineering.
4. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences.
5. EA Rawlins, Bently's Text Book of Pharmaceutics, 8th edition, ELBS
6. Essentials of pharmaceutical engineering by D.V.Derle

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II Year B. Pharm I-Sem

L	P	C
4+1	-	4

(R13202) PHARMACEUTICAL ORGANIC CHEMISTRY - II

Objective: The chemistry of highly complicated organic compounds like polynuclear hydrocarbons and heterocyclic compounds are discussed along with their stereochemical aspects

Note: Definition, nomenclature, structure, aromaticity, reactivity, acidity-basicity and characteristic reactions of the following heterocyclic compounds.of Unit I and II
Few Examples of Drugs which contain the cited ring system.

UNIT I

Five membered and six membered ring systems with one hetero atom: Furan, pyrrole, thiophene and pyridine.
Fused ring systems with one hetero atom: Indole, quinoline, iso-quinoline, and acridine.

UNIT II

Five membered and six membered ring systems with two heteroatoms: Pyrazole, imidazole, oxazole, isoxazole, thiazole, pyrazine, pyrimidine and pyridazine.
Fused ring systems with two heteroatoms: Benzimidazole and phenothiazine, Cinnoline, Quinazoline and Quinoxaline.

UNIT III

Stereochemistry of Carbon compounds: Optical rotation, plane polarized light, optical activity, chirality, notations (assignment of configuration), relative configuration (Fischer DL configuration), absolute configuration (R & S), sequence rules (with examples), enantiomers, meso compounds, racemic mixture, resolution.
Stereochemistry of alkenes: Concept of E & Z configurations.Elements of symmetry.

UNIT IV

a) Polynuclear aromatic hydrocarbons: Nomenclature, structure and aromatic character of naphthalene, anthracene, phenanthrene and naphthacene resonance structures, electron density and reactivity. Electrophilic substitution, oxidation and reduction reactions.
b)Purine derivatives (xanthine bases): Chemical structures of uric acid and methylated xanthines (caffeine, theophylline and theobromine) of physiological/ pharmaceutical significance.
c) Definitions of nucleic Acids, nucleotides, nucleosides, A brief account on structure of DNA & RNA.

UNIT V

A study of the mechanism and application in synthesis of the following named reactions:

A. Beckmann rearrangement
B. Birch reduction
C. Mannich reaction
D. Michael addition reaction
E. Wittig reaction
F. Lossen rearrangement
G. Curtius rearrangement
H. Schmidt reaction

Outcome: As the structural and stereochemical aspects and chemistry of organic compounds are discussed, it would help the students to have a good command over structural composition of organic compounds to evaluate and analyze the chemistry of these compounds

TEXT BOOKS

1. R Morrison and R. Boyd, organic chemistry, Pub by Printice Hall of India, New Delhi.
2. I L Finar, Organic Chemistry, Vol. I. & II, 6th Pearson education
3. Reagents & reaction by O.P Agarwal
4. Oraganic reactions,Stereo chemistry&mechanizam by PS Kalsi

REFERENCES

1. Jerry March, Advanced Organic Chemistry 4th Ed.
2. Cram & Hammond.Organic Chemistry.
3. A.I. Vogal, A textbook of practical organic chemistry
4. Solomons, Organic Chemistry
5. Eliel, Stereochemistry of Organic compounds.
6. Arun Bahl & S.S Bahl, Advanced Organic Chemistry

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II Year B. Pharm I-Sem

L	P	C
4+1	-	4

(R13203) STATISTICAL METHODS AND COMPUTER APPLICATIONS

Section - A: Bio-statistics

Objective: The objective of the course, centered around various techniques, collection of data and its treatment; Probability and distribution, correlation, regression and statistical inferences, besides computer application.

UNIT I

i. **Data collection and treatment:** Data Colection and organization, diagrammatic representation of data(bar, pie, 2-D and 3-D diagrams), standard deviation and standard error of means, co-efficient of variation, Correlation and regression analysis.
ii. **Probability and Distributions:** Bayer's theorem, probability theorem, elements of binomial and poison distribution, normal distribution curve and properties.

UNIT II

Statistical inference: Common parametric and non-parametric tests (t-test, F-test, X^2-test employed in testing of significance in biological/pharmaceutical experiments and elements of ANOVA (One way and two way).

UNIT III

Design of experiments: Basic concepts of CRD, RBD and Latin square designs.
Sampling and Quality Control: Concept of random sampling, statistical QC charts. Applications of statistical concepts in pharmaceutical sciences.

Section - B: Computer Applications

UNIT IV

MS-Excel: Basics, spreadsheets, data types, formulas, formatting, charts, graphs. Calculation of statistical parameters using excel.
MS-Power Point: Power point Basics, views, slide controls, applied design, page setup, templates, back ground control, colour screens, transitions, and animations, working with texts, and working with graphics.

UNIT V

Database Management: Concepts and Objectives of database management systems, advantages of the database management systems and examples of DBMS packes (like DBASE III)
Introduction to structured Query language (SQL): over view of SQL, Reserved words, SQL Commands.
Computer Applications in pharmaceutical and clinical studies,

Outcome: At the end of the course the expected outcomes are thorough knowledge of statistical techniques and application of computer in pharmacy

TEXT BOOKS

1. Sanford Boltan, Pharmaceutical statistics, Practical and clinical applications
2. Pranab Kumar Benarjee, Introduction to Biostatistics
3. Khan and Khanum, Fundamentals of Biostatistics
4. Text book of STATISTICAL Methods and computer applications by Dr. A. Ramakrishna Prasad.
5. Ron Mansfiled, Working In Microsoft Office.
6. Ivan Bayross, SQL, PL/SQL the Programming Language of oracle.

REFERENCE

1. Roger E. Kirk, Statistics an introduction, Thomson Wadsworth
2. Walter T. Ambrosius, Topics in Biostatistics, Humana Press
3. Philip Rowe, Essential Statistics for the Pharmaceutical Sciences, Wiley
4. Dona E. Knath, The Art Of Computer Programming by Pearson Education (Singapore) Pvt. Ltd Delhi, 110 092.
5. Remez Elmasi, Shankar. B. Navathe, Fundamentals Of Database System, Pearson Education (Singapore) Pvt. Ltd Delhi, 110 092.
6. Collins, Dictionary Of Computers and IT by Ian Sinclair, Harper Collins Publishers Glasgow, UK.
7. Y. Raja Raman, Computer Programming in C.
8. Introduction to Biostatistics by Dr. Pranab Kumar Banarjee
9. Introduction to Biostatistics and research methods by P.S.S. Sundar Rao and J. Richard.
10. Experimental statistics by Dr. K.Balaji: S. Chand Publication

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

II Year B. Pharm I-Sem

L	P	C
4+1	-	4

(R13204) PHYSICAL PHARMACY – I

Objective: The student shall know important physical properties of drug molecules, phase value & its importance. Different law of thermodynamics, electrolyte and non-electrolyte solutions, importance of p^H and drug research.

UNIT I

Physical properties of Drug Molecules: Dielectric constant induced polarization, dipole moment, refractive index and molar refraction and optical rotatory dispersion.

UNIT II

a. Phase equilibria and the phase rule:- System containing single component, System containing two component, two component system containing solid and liquid phases, three component systems

b. Thermodynamics: The first law of thermodynamics. The second law of thermodynamics. The third law of thermodynamics, Free energy functions and applications.

UNIT III

a. Solutions of Electrolytes: Properties of solutions of electrolytes. The Arrhenius theory of electrolyte dissociation. The modern theory of strong electrolytes and other coefficients for expressing colligative properties.

b. Solutions of Non electrolytes: Concentration expressions, ideal and real solutions, colligative properties, molecular weight determinations.

UNIT IV

Ionic equilibria: Modern theories of acids, bases and salts, Sorensen's pH scale, species concentration as a function of pH, calculation of pH and acidity constants.

UNIT V

Buffers and buffered isotonic systems: The buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions, methods of adjusting tonicity and pH (relevant numerical problems).

Outcomes: Student will know about physical properties of molecules, three laws of thermodynamics, properties of electrolytes and non electrolytes, p^H and buffers. They also understand the importance of these studies in the physical pharmaceutics & Formulation development.

TEXT BOOKS

1. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences Fifth Edition.
1. C.V.S.Subramanyam, Essentials of Physical Pharmacy, Vallabh Prakashan.
2. B.S Bahl, Arun Bahl and G.D Tuli, Essentials of Physical Chemistry.
3. Derle D.V., Essentials of Physical Pharmacy

REFERENCES

1. Pharmacopoeias, (I.P., B.P., U.S.P. and European.)
2. Martindale, The Extra Pharmacopoeia; latest edition, the Royal Pharmaceutical Society.
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
4. Robin. J. Haiwan, Hand Book of Pharmacy & Health Care ED, The Pharma Press UK.
5. Physical Pharmaceutics by Surydevara Vidhyadhara

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

II Year B. Pharm I-Sem	L	P	C
	4+1	-	4

(R13205) ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY

Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the human body. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs

UNIT I

Central Nervous System: Functions of different parts of brain and spinal cord. Neurochemical transmission in the central nervous system, reflex action, electroencephalogram, cranial nerves and their functions. epilepsy, psychosis, depression, mania, Parkinsonism, Alzheimer's disease.

Autonomic Nervous System: Physiology and functions of autonomic nervous system. Mechanism of neurohumoral transmission in the A.N.S.

UNIT II

Respiratory System: Anatomy of respiratory organs. Functions of respiration, mechanism and regulation of respiration, respiratory volumes and vital capacity. Asthma, tuberculosis.

Urinary System: Various parts, structures and functions of the kidney and urinary tract. Physiology of urine formation and acid base balance, urinary tract infections. acute and chronic renal failure.

UNIT III

Endocrine System: Basic anatomy and physiology of pituitary, thyroid, parathyroid, adrenals, pancreas, testes and ovary, their hormones and functions. Diabetes, Hyperthyroidism, and Hypothyroidism.

UNIT IV

Reproductive Systems: Male and Female reproductive systems and their hormones, physiology of menstruation, coitus and fertilization. Sex differentiation, spermatogenesis & ogeneisis. Pregnancy its maintenance and parturition.

UNIT V

Basic Principles of Cell Injury , Adaptation & process of inflammation: Causes of cellular injury, pathogenesis, morphology of cell injury. Cellular adaptations, atrophy, hypertrophy. acute and chronic inflammation, mediators of inflammation, brief outline of the process of repair.

Outcomes: Knowledge on structure and functions of various organs of the human body and the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body and the pathological states

TEXT BOOKS

1. Tortora, G.J and Anagnodokas, Principles of Anatomy and Physiology, N.P Harper & Row Publishers N.Y
2. Ross & Willson, Text Book of Human Anatomy, M.J.Mycek S.B Gerther and MMPER
3. Robbins, SL & Kumar, Basic Pathology.
4. Human physiology by D.U Silverthorn and Bruce R. Johnson:PHI Learning publication

REFERENCES:

1. Guyton, Textbook of Medical Physiology, AC Guyton WB Sannders Company, 1995.
2. K. Sembulingam and Prema Sembulingam, Essentials of Medical Physiology, 3rd Edition, Jaypee Bros., New Delhi.
3. M.N.Gosh, Human Physiology
4. Julia F. Gui, Learning Human Anatomy: A Laboratory Text
5. Elaine N. Marieb, Essential of Human Anatomy & Physiology
6. C.C.Chatterjee, Human Physiology.
7. Mc Kinley,Human Anatomy.
8. Rizzo, fundamental of Anatomy Physiology.
9. Cinnamon.V, Jennifer. R, Andrew.R, Seeley's Fundamentals of human anatomy and physiology

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

II Year B. Pharm I-Sem	L	P	C
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(R13206) PHARMACEUTICAL ORGANIC CHEMISTRY-II LAB

I. Synthesis of some simple heterocyclic compounds.

a. 3, 5-Dimethylpyrazole from Acetylacetone.
b. 3, 5-Dimethylisoxazole from Acetylacetone.
c. 4, 5-Diphenylimidazole from Benzil.
d. Benzoxazole from o-Aminophenol.
e. 2, 5-Dioxopiperazine from Glycine.
f. Oxazolone from Benzoylglycine.

II. Molecular rearrangements and named reactions

a. Benzimidazole from o-phenylenediamine (Phillip's Reaction).
b. O-hydroxyacetophenone from phenyl acetate (Fries migration)
c. Benzanilide from benzophenone oxime (Beckmann's rearrangement)
d. Preparation of 2-phenylindole from Phenylhydrazine by Fischer's method.

III. Systematic analysis of organic binary mixtures (Minimum 4 numbers)

REFERENCES

1. Indian Pharmacopoeia– 2010.
2. A.I. Vogel's – Practical Organic Chemistry
3. Mann and Sounders, Pratical organic chemistry

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II Year B. Pharm I-Sem	L	P	C
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(R13207) STATISTICAL METHODS AND COMPUTER APPLICATIONS LAB

1. **Solving biostatistics problems** related to inference, sampling, graphical representation of data etc., with the help of calculators & software programs like Graph-pad.

2. **Sample programs in C**: Program to calculate simple and complex arithmetic expressions, program using structures, program using loops and nested loops, program using functions and simple programs using arrays.

3. **Operating systems** like WINDOWS, UNIX, etc.

4. **Software packages** like MS-WORD, EXCEL, ACCESS, and POWER POINT.

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II Year B. Pharm I-Sem	L	P	C
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(R13208) PHYSICAL PHARMACY – I LAB

1. Percent composition determination by Capillary Flow method
2. Percent composition determination by polarimeter & refractometer
3. Molecular weight determination by Landsberger method.
4. Molecular weight determination by Rast camphor method.
5. Calibration of pH Meter
6. pH Estimation – pH meter
7. pH Estimation – colourimetric method.
8. pH Estimation by Half Neturalization Method
9. Refractive index of liquids.
10. Molar refraction determination
11. Effect of dielectric constant on the solubility of the drug.
12. Phenol water system – CST
13. Lower consolute temperature – Tirethanol amine and Water
14. Heat of neutralization
15. Phase diagram - Phenol – Water, Effect of Impurities.
16. Ternary phase diagram.
17. Preparation of Buffers and Buffer Capacity Determination.

REFERENCES:

1. Physical pharmacy practical book by C.V.S. Subramanyam
2. Physical pharmacy practical text by Guru Prasa Mohanta, Prabal Kumar Manne

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II Year B. Pharm I-Sem	L	P	C
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(R13209) ANATOMY, PHYSIOLOGY & PATHOPHYSIOLOGY

(14 Experiments)

1. Study of reproductive system with the help of charts and models – 2 Experiments.
2. Various devices used in Famliy planning like Copper T, Lippers loop, Pills, Diapharagm and Condom.
3. Microscopic studies of abnormal tissue sections – 4 Experiments.
4. Simple experiments involved in the analysis of normal and abnormal urine; collection of specimen, appearance, determination of pH, sugars, proteins, urea and creatinine – 4 Experiments.
5. Study of special senses with the help of charts and models

REFERENCES

1. Plummer, Practical Biochemistry
2. Chatterjee, Human Physiology
3. C.L. Ghai, Pratical Physiology

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II Year B.Pharm - II Sem	L	P	C
	4+1	-	4

(R40012) PHARMACEUTICAL UNIT OPERATIONS – II

Objective: The student shall be taught on operations like evaporation, drying, objective of size reduction, size separation and mixing.

UNIT I

Evaporation: Basic concept of phase equilibria, factors affecting the evaporation, evaporators, film evaporators, and single effect evaporators.

UNIT II

Drying: Moisture content and mechanism of drying, rate of drying and time of drying calculations, classification and types of dryers, dryers used in pharmaceutical industries tray dryer, Fluid bed dryer, spray dryer and freeze-dryer.

UNIT III

Size Reduction: Definition, objectives of size reduction, factors affecting size reduction, laws governing energy and power requirements of a mill, types of mills including ball mill, hammer mill and fluid energy mill.

UNIT IV

Size Separation: Official standards for powders, sieves, modes of motion in size separation. Sieve Analysis – Testing of powders. Equipment for size separation.

UNIT V

Mixing: Theory of mixing, solid-solid, solid-liquid and liquid-liquid mixing equipment, double cone, twin-shell, silverson mixer, colloid mill, sigma blade mixer, planatery mixer, propeller mixer and turbine mixer.

Outcome: Student will be familiar with concepts of evaporation, drying, size reduction ,mixing and understand the pharmaceutical applications in industry.

TEXT BOOKS

1. S.J. Carter, Cooper and Gunn's Tutorial Pharmacy, 6th ed., CBS publisher, Delhi.
2. CVS Subhramanyam, Pharmaceutical Engineering.
3. K. Samba Murthy, Pharmaceutical Engineering
4. Mc Cabe & Smidth.Unit Operations.

REFERENCE BOOKS

1. W.I. Macebe and J. C. Smith Macro, Unit Operations for Chemical Engineering, Hill Int. Book Co., London.

2. L. Lachman, H. Lieberman & J. L Kaniz, The Theory And Practice Of Industrial Pharmacy, Lee & Febiger Philadelphia, USA.
3. Badzer & Banchoro, Introduction to Chemical Engineering.
4. Perry's Handbook of Chemical Engineering.
5. M.E.Aulton, Pharmaceutics- The science of dosage form design, 2nd ed.
6. E.A. Rawlin's, Bentley's Text Book of Pharmaceutics, 8th ed ELBS.

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(R40013) PHARMACEUTICAL BIOCHEMISTRY

Objective: The metabolism of complex biochemical substances are discussed in detail. The Biochemical organization and Bioenergetics which will help the students to understand the concepts of biochemistry.

UNIT I

(a) Biochemical organization of the cell, molecular constitutents of membrane, active & passive transport process, sodium and potassium pumps, osmoregulation and heamostatis.

(b)Bio-energetics: The concept of free energy, laws of thermodynamics. Determination of change in free energy from equilibrium constant & reduction potential.

(c)The respiratory chain & its role in energy capture & its control. Oxidative phosphorylation & its energetics & Electron Transport Chain, mechanism of actions. Production of ATP and its biological significance

UNIT II

Enzymes & Co-enzymes: Classification, Structure, mechanism of action, properties, factors affecting enzymes action. Activators & de activators of enzymes, enzyme kinetics & enzyme inhibitions, repressions with reference to drug action.

UNIT III

Metabolism of Carbohydrates: Biochemistry of carbohydrates, Glycolysis, glycogenesis, glycogenolysis, gluconeogenesis, Kreb's cycle, HMP shunt & uronic acid pathways, anaerobic respiration in muscle.

UNIT IV

Metabolism of Proteins: Biochemistry of proteins, *Amino acid structure & classifications, de amination, Trans-amination, de-carboxylation, Urea cycle, Metabolism of* valine, cystine, cystein, tryptophan, tyrosine, methionine.

UNIT V

(a) Metabolism of Lipids:

Biochemistry of lipids, Alpha, Beta, Gama & Omega oxidations of fatty acids, bio-synthesis of fatty acids, cholesterol, ketogenesis.

(b) Introduction to xenobiotic metabolism, detoxification mechanisms, biochemistsry and metabolism of nucleic acids and vitamins.

Outcome: The metabolism of complex biochemical compounds would make the students to gain a good knowledge about biochemical organization in

the human system.

TEXT BOOKS

1. Harper's Biochemistry
2. A.L.Lehninger, Principles of Biochemistry.
3. Satyanarayana, Text Book of Biochemistry.
4. Text book of biochemistry by S.C.Rastogi.
5. Text book of biochemistry by Sindhe and Chatarjee.

REFERENCES

1. L.Stryer, Text Book of Bio Chemistry.
2. E.E Conn & P.K. Stumpf, Outlines of Biochemistry by, Publ, John Wiley & sons, New York.
3. B.Harrow and A. Mazur, Text Book of Biochemistry, WB Saunders Co., Philadelphia.
4. Boyer Rodney, Modern experimental Bio Chemistry.
5. West, Edward Text Book of Biochemistry.
6. Plummer, Practical Bio Chemistry.
7. Denniston, Topping & Caret; General, Organic, and Biochemistry, McGraw-Hill.
8. A.V.V.S. Rama Rao, Text Book of Bio Chemistry.
9. Pharmaceutical biochemistry by S.Chand, Dr. K.N.Jayveera, Dr. Subrahmanyam, Dr. K.Yogendra Reddy.
10. Biochemistry atlas by Jan Koolman Klaus - Heinrich Roehm.
11. Panini Biochemisty- an essential text review- thieme publications.

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II Year B.Pharm - II Sem	L	P	C
	4+1	-	4

(R40014) PHARMACOGNOSY -I

Objective: To know the medicinal and pharmaceutical importance of drugs obtained from the natural sources and to acquire the knowledge on crude drugs by studying them under a suitable pharmacognostic scheme.

UNIT I

Definition, History and Scope of Pharmacognosy.

Crude drugs : Organized and Unorganized crude drugs, Classification of crude drugs. Scheme for pharmcognostic study of crude drugs.

UNIT II

Cultivation, Collection, Processing of Crude drugs:

Merits and demerits of cultivation of crude drugs. Exogenous factors affecting cultivation. A brief account of pests and methods of pest control. A brief introduction to plant growth regulators. Collection and processing of crude drugs.

UNIT III

Quality Control of Crude Drugs: Crude drug adulteration; Types of adulterants, evaluation of a crude drug and methods of evaluation.

UNIT IV

a) A general introduction to carbohydrates, proteins and enzymes.

b) Systematic pharmacognostic study of Agar, Isapgol and Gelatin.

c) Biological source, collection, preparation, chemical constituents, chemical tests and uses of the following crude drugs – Guar gum, Gum acacia.

d) Honey, Pectin, Starch, Sterculia, Tragacanth, Papain and Diastase.

UNIT V

a) General Introduction to Lipids.

b) Biological source, collection, preparation, chemical constituents, chemical tests and uses of the following crude drugs – Castor oil, Olive oil, Linseed oil, Cod liver oil, Shark liver oil, Cocoa butter, Kokum butter, Bees wax, Wool fat, Lard.

Outcome: At the end of the semester the student shall be aware of different sources of crude drugs, cultivation aspects of medicinal and aromatic plants, evaluation methods for crude drugs, the medicinal importance and the role of crude drugs as excipients in various pharmaceutical dosage forms.

TEXT BOOKS

1. Kokate C.K, Purohit AP & Gokhale Pharmacognosy S.B (Nirali)
2. Trease and Evans Pharmacognosy, Latest Edition.
3. Tyler, Brady & Robert, Pharmacognosy.
4. T.E.Wallis, Textbook of Pharmacognosy, Pub by CBS Publishers and distributors, New Delhi.

REFERENCES

1. Atal C.R & Kapur B.M, Cultivation & Utilization of Medicinal Plants.
2. Ayurvedic Pharmacopoeia of India, Pub by Govt. of India.
3. A.A. Farooqi & B.S. Sree Ramu, Cultivation of Medicinal and Aromatic Crops, University Press, Hyderabad.
4. CSIR Publications, Wealth of India.
5. Handa and Kapoor, Text Book of Pharmacognosy.
6. Gokhale, Pharmacognosy.
7. Md. Ali, Pharmacognosy.
8. Heinrich, Fundamentals of Pharmacognosy and Phytotherapy.
9. B.P. Pandey, Economic Botany.
10. Pharmacognosy, Phytochemistry, Medicinal Plants by Jean Bruneton.
11. Pharmacognosy and Phytochemistry by Vinod Rangari.
12. Anatomy of crude drug by M.A.Iyengar.
13. Pharmacognosy by C.S. Shah & Qadery.
14. Pharmacognosy of powdered crude drugs by M.A.Iyengar.

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II Year B.Pharm - II Sem	L	P	C
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(R40015) PHYSICAL PHARMACY - II

Objective: The student shall be taught on industrial phenomenon of liquids, rate & order of reactants, micromeritics, flow of liquids and type of colloids and their properties.

UNIT I

Kinetics: Rates and orders of the reaction. Influence of temperature and other factors on reaction rates. Decomposition and stabilization of medicinal agents, kinetics in the solid state and accelerated stability analysis (relevant numerical problems).

UNIT II

a. Interfacial Phenomena: Liquid interfaces, measurement of surface and interfacial tensions, adsorption at liquid interfaces. Surface-active agents and HLB scale. Adsorption at solid interfaces. Electrical properties of interfaces.

b. Colloids: Introduction, types of colloidal systems, solubilization, Stability of colloids, optical properties, kinetic properties, electrical properties and Donnan Membran equilibraium.

UNIT III

Micromeritics: Particle size and size distribution, methods for determining surface area, methods for determining practicle size, pore size, particle shape and surface area, derived properties of powders.

UNIT IV

Rheology: Newtons law of flow, Newtonian systems, non-Newtonian systems, thixotropy, measurement and applications in formulations. Determination of viscosity (study of working of different viscometers like cup and bob, Brookfield, ostwald's, cone and plate, capillary viscometers) and its applications.

UNIT V

Coarse Dispersions: Suspensions: Types of suspensions, interfacial properties of suspended particles, stability evaluation, settling in suspensions, formulation of suspensions.

Emulsions: Theories of emulsification, physical stability of emulsions, preservation of emulsions, rheological properties of emulsions and suspensions.

Outcome: Student will know about influence of temperature and other factors on rate of reactants, interfacial phenomena, particle size & distribution,

Newtonian and Non-Newtonian flows.

TEXT BOOKS

1. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences 5th Edition.
2. CVS Subhramanyam, Physical Pharmacy, Vallabh prakashan.
3. L. Lachman, H. Lieberman The Theory And Practice Of Industrial Pharmacy J. L Kaniz Lee & Febiger Philadelphia, USA.

REFERENCE

1. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
2. M.E. Aulton, Pharmaceutics – The science of dosage form design, 2nd edn.
3. Derle D.V., Essentials of Physical Pharmacy

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II Year B.Pharm - II Sem	L	P	C
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(R40016) ENVIRONMENTAL STUDIES

Objectives:

1. This course will give the importance of maintenance of ecological balance for sustainable development.
2. Understanding the impacts of developmental activities and mitigation measures.
3. Understanding of environmental policies and regulations

UNIT-I :

Ecosystems: Definition, Scope and Importance of ecosystem. Classification, structure and function of an ecosystem, Food chains, food webs and ecological pyramids. Flow of energy, Biogeochemical cycles, Bioaccumulation, Biomagnification, ecosystem value, services and carrying capacity, Field visits.

UNIT-II:

Natural Resources: Classification of Resources: Living and Non-Living resources, **water resources:** use and over utilization of surface and ground water, floods and droughts, Dams: benefits and problems. **Mineral resources:** use and exploitation, environmental effects of extracting and using mineral resources, **Land resources:** Forest resources, **Energy resources:** growing energy needs, renewable and non renewable energy sources, use of alternate energy source, case studies.

UNIT-III:

Biodiversity and Biotic Resources: Introduction, Definition, genetic, species and ecosystem diversity. Value of biodiversity; consumptive use, productive use, social, ethical, aesthetic and optional values. India as a mega diversity nation, Hot spots of biodiversity. Field visit. Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts; conservation of biodiversity: In-Situ and Ex-situ conservation. National Biodiversity act.

UNIT-IV:

Environmental Pollution and Control Technologies: Environmental Pollution & control: Classification of pollution, causes, effects and control technologies. **Air Pollution:** Primary and secondary pollutants, Automobile and Industrial pollution, Ambient air quality standards. **Water pollution:** Sources and types of pollution, drinking water quality standards. **Soil Pollution:** Sources and types, Impacts of modern agriculture, degradation of soil. **Noise Pollution:** Sources and Health hazards, standards, **Pollution**

from Power projects, Solid waste: Municipal Solid Waste management, composition and characteristics of e-Waste and its management. **Pollution control technologies:** Wastewater Treatment methods: Primary, secondary and Tertiary, Air: Overview of air pollution control technologies, Concepts of bioremediation. Field visit. **Global Environmental Problems And Global Efforts: C**limate change and impacts on human environment. Ozone depletion and Ozone depleting substances (ODS). Deforestation and desertification. International conventions / Protocols: Earth summit, Kyoto protocol and Montréal Protocol.

UNIT-V:

Environmental Policy, Legislation & EIA: Environmental Protection act, Legal aspects Air Act- 1981, Water Act, Forest Act, Wild life Act, Municipal solid waste management and handling rules, biomedical waste management and handling rules, hazardous waste management and handling rules. EIA: EIA structure, methods of baseline data acquisition. Overview on Impacts of air, water, biological and Socio-economical aspects. Strategies for risk assessment, Concepts of Environmental Management Plan (EMP). **Towards Sustainable Future:** Concept of Sustainable Development, Population and its explosion, Crazy Consumerism, Environmental Education, Urban Sprawl, Human health, Environmental Ethics, Concept of Green Building, Ecological Foot Print, Life Cycle assessment (LCA), Low carbon life style.

SUGGESTED TEXT BOOKS:

1 Textbook of Environmental Studies for Undergraduate Courses by Erach Bharucha for University Grants Commission.

2 Environmental Studies by R. Rajagopalan, Oxford University Press.

REFERENCE BOOKS:

1. Environmental Science: towards a sustainable future by Richard T.Wright. 2008 PHL Learning Private Ltd. New Delhi.
2. Environmental Engineering and science by Gilbert M.Masters and Wendell P. Ela .2008 PHI Learning Pvt. Ltd.
3. Environmental Science by Daniel B.Botkin & Edward A.Keller, Wiley INDIA edition.
4. Environmental Studies by Anubha Kaushik, 4th Edition, New age international publishers.
5. Text book of Environmental Science and Technology - Dr. M. Anji Reddy 2007, BS Publications.

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II Year B.Pharm - II Sem	L	P	C
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(R40061) PHARMACEUTICAL UNIT OPERATIONS- II LAB

1. Measurement of flow of fluids and their pressure, determination of reynold's number and calculation of frictional losses.
2. Evaluation of filter media, determination of rate filtration and study of factors affecting filtration including filter aids.
3. Experiments to demonstrate applications of centrifugation.
4. Determination of Humidity-use of Dry Bulb and Wet Bulb thermometers and Psychometric charts.
5. Determination of rate of evaporation.
6. Experiments based on steam, Extractive and azeotropic distillations.
7. Determination of rate of drying, free moisture content and bound moisture content.
8. Experiments to illustrate the influence of various parameters on the time of drying.
9. Experiments to illustrate principles of size reduction, Laws governing energy and power requirements of a size reduction.
10. Experiments to illustrate solid-solid mixing, determination of mixing efficiency using different types of mixers.

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II Year B.Pharm - II Sem	L	P	C
		3	2

(R40062) PHARMACEUTICAL BIOCHEMISTRY LAB

Experiments:

1. To prepare standard buffers (citrate, phosphate & carbonate) and measure the pH.
2. Titration curve for amino acids.
3. Separation of amino acids by two dimensional paper chromatography & gel electrophoresis.
4. The separation of lipids by T.L.C.
5. Identification of carbohydrates
6. Identification of amino acid.
7. Identification of lipids.
8. Estimation of glucose in urine.
9. Estimation of creatinine in urine.
10. Estimation of urea in blood.
11. Estimation of creatinine in blood.
12. Estimation of Serum protein.
13. Estimation of bile pigments in serum.
14. Estimation of alkaline phosphatase in serum.
15. Effect of temperature on the activity of alpha-amylase.

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II Year B.Pharm - II Sem

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(R40063) PHARMACOGNOSY – I LAB

1. Introduction
   a. Introduction to the materials required for microscopic work, preparation of histological slides and their focusing to obtain the critical illumination with the instructions for the use of microscope.
   b. Preparation of commonly used reagents in microscopic work.
2. Identification of following cell contents in plant materials by microscopical and microchemical tests
   a. Starch grains in potato, maize, rice, wheat and ginger
   b. Mucilage
   c. Aleurone grains
   d. Fixed oils
3. Measurement of dimensions of cells and cell contents. Introduction to micrometer and camera lucida (drawing occular)
   a. Measurement of dimensions of starch grains in powdered ginger
   b. Identification of cinnamon by measuring the dimensions of starch grains
   c. Determination of leaf constants such as stomatal numbers, stomatal index, vein-islet and vein termination number and palisade ratio of dicot leaf drugs (demonstration)
4. Detection/ identification of following plant constituents in organized/ unorganized crude drugs by chemical tests.
   a. Carbohydrates
   b. Proteins
   c. Lipids
5. Isolation of starch from Potato.
6. Physical evaluation of crude drugs (demonstration)
   a. Determination of ash values
   b. Determination of Extractive values
   c. Determination of Swelling factor
7. Identification of crude drugs mentioned in the theory by organoleptic

method.

REFERENCES

1. Kandhelwal, Practical Pharmocognosy.
2. C.K. Kokate et.al, Practical Pharmocognosy.
3. Iyengar, Practial Pharmocognosy.
4. Practical Pharmaognosy, Dr. V. Duraiswamy, Dr. K.N. Jayaveera.
5. Anatomy of Crude Drugs by M.A.Iyengar and S.C.K.Nayak – 12th Edition.

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II Year B.Pharm - II Sem	L	P	C
	-	3	2

(R40064) PHYSICAL PHARMACY-II LAB

1. Determination of bulk density, true density and percentage of porosity.
2. Effect of particle size and effect of glidant on angle of repose.
3. Microscopic size analysis, plotting of the graphs, calculation of geometric mean, diameter etc.
4. Determination of particle size by andreason pipette.
5. Determination of CMC of a surfactant.
6. Adsorption Isotherm consturctions.
7. Partition coefficient determination.
8. Determination of sedimentation volume and degree of flocculation.
9. Determination of order of reaction – zero order
10. Determination of Order of reaction – First order.
11. Determination of Second order reaction rate constant.
12. Effect of temperature on solubility of solid in liquid.
13. Effect of addition of Salt/pH/cosolvent on the solubility
14. Surface tension determination using Stalagmometer.
15. HLB value estimation of surfactants.
16. Viscosity – by Ostwald Viscometer, Brookfield viscometer.
17. Preparation of Multiple emulsions - Demonstration.
18. Preparation of Micro emulsion - Demonstration.
19. Determination of Zeta potential - Demonstration.
20. Determination of granular density.
21. Preparation of emulsion, identification and evaluation.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

II Year B.Tech. II Sem (Common to All B.Tech. Branches and B.Pharmacy)	L	T/P/D	C
	-	-/3/-	2

GENDER SENSITIZATION
(An Activity-based Course)

Objectives of the Course:

- To develop students' sensibility with regard to issues of gender in contemporary India.
- To provide a critical perspective on the socialization of men and women.
- To introduce students to information about some key biological aspects of genders.
- To expose the students to debates on the politics and economics of work.
- To help students reflect critically on gender violence.
- To expose students to more egalitarian interactions between men and women.

Learning Outcomes:

- Students will have developed a better understanding of important issues related to gender in contemporary India.
- Students will be sensitized to basic dimensions of the biological, sociological, psychological and legal aspects of gender. This will be achieved through discussion of materials derived from research, facts, everyday life, literature and film.
- Students will attain a finer grasp of how gender discrimination works in our society and how to counter it.
- Students will acquire insight into the gendered division of labour and its relation to politics and economics.
- Men and women students and professionals will be better equipped to work and live together as equals.
- Students will develop a sense of appreciation of women in all walks of life.
- Through providing accounts of studies and movements as well as the new laws that provide protection and relief to women, the textbook will empower students to understand and respond to gender violence.

Unit-I:
UNDERSTANDING GENDER:
Gender: Why Should We Study It? (*Towards a World of Equals*: **Unit -1**)
Socialization: Making Women, Making Men (*Towards a World of Equals*: **Unit -2**)
Introduction. Preparing for Womanhood. Growing up Male. First lessons in Caste. Different Masculinities.
Just Relationships: Being Together as Equals (*Towards a World of Equals*: **Unit -12**)
Mary Kom and Onler. Love and Acid just do not Mix. Love Letters. Mothers and Fathers. Further Reading: Rosa Parks-The Brave Heart.

Unit – II:
GENDER AND BIOLOGY:
Missing Women: Sex Selection and Its Consequences (*Towards a World of Equals*: **Unit -4**)
Declining Sex Ratio. Demographic Consequences.
Gender Spectrum: Beyond the Binary (*Towards a World of Equals*: **Unit -10**)
Two or Many? Struggles with Discrimination.
Additional Reading: Our Bodies, Our Health (*Towards a World of Equals*: **Unit -13**)

Unit – III:
GENDER AND LABOUR:
Housework: the Invisible Labour (*Towards a World of Equals*: **Unit -3**)
"My Mother doesn't Work." "Share the Load."
Women's Work: Its Politics and Economics (*Towards a World of Equals*: **Unit -7**)
Fact and Fiction. Unrecognized and Unaccounted work. Further Reading: Wages and Conditions of Work.

Unit – IV:
ISSUES OF VIOLENCE:
Sexual Harassment: Say No! (*Towards a World of Equals*: **Unit -6**)
Sexual Harassment, not Eve-teasing- Coping with Everyday Harassment- Further Reading: "*Chupulu*".
Domestic Violence: Speaking Out (*Towards a World of Equals*: **Unit -8**)
Is Home a Safe Place? -When Women Unite [Film]. Rebuilding Lives. Further Reading. New Forums for Justice.
Thinking about Sexual Violence (*Towards a World of Equals*: **Unit -11**)
Blaming the Victim-"I Fought for my Life...." - Further Reading: The Caste Face of Violence.

Unit – V:
GENDER STUDIES:
Knowledge: Through the Lens of Gender (*Towards a World of Equals*: **Unit -5**)

Point of View. Gender and the Structure of Knowledge. Further Reading: Unacknowledged Women Artists of Telangana.
Whose History? Questions for Historians and Others (*Towards a World of Equals*: Unit -9)
Reclaiming a Past. Writing other Histories. Further Reading: Missing Pages from Modern Telangana History.

Essential Reading: All the Units in the Textbook, "*Towards a World of Equals: A Bilingual Textbook on Gender*" written by A.Suneetha, Uma Bhrugubanda, Duggirala Vasanta, Rama Melkote, Vasudha Nagaraj, Asma Rasheed, Gogu Shyamala, Deepa Sreenivas and Susie Tharu.
Note: Since it is Interdisciplinary Course, Resource Persons can be drawn from the fields of English Literature or Sociology or Political Science or any other qualified faculty who has expertise in this field.

REFERENCE BOOKS:

1. Sen, Amartya. "More than One Million Women are Missing." New York Review of Books 37.20 (20 December 1990). Print. *'We Were Making History...' Life Stories of Women in the Telangana People's Struggle*. New Delhi: Kali for Women, 1989.
2. Tripti Lahiri. "By the Numbers: Where Indian Women Work." *Women's Studies Journal* (14 November 2012) Available online at: http:// blogs.wsj.com/ India real time/2012/11/14/by –the-numbers-where-Indan-women-work/>
3. K. Satyanarayana and Susie Tharu (Ed.) Steel Nibs Are Sprouting: New Dalit Writing From South India, Dossier 2: Telugu And Kannada http://harpercollins.co.in/BookDetail.asp?Book_Code=3732
4. Vimala. "Vantillu (The Kitchen)". *Women Writing in India: 600 BC to the Present. Volume II*: The 20th Century. Ed. Susie Tharu and K. Lalita. Delhi: Oxford University Press, 1995. 599-601.
5. Shatrughna, Veena et al. *Women's Work and its Impact on Child Health and Nutrition*, Hyderabad, National Institute of Nutrition, Indian Council of Medical Research. 1993.
6. Stree Shakti Sanghatana. *"We Were Making History ...' Life Stories of Women in the Telangana People's Struggle*. New Delhi: Kali for Women, 1989.
7. Menon, Nivedita. Seeing like a Feminist. New Delhi: Zubaan-Penguin Books, 2012
8. Jayaprabha, A. "Chupulu (Stares)". *Women Writing in India: 600BC to the Present. Volume II*: The 20th Century Ed. Susie Tharu and K. Lalita. Delhi: Oxford University Press, 1995. 596-597.
9. Javeed, Shayan and Anupam Manuhaar. "Women and Wage Discrimination in India: A Critical Analysis." *International Journal of Humanities and Social Science Invention* 2.4(2013)
10. Gautam, Liela and Gita Ramaswamy. "A 'conversation' between a Daughter and a Mother." *Broadsheet on Contemporary Politics*. Special Issue on *Sexuality and Harassment: Gender Politics on Campus Today*. Ed. Madhumeeta Sinha and Asma Rasheed. Hyderabad: Anveshi Research Center for Women's Studies, 2014.
11. Abdulali Sohaila. *"I Fought For My Life...and Won."*Available online at: http://www.thealternative.in/lifestyle/i-fought-for-my-lifeand-won-sohaila-abdulal/
12. Jeganathan Pradeep, Partha Chatterjee (Ed). *"Community, Gender and Violence Subaltern Studies XI"*. Permanent Black and Ravi Dayal Publishers, New Delhi, 2000
13. K. Kapadia. The *Violence of Development: The Politics of Identity, Gender and Social Inequalities in India*. London: Zed Books, 2002
14. S. Benhabib. *Situating the Self: Gender, Community, and Postmodernism in Contemporary Ethics*, London: Routledge, 1992
15. Virginia Woolf. *A Room of One's Own*. Oxford: Black Swan. 1992.
16. T. Banuri and M. Mahmood, *Just Development: Beyond Adjustment with a Human Face*, Karachi: Oxford University Press, 1997

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem	L	P	C
	4+1	-	4

(R50017) PHARMACEUTICAL ANALYSIS –I

Objective: The basic concepts and analytical techniques of various pharmaceuticals are discussed in a detailed manner.

UNIT I

a. Computation of analytical results, significant figures, concept of error, precision, accuracy, standard deviation, rejection of doubtful values with special reference to volumetric analysis. Calibration of analytical equipment used in volumetric analysis.

b. **Theory of Neutralization Titrations**: Acid-base concept, Acidimetry, Alkalimetry, Common ion effect and solubility product, pH, buffers and indicators.

c. General principles and theory of oxidation-reduction methods and precipitation methods. An account of the indicators used in these titrations.

Application of the above methods in the analysis of drugs, as under IP 2010

UNIT II

a. **Complexometric titration:** Theory, types and application in pharmaceutical analysis. Masking and demasking and their applications.

b. Non-aqueous titration: Theory, types, solvents used and application in pharmaceutical analysis.

c. Gravimetry: Principles, Theory, Precipitation, **co**-precipitation and applications.

UNIT III

a. Potentiometry: Introduction, electrochemical cells and half cells. Electrode, measurement of potential, applications in pharmaceutical analysis.

b. Conductrometric titrations. Basic concepts, different types of conductrometric titrations, apparatus used, applications in pharmaceutical analysis.

c. Polarography: Basic concepts, apparatus and principles, general polarographic analysis, applications in Pharmaceutical Analysis.

d. Amperometric Titrations.

UNIT IV

Study of separations and determinations involving the following techniques and their applications in pharmacy.

a. Coloumn chromatography; Adsorption and partition theory, preparation, procedure, methods of detection.

b. Thin layer chromatography: theoretical consideration, preparation, procedure, detection of compounds.

c. Paper Chromatography: theory of partition, different techniques employed filter papers used, quantitative and quantitative detection.

UNIT V

a.Flamephotometry: Introduction, study and working priciples of instrumentations used for analysis, applications in pharmaceutical analysis.

b. Principle, instrumentation and applications involved in the follwing

i. Refractometry ii. Polarimetry iii. Nephlometry and turbidimetry

c. Physical and chemical methods of determination of moisture content (including Karl-Fisher method).

Outcome: The knowledge gained upon the detailed study of the analytical techniques will be useful to analyze the pharmaceutical substances in a systematic qualitative and quantitative manner.

TEXT BOOKS

1. Skoog-Instumental Analysis and Skoog fundamentals of analytical Chemistry
2. A.H. Beckett & J.B Stanlake Vol.I&II., Practical Pharmaceutical Chemistry, Athlone Press of the Univ of London
3. Connors, A Textbook of Pharmaceutical Analysis.
4. Chatwal & Anand, Instrumental Methods of Analysis.

REFERENCES

1. A.I Vogel, Quantitative Chemical Analysis, ELBS ed.
2. L M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry., Oxford University Press, Delhi.
3. Pharmacopoeia (IP, BP, USP).
4. Y.Anjaneyulu, K.Chandrasekhar, Valli Manickam, A Textbook of Analytical Chemistry
5. Kasture & Wadodkar, Text Book of Pharmaceutical analysis Vol.I & II.
6. A. Day Under Wood, Text Book of Quantative Analysis.
7. B.K. Sarma, Instrumental Chemical Analysis, Goel Publishers.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem	L	P	C
	4+1	-	4

(R50018) PHARMACEUTICAL MICROBIOLOGY

Objective: Microbiology is always considered to be an essential component of Pharmacy curiculum because of its relevance to pharmaceutical sciences and more specifically to pharmaceutical industry.

This course deals with the various aspects of microorganism their classification morphology, laboratory cultivation, identification, maintenance and control of microorganism, sterility testing and biosafety measures.

The course also covers bacterial genetics, drug resistance and microbiological assays and microbial limit tests.

UNIT I

a. Introduction to Microbiology: Origin, scope and discovery of spontanesous generation theory, contributions of Antony Van Leewenhoek, Louis Pasteur, Robert Koch and Joseph Lister.

b. Diversity of Microorganisms: Prokaryotes versus eukaryotes – three domains of life (bacteria, archea and eurkaryotics). A detailed study of bacteria, yeasts, molds and viruses including their classification. Characterization and identification of microorganisms.

UNIT II

Nutrition and Growth of Microbes: Nutritional requirements, Types of nutrient media and growth conditions and Nutritional types based on energy source.

Isolation, cultivation (aerobic & anaerobic) and preservation of microorganisms, physiology of growth, bacterial growth curve, influence of various factors (including environmental factors) on microbial growth, Enumeration of bacteria. Exponential growth and generation time. Bacterial growth in batch and continous culture (chemostat and turbidostat) synchronous growth.

UNIT III

a. Control of Microorganisms: General concepts, Inhibition of growth and killing, sterilization and disinfection, antisepis and sanitation, mode of action applications & limitations of physical agents (moist and dry heat, radiation and filtration) and chemical agents. Various types of disinfectants, factors affecting sterilization and disinfection, evaluation of antimicrobial activity.

b. Official methods of sterility testing of pharmaceuticals and biosafety measures.

UNIT IV

Bacterial Genetics: Genetic recombination in bacteria, DNA replication, transcription and translation. Gene regulation (lac operon and tryptophan operon). Mutagenesis, chemical and physical mutagens. A study on drug resistance.

UNIT V

a. Introduction to Microbiology of Air, Water and milk. Methods of quantitative evaluation of microbial contamination.

b. Microbiological Assays: Principles and methods involved in assay of Antibiotics, Vitamins, Amino acids & Bio-Sensors in Analysis.

c. Microbial limit tests official in IP

Outcome: Upon completion of the subject student shall be able to –

- know the anatomy, identification & cultivation of microorganisms
- Perform sterilization of various pharmaceutical products, equipment, culture media etc.
- Perform sterility testing of pharmaceutical products.
- Perform microbiological assay of antibiotics, Vitamins and amino acids
- Do microbiological analysis of air, water and milk.

TEXT BOOKS

1. Pelzar and Reid, Text Book of Microbiology.
2. Anantha Narayan and Jayram Panikar, Text Book of Microbiology, Orient Longman, Delhi, Hyderabad.
3. Indian Pharmacopoeia, 1996.

REFERENCES

1. Tortora / Funke / Care / Microbiology an introduction.
2. Stephen. P, Denyer, N.A. Hodger- Hugo & Russel's Pharmaceutical Microbiology.
3. Tortora, Gerard Text Book of Microbiology.
4. E.A Rawlins, Bentley's Text Book of Pharmaceutics, 8th ed.
5. N.K. Jain, Pharmaceutical Microbiology.
6. Dr. Chandrakanth Kokare – Pharmaceutical Microbiology. Prescott. L.M, Jarley G.P., Klein D.A." Microbiology" 2nd Edition.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem

L	P	C
4+1	-	4

(R50019) PHARMACOGNOSY – II

Objective: To have knowledge on the formation of pharmaceutically important secondary metabolites in plants and their commercial significance. The role of fibres, natural sweetening agents, colorants, volatile oils, tannins, resins in pharmaceutical, cosmetic and food industry. To make the student aware of what is Ayurveda and its various preparations.

UNIT I

Biogenesis of Natural Products:

a. A brief account of primary and secondary metabolite production from carbon metabolism in plants.

b. Production of amino acids by Shikimic acid pathway.

c. Biogenesis of Atropine, Morphine, Isoprenoid compounds and Cardiac glycosides.

UNIT II

a) General introduction to Volatile oils.

b) Systematic pharmacognostic study of the following: Cinnamon, Cassia, Clove, Capsicum, Ginger and Cardamom.

c) Biological source, collection and preparation, chemical constituents and tests for identification, uses, substitutes and adulterants of following – Fennel, Dill, Eucalyptus oil, Gaultheria, Lemon grass oil, Oil of Citronella, Mentha oil, Musk, Palmrose and Sandalwood.

UNIT III

a) General introduction to Tannins and Resins.

b) Biological source, collection and preparation, chemical constituents and tests for identification and uses of following – Black Catechu, Pale Catechu, Myrobalan, Arjuna, Gall, Balsam of Tolu, Benzoin, Guggul, Myrrh and Podophyllum.

UNIT IV

a) A brief introduction to Ayurveda and its preparations like Arishtas, Asavas, Gutickas, Tailas, Churnas, Lehyas and Bhasmas.

b) A brief account of phytopharmaceuticals of commercial significance.

UNIT V

a) Study of Fibres used in Pharmacy such as Cotton, Silk, Wool and Glass wool.

b) A brief introduction to natural Sweeteners and Colorants with the following as examples.

i) Steviol glycosides ii) Thaumatin iii) Henna

iv) Cochineal v) Saffron

c) Study of mineral drugs: Bentonite, Kaolin and Talc

Outcome: After the study of the course, the student shall be able to know about the phytopharmaceuticals of commercial significance and the various applications of the crude drugs in the preparation of formulations as medicaments and excipients (Flavors, perfumes, sweeterners and colorants).

TEXT BOOKS

1. Kokate C.K , Purohit AP & Gokhale, The Pharmacognosy S.B (Nirali).
2. Trease and Evans, Pharmacognosy, Latest Edition.
3. Tyler, Brady & Robert, Pharmacognosy.
4. Text Book of Pharmacognosy by S.S.Khadabadi.

REFERENCES

1. Atal C.R & Kapur B.M, Cultivation & Utilization of Medicinal Plants.
2. Wallis, Textbook of pharmacognosy, Pub by CBS Publishers and distributors, New Delhi.
3. Ayurvedic Pharmacopoeia of India, Pub by Govt. of India.
4. Herbal Drug Industry Eastern Publishers., New Delhi.
5. J.B.Harbone, Phytochemical Methods: A guide to modern techniques of Plant analysis.
6. Pharmacognosy, Phytochemistry, Medicinal Plants by Jean Bruneton.
7. Pharmacognosy and Phytochemistry by Vinod Rangari.
8. Plant Drug Analysis by Wagner. H. & Blandt. S.
9. Ayurvedic Pharmacopoeia of India, Pub by Govt. of India.
10. Khare C.P, Indian Medicinal plants – An Illustrated dictionary.
11. Mohammad Ali, Pharmacognosy. CBS Publications.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem	L	P	C
	4+1	-	4

(R50020) PHARMACEUTICAL TECHNOLOGY – I

Objective: The student shall be taught on preformulation factors and objectives of preformulation, stability and Bioavailability of formulation, concept of products, semisolids, aerosols and cosmetic preparations.

UNIT I

Preformulation:

a. Introduction and objectives of preformulation study and development of dosage forms, Physical and Chemical aspects.

b. Stability and bioavailability study of prodrugs in solving problems related to stability bio availability in formulations.

c. Stability testing of finished products as per ICH guidelines.

UNIT II

a. Semisolid dosage forms: Definitions, types, mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semi solids, clear gels manufacturing procedure, evaluation and packaging.

b. Opthalmic Preparations: Requirements, formulation, methods of preparation, containers and evaluation.

UNIT III

a. Pharmaceutical aerosols: Definition, propellants general formulation, manufacturing and packaging methods, pharmaceutical applications and evaluation.

b. Dry Syrups, Formulation, Preparation, Evaluation and special applications with examples.

UNIT IV

Cosmeticology and Cosmetic Preparations: Fundamentals of cosmetic science, Formulation, preparation and packaging of cosmetics for skin, hair, dentrificers like tooth powders, paste, gels and manicure preparations like nail polish, lipsticks, eye lashes, baby care products etc.

UNIT V

a. Packaging of Pharmaceutical products: Packaging components, types, specifications and methods of evaluation as per I.P. Factors influencing choice of containers, package testing, legal and other official requirements for containers, packing testing.

b. Methods of packing of solid, liquid and semi-solid dosage forms, Factors influencing packing material and stability aspects of packaging.

Outcome: Student will know the preformulation parameters in designing the dosage form, ICH guidelines, preparation and evaluation of semisolids, ophthalmic and cosmetics.

TEXT BOOKS

1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial Pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.

REFERENCES

1. Shobha Rani, Text of Industrial Pharmacy, Hiremath Orient Longman.
2. Essentials of pharmaceutical technology by Ajay semelty, Mona Semalty.
3. Sagarian & MS Balsam, Cosmetics Sciences &Technology Vol.1, 2 & 3.
4. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
5. E.A.Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publ.
6. HC Ansel Introduction to Pharmaceutical Dosage forms.
7. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, Marcel Dekker, Inc., New York 1998.
8. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IVth ed, Marcel Dekker, USA, 2005.
9. Yiew Chien, novel drug delivery systems, Marcel Dekker 2003.
10. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
11. Good Manufacturing Practices – Schedule M Read With The Drugs And Cosmetic Rules 1945.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem	L	P	C
	4+1	-	4

(R50021) PHARMACOLOGY – I

Objectives: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, and route of administration, precautions, contraindications and interaction with other drugs.

UNIT I

General Pharmacology: Introduction to pharmacology, sources of drugs, dosage forms and routes of administration, Absorption, distribution, Metabolism and excretion of drugs, mechanism of action, combined effect of drugs, factors modifying drug action, Adverse drug reactions, tolerance and dependence, pharmacogenetics., principles of drug discovery and phases of drug development.

UNIT II

Pharmacology of Peripheral Nervous System:

a. Neurohumoral transmission (autonomic and Somatic).

b. Parasympathomimetics, parasympatholytics, sympathomimetics & sympatholytics.

c. Skeleton muscle relaxants.

UNIT III

Pharmacology of Central Nervous System:

a. Neurohumoral transmission in the C.N.S.

b. General anesthetics.

c. Alcohols and disulfiram.

d. Pharmacology of Sedatives, hypnotics, anti-anxiety agents.

UNIT IV

a. Analgesics, Antipyretics, Anti-inflammatory and Anti-gout drugs.

b. Narcotic analgesics and antagonists.

c. C.N.S. stimulants.

d. Drug Addiction and Drug Abuse.

e. Local anesthetic agents.

UNIT V

a. Psychopharmacological agents (antipsychotics) Antidepressants, anti-maniacs and hallucinogens.

b. Pharmacology of Anti-epileptic drugs

c. Anti-Parkinsonian Drugs

Outcome: Understand the pharmacological aspects of drugs, importance of pharmacology subject as a basis of therapeutics and correlate the knowledge therapeutically.

TEXT BOOKS:

1. Tripathi, Textbook of Pharmacology, JAYPEE.
2. F.S.K Barar, Essentials of Pharamcotheraptics.

REFERENCES:

1. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann: The Pharmacological basis of therapeutics, Mc Graw hill, Health Professions Dvn.
2. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology,: Churchill Living stone, 4th Ed.
3. J. Crossland, Lewis 's Pharmacology, Church living stone.
4. Mark A. Simmons, Pharmacology An Illustrated Review.
5. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
6. Bertram. G. Katzung, Basic and clinical pharmacology, 9th Edn, Mc Graw hill.
7. Mrinal Kaushik, Pharmacology basics & Clinical aspects, University press.
8. Pharmacology, An illustrated review by Mark A Simmons.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem

L	P	C
-	3	2

(R50065) PHARMACEUTICAL ANALYSIS – I LAB

1. Assay of Pharmaceutical compounds based on chemical methods such as acid base, oxidation-reduction, non-aqueous, complexometric titration method.
2. Conductometric determination of equivalent point of titration of HCl with NaoH.
3. Potentiometric determination of pH of a solution.
4. Potentiometric titration of strong Acid vs strong Base.
5. Potentiometric determination of strength of unknown solution and HCL with NaoH.
6. Nephelometric determination of sulphate & chloride.
7. Fluorimetric estimation of quinine sulphate.
8. Polarographic determination of amount of Nitrobenzene in solutions.
9. Flame photometric determination of Sodium and Calcium.
10. Flame photometric determination of Potassium.
11. Determination of refractive index of liquids by Abbe refractometer.
12. Identification of amino acids by paper chromatography(Ascending and Radial).
13. Identification of alkaloids by TLC.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem	L	P	C
	-	3	2

(R50066) PHARMACEUTICAL MICROBIOLOGY LAB

1. Introduction to equipment and glassware used in microbiology laboratory.
2. Study of morphology of different microbes.
3. Preparation of various culture media, cultivation of microbes and observation of colony characteristics.
4. Sterilization techniques (moist and dry heat) and their validations.
5. Aseptic transfer of culture into different types of media.
6. Characterisation of microbes by staining techniques (simple, gram's, acid fast and negative staining).
7. Study of motility of bacteria by hanging drop method.
8. Characterization of microbes through Bio chemical reactions:
   i) Indole test.
   ii) Methyl red test.
   iii) Voges proskauer test.
   iv) Starch hydrolysis test.
   v) Fermentation of carbohydrates.
9. Isolation of pure cultures by streak plate, spread plate & pour plate techniques.
10. Enumeration of bacteria by pour plate/spread plate technique.
11. Enumeration of bacteria by direct microscopic count.
12. Evaluation of any disinfectant by phenol coefficient test.
13. Study of Oligodynamic action (of metals on bacteria).
14. Preservation of microrganisms (slant and stab cultures).
15. Microbiological Analysis of Water.

REFERENCES

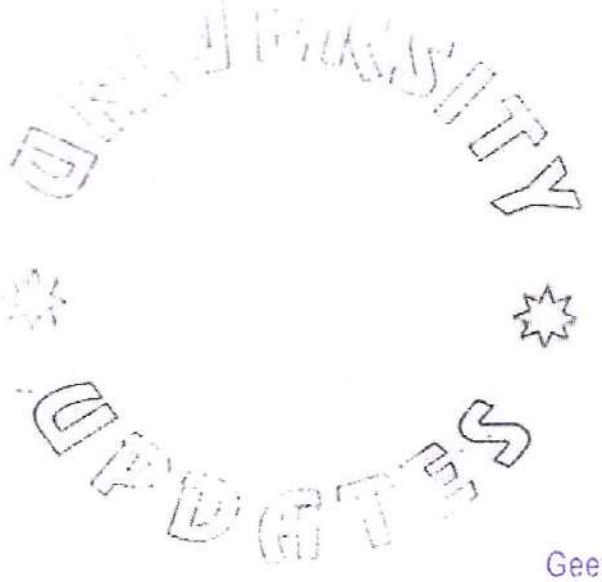
1. Garg,F C Experimental Microbiology.
2. Gaud.R.S, Gupta G.D, Practical Microbiology.
3. Vanitha Kale and kishore Bhusari, Pratical microbiology principles and Techniques.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem	L	P	C
	-	3	2

(R50067) PHARMACOGNOSY II LAB

1. Determination of essential oil content of Eucalyptus/Fennel by Clavenger's apparatus.
2. Detection of Eugenol in Clove oil by TLC.
3. Detection of Eucalyptol in Eucalyptus oil by TLC.
4. Extraction and TLC of Curcuminoids.
5. Detection/Identification of Tannins in crude drugs referred in theory by chemical tests.
6. Detection/Identification of Resinous crude drugs.
   i) Detection of Oleo-gum-resins. Eg. Asafoetida
   ii) Identification of Balsamic resins. Eg. Benzoin, Tolu Balsam.
7. Morphological and microscopical study of – Fennel, Clove, Cinnamon, Ginger and Eucalyptus.
8. Spotting : Identification of crude drugs mentioned in theory by Organoleptic method.



JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - I Sem

L	P	C
-	3	2

(R50068) PHARMACEUTICAL TECHNOLOGY - I LAB

1. Preformulation studies

   Bulk properties, different densities, size and size distribution analysis, compressibility, Carr's index, angle of repose, hausner's ratio.
2. Solubility profile estimation in different pH media.
3. Partition coefficient determination.
4. Effect of crystallinity/amorphous structures on the solubility of the given drugs.
5. Preparation and evaluation of official ointements and gels (in each category any two).
6. Preparation and evaluation of dry syrups (ampicillin, amoxicillin).
7. Preparation and evaluation of the following cosmetics Shampoos, tooth pastes, tooth powders, nail polish, baby shampoo, baby powders, lipsticks, vanishing cream, cold cream, depillators.
8. Evaluation of packaging materials such as glass, plastics, cotton (hydrolytic resistance test for glass) and light absorption test for rubber and closures.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - II Sem	L	P	C
	3+1	-	3

(R60022) MEDICINAL CHEMISTRY – I

Objective: The basic consideration of drug activity, drug metabolism and medicinal substances belonging to different categories are discussed in an elaborative manner. The synthesis and mechanism of action of the medicinal compounds are explained in an organized way which helps the students to understand the medicinal uses of the compounds.

UNIT I

a. Basic considerations of Drug activity: Physico chemical properties of drug molecules in relation to biological activity – Solubility, lipophilicity, partition-coefficient, Ionization, hydrogen bonding, Chelation, redox potential and surface activity. Bioisosterism and steric features of drugs, drug distribution and protein binding: Introduction to Pro and soft drug approaches.

b. Drug metabolism and inactivation: Introduction, Phase-I and Phase-II reactions.

Note: Introduction, definition, nomenclature, chemical classification, structure, synthesis, general mechanism, and mode of action, SAR including physicochemical and stereo chemical aspects, metabolism and therapeutic uses of the drugs from each category shall be studied for the following units. An outline of synthetic procedure of only the drugs mentioned in each category.

UNIT II

Drugs acting on CNS: ***A brief study of the chemistry of neurotransmitters.***

a. Hypnotics and Anxiolytics: Phenobarbital, diazepam, alprazolam, glutethimide

Anti-psychotics: Chlorpromazine, haloperidol, clozapine, oxypentine.

Anti-epileptics: Phenytoin, valproic acid, carbamazepine, ethosuximide.

Anti-depressants: Imipramine, fluoxetine, doxepine.

b. Local anesthetic and General anesthetic agents: benzocaine, procaine, dibucaine and lidocaine, halothane and thiopental sodium.

UNIT III

a. Adrenergic agents and adrenergic blockers. Isoproterenol, atenolol, henoxybenzamine, amphetamine, ephedrine, salbutamol.

b. Cholinergic agents and acetyl cholinesterase inhibitors

Cholinergics: Carbachol, bethanichol.

Anticholinesterase: Neostigmine, pyridostigmine

Neuromuscular blockers: succinyl choline.

(c) Anti-cholinergics: atropine, ipratropium bromide, dicyclomine, bipyridine, propantheline.

UNIT IV

a. Prostaglandins. Introduction, nomenclature, functions,bio synthesis of prostaglandin E1, Structures of clinically useful prostaglandins.

b. Analgesics and NSAIDS (Non-steroidal anti-inflamatory agents):

i. Introduction and types of pain and inflammation.

ii Classification and systematic development of analgesics of morphine, mild analgesics and strong analgesics: Meperidine and Methadone.

iii. NSAIDS – Aspirin, paracetamol, oxyphenbutazone, ibuprofen, indomethacin, diclofenac and meloxicam.

iv. A brief account on Cox-2 inhibitors and nimsulide.

UNIT V

General account of cardiovascular diseases

a. Antihypertensives: methyldopa, amlodipine, enalapril, losartan.

b. Anti-arrhythmics: procainamide.

c. Diuretics: acetazolamide, hydrochlorthiazide, furosemide.

d. Anticoagulants, Anti-anginals and Coronary vasodilators: Isosorbide dinitrate, verapamil, diltiazem.

Outcome: The students gain good knowledge about the usage of medicinal substances, the synthesis and drug-drug interactions, so that they can get involved with confidence in the patient counseling.

TEXT BOOKS:

1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.
2. JH Block & JM Beale (Eds), Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcott, Raven, Philadelphia, 2004.
3. Medicinal Chemistry by Korol Kavas.

REFERENCES

1. D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol. 1 & John Wiley & Sons, New York 2003, 6th Ed.
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences; 20th Edition.

3. C. Hansch, Comprehensive Medicinal Chemistry, Vol 1 – 6 Elsevier pergmon press, Oxford.
4. Daniel lednicer, Strategies for Organic Drug Synthesis and Design, John Wiley, N. Y. 1998.
5. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J.Wiley N.Y.
6. Kadam, Textbook of Medicinal Chemistry Vol. 1 & 2.
7. T Nogrady, Medicinal Chemistry – A Biochemical Approach. Oxford University Press, New York, Oxford.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - II Sem

L	P	C
+1	-	3

(R60023) PHARMACEUTICAL TECHNOLOGY – II

Objective: Student will know the formulation and evaluation of tablets, coated tablets, capsules, micro-encapsules and parenteral preparations in laboratories and industrial scale.

UNIT I

a) Tablets: Formulation and evaluation of tablets:

Conventional, matrix, chewable, multi-layered tablets, buccal and sublingual, fast dissolving tablets and gastric retention drug delivery systems.

b) Machinery used in granulation techniques like rapid mixer granulation, fluidised bed systems and tablet compression.

UNIT II

Coating of Tablets: Types of coating, coating materials and their selection, formulation of coating solution, equipment for coating, coating processes and evaluation of coated tablets. Pellet technology.

UNIT III

a) Capsules: Advantage and disadvantages of capsule dosage forms, material for production of hard and soft gelatin capsules, sizes of capsules, capsule filling, processing problems in capsule manufacturing, importance of base absorption and minimum/gm factors in soft capsules, quality control, stability testing and storage of capsule dosage forms.

b) Microencapsulation: Types and importance in pharmacy, microencapsulation by coacervation phase separator, multi orifice centrifugal separation. Spray drying, spray congealing, polymerization complex emulsion, air suspension technique, and pan coating techniques and evaluation of microcapsules.

UNIT IV

Parenteral Products

a. Preformulation factors, routes of administration, water for injection, treatment apyrogenicity, non-aqueous vehicles, Isotonicity and methods of its adjustment.

b. Formulation details, container and closures and selection.

c. Prefilling treatment, washing and sterilization of containers and closures, preparation of solution and suspensions, filling and closing of ampules, vials, infusion flulids, lyophillization & preparation of sterile powders, equipment for large-scale manufacture and evaluation of

parenteral products.

UNIT V

Aseptic techniques, sources of contamination and method of prevention. Design of aseptic area, laminar flow benches, services and maintenance.

Outcome: The students shall be exposed to various aspects of pharmaceutical product preparations and evaluations of tablets, capsules etc.

TEXT BOOKS

1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. HC Ansel introduction to Pharmaceutical Dosage forms.
3. Pharmaceutical Dosage forms Tablet by Lieberman, Lachman.
4. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.

REFERENCES

1. Sagarian & MS Balsam, Cosmetics Sciences &Technology,Vol.1, 2 & 3.
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
3. E.A.Rawlkins Bentley's Text Book of Pharmaceutics, Elbs publ.
4. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, 2nd ed, Marcel Dekker, Inc., New York 1998.
5. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IVth ed, marcel dekker, USA, 2005.
6. Yiew chien, novel drug delivery systems, 2nd ed, marcel dekker 2003.
7. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
8. Good Manufacturing Practices – Schedule M. Read With The Drugs and Cosmetic Rules 1945 M.E. Aulton, Pharmaceuitcs- The science of Dosage form Design 2nd ed.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - II Sem

L	P	C
4+1	-	4

(R60024) PHARMACOLOGY – II

Objectives: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs.

UNIT I

Pharmacology of drugs acting in cardiovascular diseases

a. Congestive heart failure

b. Hypertension.

c. Shock.

d. Arrhythmias

UNIT II

a. Pharmacology of Drugs used in coronary artery disease and Hyperlipidemias.

b. Pharmacology of Drugs acting on hematopoietic system Anti-coagulants, Anti-platelets, Thrombolytics & Hematinics.

c. Pharmacology of Drugs acting on Urinary system Diuretics.

UNIT III

Autacoids

a. Histamine, 5-HT and their antagonists.

b. Prostaglandins, thromboxanes and leukotrienes.

c. Bradykinin and substance P.

UNIT IV

a. Drugs acting on the respiratory system.
Anti-asthmatic drugs.
Anti-tussives and expectorants.
Respiratory stimulants.

b. Bioassays: Applications, Principles and Methods of Bioassays.

c. Study of bioassay methods for the following drugs.
a. Digitalis, b. D – tubocurarine, c. Oxytocine d. HCG.

UNIT V

Drugs acting on Endocrine system

a. Insulin, Oral hypoglycaemic agents

b. Adrenal steroids

c. Anti thyroid agents.

d. Oral contraceptives

Outcome: Understands the pharmacological aspects of drugs, importance of pharmacology subject as a basis of therapeutics and correlate the knowledge therapeutically.

TEXT BOOKS

1. Tripathi, Textbook of Pharmacology, JAYPEE.
2. F.S.K Barar, Essentials of Pharamcotheraptics.

REFERENCES

1. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann: The Pharmacological basis of therapeutics, Mc Graw hill, Health Professions Dvn.
2. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology,: Churchill Living stone, 4th Ed.
3. Crossland, Lewis 's Pharmacology, Church living stone.
4. Mark A. Simmons, Pharmacology An Illustrated Review.
5. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
6. Bertram. G. Katzung, Basic and clinical pharmacology, 9th Edn, Mc Graw hill.
7. Mrinal Kaushik, Pharmacology basics & Clinical aspects, University press.

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III Year B.Pharm - II Sem

L	P	C
4+1	-	4

(R60025) CHEMISTRY OF NATURAL PRODUCTS

Objective: The chemistry including the structure elucidation of the natural products belonging to different groups such as amino acids, alkaloids, carbohydrates, steroids etc. are discussed in depth.

UNIT I

Poly Functional Natural Products

(a) Carbohydrates: Introduction, Definition, Classification, Isolation, General Properties (including isomerism) and Pharmaceutical importance of Carbohydrates, Chemistry (Structme, Nomenclatme and Reactions) of glucose, fructose, sucrose, maltose, cellulose and starch.

(b) Oils & Fats: Introduction, Definition, Classification, Isolation, General properties and Pharmaceutical importance of oils and fats. Chemistry (structure, nomenclature and reactions) of oils and fats and analysis according to Pharmacopoeial methods.

UNIT II

Amino Acids and Proteins

Introduction, definition, classification, isolation, general properties and pharmaceutical importance of amino acids and their relationship to proteins and polypeptides.

Chemistry of Protein Hormones: Insulin, Oxytocin, Thyroxin and Anti-thyroid drugs.

UNIT III

a. Flavonoids: Sources, uses, chemistry and General methods of structural determination (chemical & spectral analysis) of Amygdalin, arbutin and quercetin.

b. Terpenoids: Definiton and Classification: Isoprene rule, Special Isoprene rule for terpenes, General methods of isolation. Chemistry and structure elucidation of citral, menthol and camphor.

UNIT IV

a. Alkaloids

Introduction, definition, occurence, classification, isolation, general properties and pharmaceutical importance of alkaloids. General methods of extraction, structure elucidation and chemistry (structure, nomenclatme and reactions) of ephedrine, atropine, papaverine and quinine.

b.Purine and Xanthine Derivatives

Chemistry and Pharmaceutical importance Caffeine, Theophylline, Theobromine and Uric acid.

UNIT V

Steroids

Introduction, Definition, Occurence, Classification, Isolation, General properties and Pharmaceutical importance of Sterols: color reactions of cholesterol, stigmasterol, ergosterol. Importance & general concepts of bile acids. Steroidal saponins: Diosgenin and hecogenin. Androgens, Estrogens, Progestational agents, Steroidal contraceptives. Adrenocorticoids, Deoxycorticosterone, Cortisone, Prednisone, Aldosterone. Cardiac Glycosides of Digitalis other Cardiac drugs, Strophanthus and Squill.

Outcome: The knowledge of the students is enhanced with the clear information about the natural products which are having medicinal importance.

TEXT BOOKS

1. **Organic Chemistry, Vol.II by** I.L. Finar, The English Language Book Society, London.
2. **Natural Products Vol.I & II** by O.P. Agarwal Goel publications – Meerut.

REFERENCE BOOKS

1. R.T. Morrison and R.N. Boyd, **Organic Chemistry**, Allyn and Bacon, Ine., Boston.
2. **Burger's Medicinal Chemistry**, M.E. – Wolff, Ed., John Wiley & Sons, New York.
3. F.G.Mann & B. Saunders, **Practical Organic Chemistry** Longamans Green & Co. Ltd., U.K .
4. R. M. Acheson, An Introduction to the Chemistry of Heterocyclic Compounds, Interscience NY.
5. The Chemistry of Organic Medicinal Products by Jenkins.
6. Elements of Pharmacoinformatics by Duraih Anand.
7. Structure based drug design by Veerapandian.
8. Chemsitry of natural products; A laboratory handbook, second edition, N R Krishna Swami.
9. Biosyntesis of Natural products by Paolo Manitto-Wiley India publisher.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - II Sem	L	P	C
	4+1	-	4

(R60026) PHARMACEUTICAL JURISPRUDENCE

Objective: The objective of the course is to expose the students, all the laws and roles, which are vogues in the country. The scope of the course is extended to update the all the laws and roles including recent amendments taken place.

UNIT I

Introduction

a. Pharmaceutical Legislations - A brief review

b. Drugs & Pharmaceutical Industry - A brief review

c. Pharmaceutical Education - A brief review.

d. Pharmaceutical ethics & policy

An elaborate study of the following

Pharmacy Act 1948.

Drugs and Cosmetics Act 1940 and Rules 1945.

UNIT II

Medicinal & Toilet Preparations (Excise Duties) Act 1955.

Drugs (Prices Control) Order 1995.

UNIT III

Narcotic Drugs & Psychotropic Substances Act 1985 &A.P. N. D. P.S Rules 1986.

UNIT IV

Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and Rules 1955.

UNIT V

A study of the salient features of the following.

a. Prevention of Cruelty to animals Act 1960.

b. AP State Shops & Establishments Act 1988 & Rules 1990.

c. Factories Act 1948.

d. WTO, GATT and The Indian Patents Act 1970

e. Pharmaceutical Policy 2002.

Note: The teaching of all the above Acts should cover the latest amendments.

OUTCOME

The outcomes which are expected from the students at the end of the course are: Familiarization of the students with all the legal tenets and enforceable in the country, besides Pharmaceutical ethics and policies.

TEXT BOOKS

1. B.M.Mithal, Text book of Forensic Pharmacy, publ by Vallabh Prakashan.
2. Prof. Suresh Kumar J.N, Text book of Forensic Pharmacy by. Frontline Publications.
3. C.K.Kokate & S.B.Gokhale, Textbook of Forensic Pharmacy.

REFERENCE BOOK

1. Bare Acts and Rules Publ by Govt of India/state Govt from time to time.
2. AIR – reported judgments of Supreme Court of India and other High Courts.
3. Pharmaceutical policy of India.
4. Notification from NPPA.
5. Vijay Malik, Drugs & Cosmetics act 1940 and Rules, Eastern Law House Co. Delhi, Kolkata.
6. K.Sampath, Pharmaceutical Jurisprudence (Forensic Pharmacy).

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III Year B.Pharm - II Sem

L	P	C
-	3	2

(R60069) ADVANCED COMMUNICATION SKILLS (ACS) LAB

Introduction

The introduction of the Advanced Communication Skills Lab is considered essential at 3rd year level. At this stage, the students need to prepare themselves for their careers which may require them to listen to, read, speak and write in English both for their professional and interpersonal communication in the globalised context.

The proposed course should be a laboratory course to enable students to use 'good' English and perform the following:

- Gathering ideas and information to organise ideas relevantly and coherently.
- Engaging in debates.
- Participating in group discussions.
- Facing interviews.
- Writing project/research reports/technical reports.
- Making oral presentations.
- Writing formal letters.
- Transferring information from non-verbal to verbal texts and vice-versa.
- Taking part in social and professional communication.

Objectives:

This Lab focuses on using multi-media instruction for language development to meet the following targets:

- To improve the students' fluency in English, through a well-developed vocabulary and enable them to listen to English spoken at normal conversational speed by educated English speakers and respond appropriately in different socio-cultural and professional contexts.
- Further, they would be required to communicate their ideas relevantly and coherently in writing.
- To prepare all the students for their placements.

Syllabus:

The following course content to conduct the activities is prescribed for the Advanced Communication Skills (ACS) Lab:

1. **Activities on Fundamentals of Inter-personal Communication and**

Building Vocabulary - Starting a conversation – responding appropriately and relevantly – using the right body language – Role Play in different situations & Discourse Skills- using visuals - Synonyms and antonyms, word roots, one-word substitutes, prefixes and suffixes, study of word origin, business vocabulary, analogy, idioms and phrases, collocations & usage of vocabulary.

2. **Activities on Reading Comprehension** –General Vs Local comprehension, reading for facts, guessing meanings from context, scanning, skimming, inferring meaning, critical reading & effective googling.

3. **Activities on Writing Skills** – Structure and presentation of different types of writing – *letter writing/Resume writing/ e-correspondence/ Technical report writing/ Portfolio writing* – planning for writing – improving one's writing.

4. **Activities on Presentation Skills** – Oral presentations (individual and group) through JAM sessions/seminars/**PPTs** and written presentations through posters/projects/reports/ e-mails/assignments etc.

5. **Activities on Group Discussion and Interview Skills** – Dynamics of group discussion, intervention/ summarizing, modulation of voice, body language, relevance, fluency and organization of ideas and rubrics for evaluation- Concept and process, pre-interview planning, opening strategies, answering strategies, interview through tele-conference & video-conference and Mock Interviews.

Minimum Requirement:

The Advanced Communication Skills (ACS) Laboratory shall have the following infra-structural facilities to accommodate at least 35 students in the lab:

- **Spacious room with appropriate acoustics.**
- **Round Tables with movable chairs**
- **Audio-visual aids**
- **LCD Projector**
- **Public Address system**
- **P – IV Processor, Hard Disk – 80 GB, RAM–512 MB Minimum, Speed – 2.8 GHZ**
- **T. V, a digital stereo & Camcorder**
- **Headphones of High quality**

Prescribed Lab Manual: A book titled ***A Course Book of Advanced Communication Skills (ACS) Lab*** published by Universities Press,

Hyderabad.

Suggested Software:

The software consisting of the prescribed topics elaborated above should be procured and used.

- **Oxford Advanced Learner's Compass**, 7th Edition.
- **DELTA's key to the Next Generation TOEFL Test: Advanced Skill Practice.**
- **Lingua TOEFL CBT Insider**, by Dreamtech.
- **TOEFL & GRE**(KAPLAN, AARCO & BARRONS, USA, Cracking GRE by CLIFFS).
- **The following software from 'train2success.com'**
  - **Preparing for being Interviewed**
  - **Positive Thinking**
  - **Interviewing Skills**
  - **Telephone Skills**
  - **Time Management**

Books Recommended

1. Technical Communication by Meenakshi Raman & Sangeeta Sharma, Oxford University Press 2009.
2. Advanced Communication Skills Laboratory Manual by Sudha Rani, D, Pearson Education 2011.
3. Technical Communication by Paul-V. Anderson. 2007. Cengage Learning pvt. Ltd. New Delhi.
4. Business and Professional Communication: Keys for Workplace Excellence. Kelly M. Quintanilla & Shawn T. Wahl. Sage South Asia Edition. Sage Publications. 2011.
5. The Basics of Communication: A Relational Perspective. Steve Duck & David T. McMahan. Sage South Asia Edition. Sage Publications. 2012.
6. English Vocabulary in Use series, Cambridge University Press 2008.
7. Management Shapers Series by Universities Press(India)Pvt Ltd., Himayatnagar, Hyderabad 2008.
8. Handbook for Technical Communication by David A. McMurrey & Joanne Buckley. 2012. Cengage Learning
9. Communication Skills by Leena Sen, PHI Learning Pvt Ltd., New Delhi, 2009.
10. Handbook for Technical Writing by David A McMurrey & Joanne

Buckely CENGAGE Learning 2008.

11. Job Hunting by Colm Downes, Cambridge University Press 2008.
12. Master Public Speaking by Anne Nicholls, JAICO Publishing House, 2006.
13. English for Technical Communication for Engineering Students, Aysha Vishwamohan, Tata Mc Graw-Hill 2009.
14. Books on TOEFL/GRE/GMAT/CAT/ IELTS by Barron's/DELTA/ Cambridge University Press.
15. International English for Call Centres by Barry Tomalin and Suhashini Thomas, Macmillan Publishers, 2009.

DISTRIBUTION AND WEIGHTAGE OF MARKS:

Advanced Communication Skills Lab Practicals:

1. The practical examinations for the ACS Laboratory practice shall be conducted as per the University norms prescribed for the core engineering practical sessions.
2. For the English Language lab sessions, there shall be continuous evaluation during the year for 25 sessional marks and 50 End Examination marks. Of the 25 marks, 15 marks shall be awarded for day-to-day work and 10 marks to be awarded by conducting Internal Lab Test(s). The End Examination shall be conducted by the teacher concerned, by inviting the External Examiner from outside. In case of the non-availability of the External Examiner, other teacher of the same department can act as the External Examiner.

Mini Project: As a part of Internal Evaluation

1. **Seminar/ Professional Presentation**
2. **A Report on the same has to be prepared and presented.**

* ***Teachers may use their discretion to choose topics relevant and suitable to the needs of students.***

* ***Not more than two students to work on each mini project.***

* ***Students may be assessed by their performance both in oral presentation and written report.***

Outcomes

- Accomplishment of sound vocabulary and its proper use contextually.
- Flair in Writing and felicity in written expression.
- Enhanced job prospects.
- Effective Speaking Abilities.

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III Year B.Pharm - II Sem

L	P	C
-	3	2

(R60070) MEDICINAL CHEMISTRY – I LAB

I. Synthesis of some medicinal compounds and their analogues.

a. Barbituric acid from Diethyl Malonate.
b. Phenytion from Benzoin or Benzil.
c. Paracetomol from *para*- nitro phenol or *para*- aminophenol.
d. 1,4- di hydro pyridine from ethyl aceto acetate.
e. Quinazolinone from anthranilic acid via benzoxazinone.
f. Systhesis of Finofibrate
g. Isoniazid from γ-picoline.
h. Antipyrine from ethyl aceto acetate.
i. Benzocaine from *para*- nitro benzoic acid.

II. Qualitative estimation of some functional groups.*

a. Halogens (Strepheno's method).
b. Hydroxyl groups (acetylation method)
c. Methoxyl groups (Zeissel's method)
d. Carboxyl groups (silver salt method).

REFERENCES

1. A.I. Vogel, Text Book of Practical Organic Chemistry, 5th Edition.
2. R.K. Bansal, Laboratory Manual of Organic Chemistry.
3. F.G. Mann & B.C. Saunders, Pratical Organic Chemistry, 4th Edition.
4. Advacned medicinal chemistry lab guide by N. Raghu Prasad and M. Raghuram Rao.
5. Organic chemistry a Lab manual, Cengage learning India Pvt. Ltd. By Pavia.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

III Year B.Pharm - II Sem

L	P	C
-	3	2

(R60071) PHARMACEUTICAL TECHNOLOGY – II LAB

1. Experiments to illustrate preparation, stabilization and evaluation of pharmaceutical products like capsules and tablets like conventional, matrix, fast dissolving, multilayered, chewable, buccal, sublingual and Gastric retention.
2. Coating of tablets like sugar, film, enteric coating and evaluation.

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III Year B.Pharm - II Sem

L	P	C
-	3	2

(R60072) PHARMACOLOGY – II LAB

1. **Introduction to Experimental Pharmacology**

   Preparation of different solutions for experiments.

   Drug dilutions, use of molar and w/v solutions in experimental Pharmacology.

   Common laboratory animals and anesthetics used in animal studies.

   Commonly used instruments in experimental pharmacology.

   Some common and standard techniques:

   Bleeding and intravenous injection, intragastric administration.

2. **Experiments on intact preparations:**

   Study of different routes of administration of drugs in mice/rats.

3. **Experiments in Central Nervous system:**

   Recording of spontaneous motor activity, stereotype, analgesia, anticonvulsant activity, anti-inflammatory activity.

4. **To study the effect of autonomic drugs on rabbit's eye**

5. **Experiments on Isolated Preparations:**

   I. To study the effects of various agonists and antagonists and their characterisation using isolated preparations like frog's rectus abdominus muscle and isolated ileum preparation of rat& guinea pig.

a) To record the concentration response curve (CRC) of acetylcholine using rectus abdominus muscle preparation of frog.

b) To study the effects of physostigmine and d-tubocurarine on the CRC of acetylcholine using frog rectus abdominus muscle preparation of frog.

c) To record the CRC of 5-HT on rat fundus preparation.

d) To record the CRC of histamine on guineapig ileum preparation.

II. a. To study the inotropic and chronotropic effects of drugs on isolated frog heart.

b. To study the effects of drugs on normal and hypodynamic frog heart.

6. **Experiments pertaining to analgesia, anti-convulsant activity, anti-inflammatory activity (Only demonstration).**

   Experimental Pharmacology, M.C. Prabhakar.

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III Year B.Pharm - II Sem	L	P	C
	-	3	2

(R60073) CHEMISTRY OF NATURAL PRODUCTS LAB

1. Preparation of different alkaloid testing reagents like Dragendroff, Mayer' Wagner's, etc. and testing some alkaloids and plant extracts using these reagents.
2. Identification of alkaloids by specific colour tests.
3. Tests for steroids, steroidal glycosides and cardiac glycosides. Liberman- Burchard test, Salkowski reaction, Kedde reaction, etc.
4. Tests for flavanoids and their glycosides. Shinoda test (Mg /Hcl test), $FeCl_3$ test.
5. TLC end examination of alkaloids, steroids, steroidal glycosides and cardiac glycosides.
6. Identification of natural products.
7. Extraction of caffeine from tea leaves.
8. Extraction of lactose from milk.
9. Extraction of nicotine from tobacco.
10. Extraction of piperine from black pepper.
11. Extraction of lycopene from tomatoes.
12. Extraction of beta - carotene from carrots.
13. Volatile oil production by steam distillation (***Demonstration only)***

TEXT BOOKS

1. Indian Pharmacopoeia – 1996.
2. Weagners, Phyto Chemical Methods of Drug Analysis.
3. C.K. Kokate, Practical Pharmacognosy.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

IV Year B.Pharm - I Sem

L	P	C
3+1	-	3

(R70027) PHARMACOGNOSY -III

Objective: To learn about the therapeutically important crude drugs and phytopharmaceuticals under a suitable pharmacognostic scheme and the importance of plant tissue culture in pharmacy. To make the student aware of biologically important molecules from marine sources and neutraceuticals.

UNIT I

General introduction to Alkaloids. Systematic pharmacognostic study of following: Cinchona, Ergot, Opium, Ipecac. Biological source, diagnostic features, chemical constituents and tests for identification, uses, adulterants and substituents of following: Belladonna, Catharanthus, Ephedra, Coffee, Colchicum, Datura, Duboisia, Hyosyamus, Kurchi, Nux-vomica, Pilocarpus, Solanum, Tobacco, Tea, Withania, Rauwolfia and Vasaka.

UNIT II

General introduction to Glycosides. Systematic pharmacognostic study of following: Aloe, Digitalis, Senna and Saffron. Biological sources, diagnostic features, chemical constituents and tests for identification, uses, adulterants and substitutes of following: Ammi, Vishaga, Cascara, Chirata, Dioscoria, Gentian, Ginseng, Strophanthus gratus and Liquorice.

UNIT III

Historical development of plant tissue culture: Types of cultures, nutritional requirements, establishment of cultures, measurement of growth in cultures and their maintenance. Applications of plant tissue culture in production of pharmaceutically important secondary metabolites.

UNIT IV

Biological source, chemical nature (with structure) and uses of following phytoconstituents: Artemesinin, Asiaticosides, Bacoposides, Camptothecin, Gymnemic acid and taxol. A brief account of Neem active constituents (chemical structures not necessary).

UNIT V

a. An introduction to potential cardiovascular, anticancer/cytotoxic and antibiotic drugs from marine sources.

b. Neutraceuticals : Definition of functional foods and neutraceuticals, classification of neutraceuticals. Source, Name of marker compounds and their chemical nature, medicinal uses and health benefits of Spirulina, Garlic, Soya and Gingko.

Outcome: Since it is being the last part of Pharmacognosy subject, the student must be enriched with the knowledge on the crude drugs in a systematic way and in the use of crude drugs and phytopharmaceuticals in various systems of medicine for the treatment of different ailments and in various industries.

TEXT BOOKS

1. J.B.Harbone, Phytochemical Methods: A guide to modern techniques of Plant analysis by
2. Kokate C.K, Purohit AP & Gokhale S.B, The Pharmacognosy (Nirali).
3. Trease and Evans, Pharmacognosy, Latest Edition.
4. T.E. Wallis, Text Book of Pharmacognosy.

REFERENCES

1. Arya Vaidyasala Vol. 1-5, Indian Medicinal Plants – Universities Press
2. Atal C.R & Kapur B.M Cultivation & Utilization of Medicinal Plants.
3. Ayurvedic Pharmacopoeia of India, Pub by Govt. of India.
4. Pharmacognosy and Phytotherapy Research: Chapter contributed by Subhash C. Mandal & S.Mohana Lakshmi in the book Biodiversity and Environmental Biotechnology by P.Dwiveit ateal, Scientific Publisher, Jodhpur.
5. Handa & Kapoor, Text book of Pharmacognosy.
6. S.S. Agarwal & M. Paridhavi, Herbal Drug Technology, University Press, Hyderabad.
7. Timir Baran JHa & Biswajit Gosh, Plant Tissue Culture, University Press, Hyderabad.
8. P. Dwiveti, Tissue Culture and Plant Science, Scientific Publisher, Jodhpur.
9. M. K. Razdan, An Introduction To Plant Tissue Culture, Oxford & IBH Publishing Co., New Delhi.
10. Organic Chemistry of Natural products. Vol-I & II R.Chatwal of Arora Publishning House Pvt. Ltd.

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L	P	C
1+1	-	3

(R70028) BIOPHARMACEUTICS AND PHARMACOKINETICS

Objective: This course is designed to impart fundamental knowledge of Biopharmaceutics and Pharmacokinetics. It also helps to know how the absorption distribution, metabolism, excretion takes place and bioavailability and bioequivalence parameters.

UNIT I

a) Introduction: Definitions of Biopharmaceuitics, Pharmacokinetics and Pharmacodynamics.

b) Drug Absorption. Mechanisms of GI absorption, physico-chemical, biological and dosage form factors influencing absorption.

UNIT II

Drug distribution: Factors of drug distribution, volume of distribution, protein binding – factors affecting and significance and kinetics of protein binding.

UNIT III

a) Drug Metabolism: Pathways of drug metabolism. Phase-I (oxidative, reductive and hydrolytic reactions). Phase II reactions (conjugation) Enzyme induction and inhibition.

b) Drug excretion. Glomerular filtration, tubular secretion and reabsorption, effect of pH and other drugs. Clearance concept, excretion through bile, feces, lungs and skin in brief.

UNIT IV

Bioavailability and bioequivalence

Definitions, concept of equivalence, Definitions of various types of equivalence, types of Bioavailability studies, measurement of Bioavailability, plasma level and urinary excretion studies. Bioequivalence study design. Bioavailability testing procedure and protocol (CDSCO), Invitro – Invivo correlation of data.

UNIT V

Pharmacokinetics: Basic considerations, compartment modeling, one compartment open model - i.v. bolus and extra vascular administration, urinary excretion studies. Calculation of pharmacokinetic parameters, brief over view of nonlinear kinetics, noncompartmental models.

Outcome: The students shall be able to understand Bioavailability, Bioequivalence, Biopharmaceutical parameters, Pharmacodynamic and Pharmacokinetics of the drug. It also explains the ADME of the drug besides

non-linear pharmacokinetics.

TEXT BOOKS

1. Venkateshwarlu, Fundamentals of Biopharmaceutics and Pharmacokinetics, Pharma Book Syndicate.
2. Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma Book Syndicate.Hyderabad.
3. DM Brahmankar and SB Jaiswal, biophamaceutics and pharmacokinetics- a treatise, vallabh prakasham, Delhi.
4. P.L. Madan, Biopharmaceuticas and Pharmacokinnetics, Jaypee Bros.

REFERENCES

1. Remington's pharmaceutical sciences, Mac Pub. Co., Easton Pensylvania.
2. Modern pharmaceutics by banker Marcel Dekker Inc., NY.
3. L. Iachman, H.A.Lieberman, JL. Kanig, the theory aad practice of industrial pharmacy, Varghese publ house, Mumbai.
4. AR. Gennerio Remington: the science andpractice of pharmacy, vol 1 &2 Lippincott Williams & wilkins, Philadelphia, 2004.
5. Robert E notary, Biopharmaceutics and pharmacokinetics – an introduction, arcel dekker inc., NY.
6. L. Shargel and ABC Yu, textbook of applied biopharmaceutics & pharmacokinetics, 4th edn, Appleton – centuary – crofts, Connecticut, 2004.

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IV Year B.Pharm - I Sem	L	P	C
	4+1	-	4

(R70029) PHARMACOLOGY – III

Objectives: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs.The basic practical knowledge relevant to therapeutics will be imparted.This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

UNIT I

Drugs Acting on the Gastrointestinal Tract

a. Antacids, Antisecretory and Anti-ulcer Drugs
b. Laxatives and antidiarrhoeal drugs
c. Appetite Stimulants and Suppressants.
d. Emetics and anti-emetics
e. Miscellaneous; Carminatives, demulcents, protectives, adsorbents, astringents, digestants, enzymes and mucolytics.

UNIT II

Chemotherapeutic agents and their applications:

a. General principles of chemotherapy.
b. Sulphonamides and co-trimoxazole.
c. Antibiotics: Penicillins, cephalosoporins, betalactams,
d. Tetracyclines aminoglycosides, chloramphenicol, erythromycin,
e. Quinolones and miscellaneous antibiotics.

UNIT III

Chemotherapy of following diseases

a. Tuberculosis
b. Leprosy
c. Urinary tract infections
d. Fungal diseases
e. Viral diseases,

UNIT IV

a. Antineoplastic agents

b. Immunopharmacology: Immunosupressants and Immunostimulants

c. Antimalarial & Anti-protozoal agents

d. Anti-filarial agents

UNIT V

Principles of Toxicology: Definition of poison, general principles of treatment of poisoning with particular reference to barbiturates opioids, organ phosphorous and atropine poisoning. Heavy metals and heavy metals antagonisits, Diagnostic agents.

Outcome : Understand the pharmacological aspects of drugs, importance of pharmacology subject as a basis of therapeutics and correlate the knowledge therapeutically.Knowledge on experimental methodologies on various animal models is carried out. The pathophysiology of selected disease states and the rationale for drug therapy, and the therapeutic approach to management of these diseases.

TEXT BOOKS

1. Tripathi, Textbook of Pharmacology, JAYPEE
2. F.S.K Barar, Essentials of Pharamcotheraptics.

REFERENCES

1. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann: The Pharmacological basis of therapeutics, Mc Graw hill, Health Professions Dvn.
2. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology,: Churchill Living stone, 4th Ed.
3. Crossland, Lewis 's Pharmacology, Church living stone.
4. Mark A. Simmons, Pharmacology An Illustrated Review.
5. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
6. Bertram. G. Katzung, Basic and clinical pharmacology, 9th Edn, Mc Graw hill.

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IV Year B.Pharm - I Sem

L	P	C
4+1	-	4

(R70030) MEDICINAL CHEMISTRY – II

Objective: The drug discovery and design with respect to the lead molecules and its optimization is clearly discussed. The concept of CADD is also discussed. Sufficient information about various antibiotics and their chemotherapeutic agents are also studied in depth.

UNIT I

(a) Drug discovery and drug design

Introduction to discovery of lead molecule, lead optimization, pharmacophore identification, General structure activity relationship studies.

(b) Computer aided drug design: Introduction to CADD, Parameters in QSAR, Hansch analysis, Free Wilson analysis.

UNIT II

a. Antibiotics: Brief historical background, definition, classification of antibiotics.

Penicillins: Historical background and biological sources. Structures of different penicillins.

Reactions: Hydrolysis of penicillin by cold and hot dilute mineral acid, alkali, enzymatic hydrolysis with Pencillinase, amidase.

Classification: Oral and parenteral, based on spectrum of β, γ – lactamase, as natural, biosynthetic and semi-synthetic.

General method of synthesis of pencillins from 6-APA; SAR, mechanism of action, therapeutic uses, toxicity. β–lactamase inhibitors.

b. Cephalosporins: Structures of some important compounds (Cephalosporins, Cephamycins. Cefadroxil, Cefoxitin. Acid hydrolysis of Cephalosporin C. Comparison of 6-APA and 7-ACA, penam and cepham.

Classification: Generations of cephalosporins, Oral and parenteral, SAR and Advantages over penicillins.

UNIT III

a.Tetracyclins: Biological sources, structures of the important tetracyclines, Important structural units and the three acidity constants in the tetracycline molecule, Amphoteric nature, mechanism of action, spectrum of activity, SAR and toxicity.

b. Aminoglycosides: Structure of streptomycin, acid hydrolysis, mechanism of action, therapeutic uses and toxicity. Dihydrostreptomycin and its importance and mention other aminoglycoside antibiotics.

A brief account of chloramphenicol and its synthesis, macrolide and polypeptide antibiotics and rifampicin (Structures not included).

c. Quinoline type: Ciprofloxacin & norfloxacin

UNIT IV

a. Chemotherapeutic Agents:

Sulphadrugs :Sulphadiazine, Suphasalzine, Trimethoprim, Sulphamethoxazole, Sulphameter

b. Antifungal Agents :Fluconazole and Itraconazole.

c. Anti viral Drugs : Acyclovir, Zidovudine

d. Anti tubercular agents : Isonicotinic acid hydrazide and ethambutol,

e. Anti leprotic agents : Dapsone, clofazemine

f. Antiamoebics : Metronidazole, diloxanide furoate

g. Anthelmintics :Diethylcarbamazine citrate, pyrantel pamoate, mebendazole, Ibendazole

h. Antimalarial drugs :Chloroquine, primaquine and pyrimethamine, norflaxacin and ciprofloxacin

UNIT V

a. Anticancer Drugs :Chlorambucil, busulphan, procarbazine, carmustine, 5-flurouracil, 5-mercaptopurine methotrexate, vinca alkaloids – vinblastin, vincristine

b. Immunosuppressive agents.

Brief introduction to therapeutic agents developed from recombinant DNA technology

c. Diagnostic agents and radioprotective agents.

Outcome: The students would be in a position to participate in the community pharmacy activities with the knowledge they gained through the study of the various topics of the syllabus.

TEXT BOOKS

1. William O. Foye, Textbook of Medicinal Chemistry, Lea & Febiger, Philadelphia.
2. JH Block & JM Beale, Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry by (Eds), 11th Ed, Lipincott, Raven, Philadelphia, 2004.
3. S. N. Pandeya, Textbook of mediacinal chemistry, SG Publ. Varanasi, 2003.

REFERENCES

1. D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol.

1 & 2. John Wiley & Sons, New York 2003.

2. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences.
3. L. M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry. Oxford University Press, Delhi.
4. B.N. Lads, MG.Mandel and F.I. way, Fundamentals of drug metabolism & disposition, William & welking co, Baltimore USA.
5. C. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, oxford 1991.
6. Daniel lednicer, Strategies for Organic Drug Synthesis and Design, John Wiley, N. Y. 1998.
7. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J.Wiley N.Y.
8. Kadam, Textbook of Medicinal Chemistry Vol. 1 & 2.
9. O.P.Agarwal, Text book of natural products by Vol. 1 & 2.
10. Sri Ram, Medicinal Chemistry.
11. Rama Rao Nadendla, Medicinal Chemistry.

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IV Year B.Pharm - I Sem	L	P	C
	4+1	-	4

(R70031) PHARMACY ADMNISTRATION

Objective: 1.To expose the students, fecets of business administration in the new economic environment.

2. The manufacturing management.

3. Social and behaviour aspects of pharmacy:

Pharmaceutical outcomes, Pharmacoeconomics and Pharmacovigilance.

UNIT I

Features of Business Organisations & New Economic Environment:

Characteristic features of Business, Features and evaluation of Sole Proprietorship, Partnership, Joint Stock Company, Public Enterprises and their types, Changing Business Environment in Post-Liberalisation scenario.

UNIT II

Manufacturing Management: Goals of Production Management and Organisation – Production, Planning and Control – Plant location –Principles and Types of Plant Layout-Methods of production (Job, batch and Mass Production), New Product Development.

Work Study –Basic procedure involved in Method Study and Work Measurement-Statistical Quality Control: $\overline{X}$ chart, R chart, *c* chart, *p* chart, (simple Problems), Acceptance Sampling, Deming's contribution to quality.

UNIT III

Social Pharmacy: Social uses of drugs; Abuse of prescription drugs.

Behavioral Pharmacy: Compliance / Adherence to medications.

Introduction to pharmacoeconomics: Definitions of Efficacy; Comparative cost effectiveness ratios; Comparative Clinical Effectiveness and cost Benefit ratios.

Pharmaceutical Outcomes (Quality of life concepts)

History of Pharmaceutical out comes movements in India and abroad.

Pharmaceovigilence / Pharmacoepidemiology:

Present status in India; State and Central initiatives; Reporting of Adverse Drug Reactions; Prescribed format for reporting Adverse Drug Reactions; Irrational Drug Combinations, CDSCO: List of Drugs banned by Government of India and other State Governments.

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UNIT IV

Organisation of Distribution and Marketing: Functions of Marketing, Marketing ix, Marketing Strategies based on Product Life Cycle., Channels of distribution –Factors influencing channels of distribution, sales organization and sales promotion.

UNIT V

Pharma Industry: Growth of pharma industry in India – current status and its role in building national economy and national health – Structure of pharma industry in India – PSUs in pharma industry –Progress in the manufacture of basic drugs, synthetic and drugs of vegetable origin. Export and import of drugs and pharmaceuticals – Export and import Trade.

Outcome: At the end of the course, these students will be familiarized with the above all areas.

TEXT BOOK

1. Aryasri and Subbarao, Pharmaceutical Administration, TMH.
2. Smarta, Strategic Pharma Marketing.
3. Pharmaceutical Industrial Management by G.Vidya Saga.
4. Pharmacy administration by G. Vidya Sagar.

REFERENCES

1. Subbarao Chaganti, Pharmaceutal Marketing in India – Concepts and Strategy Cases, Pharma Book Syndicate.
2. O.P.Khanna, Industrial Management, Dhanpatrai, New Delhi.

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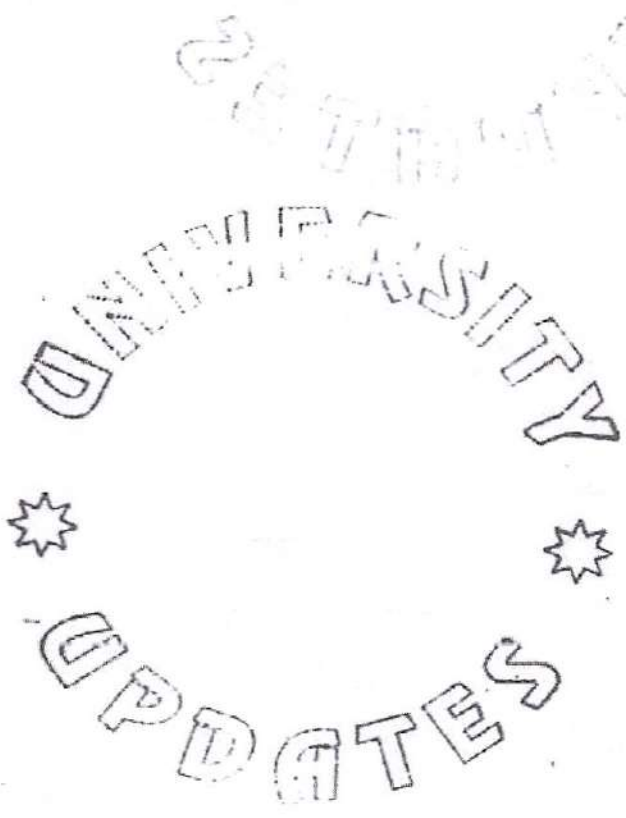
IV Year B.Pharm - I Sem	L	P	C
	-	-	2

(R70074) SEMINAR/ INDUSTRIAL VISIT

a. Industrial Pharmacy.
b. Clinical Pharmacy/Pharmacology.
c. Pharmacognosy/Med. Chem.
d. Pharmaceutical Analysis/Quality assurance.
e. Pharmaceutical Marketing.



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IV Year B.Pharm - I Sem	L	P	C
	-	3	2

(R70075) PHARMACOGNOSY – III LAB

1. Isolation of Caffeine from a marketed formulation (Paracetamol + Caffeine).
2. Isolation of Piperine from Black Pepper.
3. Detection of alkaloids in a powdered crude drug by precipitation tests
4. Extraction and TLC of Nux-vomica/Cinchona alkaloids.
5. Detection of Steroidal/Triterpenoidal and Flavonoidal glycosides in powdered crude drugs by test tube reaction method.
6. Differentiation of a glycoside and its aglycone by TLC.
7. Identification of following powdered crude drugs and their constituents by microscopical, microchemical and chemical methods (If any).
   a) Senna b) Vasaka c) Cinchona d) Cassia
   e) Kurchi f) Nux-vomica g) Ipecac h) Rauwolfia
   i) Liquorice
8. Spotting – Identification of crude drugs mentioned in theory by organoleptic method.

REFERENCES

1. Pharmacognosy, Phytochemistry, Medicinal Plants by Jean Bruneton.
2. Pharmacognosy by C. K. Kokate.
3. Pharmacognosy by Trease and Evans.
4 Pharmacognosy and Phytochemistry by Vinod Rangari.
5. Pharmacognosy by Brady Taylor et. al.
6. Plant Drug Analysis by Wagner. H. & Blandt. S.

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IV Year B.Pharm - I Sem

L	P	C
-	3	2

(R70076) BIOPHARMACEUTICS & PHARMACOKINETICS LAB

1. Estimation of various Pharmacokinetic parameters from the given data.
2. Influence of dosage form on dissolution behaviour of same API.
3. Influence of Physico-chemical properties (Particle size, salt form, crystalline form) on dissolution rate of drug substances.
4. Approaches to enhance the dissolution rate of drugs.
   i.e.,i) Cyclodextrin complexation.
   ii) Inclusion of Hydrophilic polymers such as PVP, PEG.
   iii) Co-solvency.
5. Absorption studies – invitro and invivo.
6. Determination of rate of clearance.
7. Statistical treatment of Pharmaceutical data Ie.,
   i) test ii) Chi-square test iii) ANOVA.

Reference book

1. Dr. D. Dhachinamoorthi- Biopharmaceutical and Pharmacokinetic- A Practical Manual.

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IV Year B.Pharm - I Sem

L	P	C
-	3	2

(R70077) PHARMACOLOGY – III LAB

1. Experiments on Isolated Preparations:

a. To calculate the PA_2 value of atropine using acetylcholine as an agonist on rat ileum preparation.

b. To calculate the PA_2 value of mepyramine or chloramphenicol using histamine as agonist on guinea pig ileum.

c. To find out the strength of the given sample on (e.g. Acetycholine, Histamine, 5-HT. Oxytocinzetc.) Using a suitable isolated muscle preparation by

   i. Matching Assay.

   ii. Two point Assay.

   iii. Three point Assay.

2. Pharmacology of the Gastrointestinal Tract.

   To study the anti-secretory and anti-ulcer activity using pylorus ligated rats.

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IV Year B.Pharm - I Sem	L	P	C
	-	3	2

(R70078) MEDICINAL CHEMISTRY – II LAB

Estimations of the following.

1. Ascorbic acid.
2. Vitamin B1.
3. Penicillin.
4. Alkaloid (by gravimetry).
5. Ibuprofen by volumetric method.
6. Aspirin by volumetric method.
7. Metronidazole (antiprotozoal).
8. Ibuprofen (analgesic, antiinflammatory).
9. Furosemide (diuretic).
10. Isoniazid (anti tubercular).
11. Compound benzoic acid (anti fungal).

REFERENCES

1. Indian Pharmacopoeia.. – 1996, 4th Edition.
2. P.D.Sethi – Quantitative Analysis of Drugs and Pharmaceuticals.
3. B.G.Nagavi Lab Hand Book of Instrumental Drug Analysis.
4. Organic chemistry a Lab manual Cengage India Pvt. Ltd. by Pavia.

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IV Year B.Pharm - II Sem

L	P	C
3+1	-	3

(R80032) NOVEL DRUG DELIVERY SYSTEMS & REGULATORY AFFAIRS

Objective: This course is designed to impart knowledge on controlled drug delivery systems including oral, transdermal, mocuadhesive, targeted (Liposomes and Nanoparticles). It also helps to know how regulatory agencies (Indian CDSCO, USFDA, Canadian HPFBI and Australian TGA) act on release of NDA & ANDA.

UNIT I

Oral Control Drug Delivery Systems: Fundamental study of different types of Oral Contolled drug delivery systems, sustained release concept, design of sustained release dosage form, Zero order release, first order release approximation, multiple dosing.

Dissolution Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems.

UNIT II

a. Transdermal Drug Delivery Systems: Fundamentals, types of TDDS, Materials Employed and Evaluation of TDDS.

b. Introduction to Good Manufacturing Practices: Salient features of Schedule – M (India).

UNIT III

a. Mucoadhesive Delivery Systems: Mechanism of bioadhesion, mucoadhesive materials, forumulation and development of mucoadhesive-based systems.

b. Targeted Drug Delivery Systems: Fundamentals and applications, formulation and evaluation of liposomes, resealed erythrocytes and nano particles.

UNIT IV

Governing Regulatory bodies across the globe

USFDA, CDSCO, Australian TGA, European FDA, NDA & ANDA Submissions of USFDA, Product filing.

UNIT V

Introduction to Validations: Process validation (prospective, retrospective & concurrent), analytical method validation (accuracy, precision, specificity, linearity, range, robustness etc.), cleaning validation (sampling procedure and acceptance criteria).

Outcome: Student shall be able to know the controlled, sustained drug delivery systems, their methods of preparation. They also know how regulatory agencies help filing and submissions of USFDA; Student shall be able to know the validation of the Analytical methods.

TEXT BOOKS

1. Novel drug delivery system by Prof. (Dr) A.K. Bandyopadhyay.
2. N.K. Jain, Control Drug Delivery Systems by
3. Y.Anjaneyulu & Maraiah, Quality Assurance & Quality Management in Pharmaceutical Industry.
4. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy by, Lea & Febieger, Philadelphia Latest Edn.

REFERENCES

1. Leon Shargel Isadore Kanfer, Generic Drug Product Development, Solid Oral Dosage Forms, Marcel Dekker.
2. Sagarian & MS Balsam, Cosmetics Sciences &Technology.Vol.1, 2 & 3.
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
4. E.A Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publ.
5. HC Ansel, Introduction to Pharmaceutical Dosage forms.
6. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, Marcel Dekker, Inc., New York.
7. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, Ivth ed, marcel dekker, usa, 2005.
8. Yiew Chien, novel drug delivery systems, 2nd ed, marcel dekker 2003.
9. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
10. Good Manufacturing Practices – Schedule M Read with The Drugs And Cosmetic Rules 1945.
11. M.E. Aulton, Pharmaceuitcs- The science of Dosage form Design 2nd ed.
12. Aukunuru Jithan, Oral Drug Delivery Technology.
13. Quality Assurance of Pharmaceuticals WHO PMP.
14. Novel drug delivery system and regulatory affairs by S.Chand, Dr. Yajaman Sudhakar, Dr. K.N.Jayaveera.
15. Novel drug delivery system by, V.Sankar, S.Ramesh, V. Shanmugam.
16. Advances in Drug delivery systems by Y. Madhusudan Rao.

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IV Year B.Pharm - II Sem	L	P	C
	1	-	4

(R80033) PHARMACEUTICAL BIOTECHNOLOGY

Objective: Pharmaceutical biotechnology is considered to be a logical extension of pharmaceutical microbiology, thus expected to show a dramatic change in the drug product scenario in future.

This course is designed to impart knowledge on isolation of industrially interesting microbes, various techniques employed in biotechnology Viz., r-DNA technology, Hybridoma technology, enzyme technology and the products derived using these techniques.

UNIT I

a. Fermentation Technology: Isolation, Selection and Screening of Industrially important microbes, Strain improvement. Types of fermentations, optimization of fermentation process. Types, design & operation of Bioreactor.

b. Specific Fermentations: Selection of organism, fermentation & purification of various antibiotics, vitamins, aminoacids, organic acids, solvents, biomass like penicillin, streptomycin, tertacycline, erythromycin, cyanocobalamin, glutamic acid, citric acid, alcohol, Lactobacillus sporogenes.

UNIT II

a. Recombinant DNA Technology: Introduction to r-DNA technology and genetic engineering, steps involved in isolation of enzymes, vectors, recombination and cloning of genes.

Production of r-DNA technology derived therapeutic proteins like humulin, humatrope, intron a, recombivax HB(hepatitis b).

b. Hybridoma Technology: Production and applications of Monoclonal Antibodies.

UNIT III

Immunology & Immunological Preparations: Principles of Immunity, Humoral immunity, cell mediated immunity, Antigen – Antibody reactions, Hypersensitivity reactions.

Active & passive immunizations preparation of vaccines, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoid, immuno serum & diagnostic agents.

UNIT IV

a. Enzyme Technology: Methods of immobilization of enzymes and cells and their applications, factors affecting immobilized enzyme kinetics, advantages of immobilized enzymes over isolated enzymes. Study of enzymes such as hyaluronidase, penicillinase, streptokinase & streptodornase, protease.

b. Blood Products: Collection processing, storage and control of official blood products, plasma substitutes (dextran) and sutures & ligatures.

UNIT V

a. Microbial Transformations: Types, Methods of bioconversions & Application in Pharma Industry, Steroidal transformations.

b. An introductory study on bioinformatics and its applications, Regulatory control of Biotechnological products.

Outcome: Upon completion of the course, the student shall be able to-

- Know screeing of industrially interesting microbes.
- Optimize fermentation process parameters
- Know about preparation, standardization, storage and labelling of biotechnologically derived products
- Know about bioinformatics and its applications in pharmacy.
- Know about the regulatory control of biotechnological products.

TEXT BOOKS

1. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press.
2. Sambamurthy. K, Text Book of Pharmaceutical Biotechnology.
3. S. S. Kori, Pharmaceutical biotechnology.

REFERENCES.

1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2nd Ed, Publ-Panima publication co-peration, New Delhi.
2. U. Satyanarayana, Text book of Biotechnology
3. J. D. Watson, Recombinant DNA technology.
4. E.A. Rawlins, Bentley's, A text book of pharmaceutics, 8th Ed, 1982 Bailler Tindall & Co.
5. Alexander N. Glazer & Hiroshi Nikaido, Microbial biotechnology, W. H. Freeman Co.
6. Casida, Industrial microbiology.
7. Dr. P. K. Shiva kumar, Dr. M. M. Joe, Dr. K. Suresh An Introduction to industrial micro biology.
8. Pharmaceutical Bio technology by Dr. Chandrakanth Kokare.
9. S.P. Vyas and V.K. Dixit CBS Publisher, Delhi, Pharmaceutical Biotechnology.
10. I.D'Souza, Suresh G. Killedar - Biotechnology and fermentation process Indian Pharmacopoein, 1996.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

IV Year B.Pharm - II Sem	L	P	C
	3+1	-	3

(R80034) PHARMACEUTICAL ANALYSIS - II

Objective: The principles involved in the determination of various bulk drugs and formulations are discussed. Modern methods and instrumental techniques are applied in the study and analysis of pharmaceutical substances.

UNIT I

a. UV & Visible Spectrophotometry: Introduction to Spectroscopy, Basic terminology – Chromophore, Auxochrome, Bathochromic shift, Hypsochromic shift, hyperchromic and hypochromic shift. UV & Visible Spectrophotometry: Principle, Theory, Beer-Lamberts Law & Deviations, Instrumentation – Single Beam and Double Beam Spectrophotometers, Applications, Woodward – Feiser rule.

b. Flourimetry: Principle, Theory, Quenching, Instrumentation and applications.

UNIT II

a. Infrared Spectrophotometry (IR): Introduction, principle, theory, types of vibrations, Instrumentation, Single and double beam spectrophotometer, sampling techniques, applications, basic principles in the interpretation of IR Spectra.

b. Atomic Absorption Spectroscopy: Principle, Theory, Instrumentation and applications.

UNIT III

Nuclear Magnetic Resonance Spectrophotometry (NMR) : Basic Principle, theory, instrumentation, chemical shift, shielding and deshielding, relaxation processes, spin-spin splitting, applications, basic principles in the interpretation of NMR spectra.

UNIT IV

Mass Spectrometry: Basic principle, theory, instrumentation and applications, basic principles in the interpretation of Mass Spectra.

UNIT V

An Elementary study of the following:

(a) GC: Columns, Carrier gas and detectors used

(b) HPLC & HPTLC: Basic Principles

(c) Electrophoresis: Various types of Electrohoresis

(d) ORD Curves, RIA & ELISA: Basic principles

Outcome: The students are exposed to the modern instrumental techniques for the study of pharmaceuticals to a high level which would be useful for their future in academia and industry.

TEXT BOOKS

1. R.M. Silvesterin and G.C. Bassler.Spectrometric Identification of Organic Compounds.
2. AH Beckett & Stenlake, Text book of Practical Pharmaceutical chemistry, Vol. I & II.
3. Al Vogel, Quantitative Chemical Analysis.
4. Hobart. H. Willard and others, Instrumental methods of analysis, CBS publ and Distributors New Delhi.

REFERENCES

1. Settle, Handbook of Instrumental Techniques for Analytical Chemistry.
2. Y.Anjaneyulu & Marajah, Quality Assurance & Quality Management in Pharmaceutical Industry.
3. P.D. Sethi, Quantitative analysis of Drugs and Pharmaceuticals.
4. K. A. Connors, A Textbook of pharmaceutical analysis, Wiley Interscienc, NY.
5. A.M. Knevel & F.E. Digengl, Jenkin's quantitative pharmaceutical chemistry, Mc Graw Hill Book Co., NY.
6. Pharmacopoeia (IP, BP, USP, PhI, Eu. PhI).
7. Robert D. Brown, Introduction to Instrumental Analysis.
8. Skoog, Principles of Instrumental Analysis.
9. B.K.Sharma, Instrumental and Chemical Analysis, Goel Publ House,
10. Organic spectroscopy by Y. R Sharma.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

IV Year B.Pharm - II Sem

L	P	C
4	-	4

(R80035) HUMAN VALUES AND PROFESSIONAL ETHICS

Objectives : This introductory course input is intended

- To help the students appreciate the essential complementarity between 'VALUES' and 'SKILLS' to ensure sustained happiness and prosperity which are the core aspirations of all human beings.
- To facilitate the development of a Holistic perspective among students towards life, profession and happiness, based on a correct understanding of the Human reality and the rest of Existence. Such a holistic perspective forms the basis of Value based living in a natural way.
- To highlight plausible implications of such a Holistic understanding in terms of ethical human conduct, trustful and mutually satisfying human behavior and mutually enriching interaction with Nature.

Unit I:

Course Introduction - Need, Basic Guidelines, Content and Process for Value Education: Understanding the need, basic guidelines, content and process for Value Education. Self Exploration–what is it? - its content and process; 'Natural Acceptance' and Experiential Validation- as the mechanism for self exploration. Continuous Happiness and Prosperity- A look at basic Human Aspirations. Right understanding, Relationship and Physical Facilities- the basic requirements for fulfillment of aspirations of every human being with their correct priority. Understanding Happiness and Prosperity correctly- A critical appraisal of the current scenario. Method to fulfill the above human aspirations: understanding and living in harmony at various levels.

Unit II:

Understanding Harmony in the Human Being - Harmony in Myself! : Understanding human being as a co-existence of the sentient 'I' and the material 'Body'. Understanding the needs of Self ('I') and 'Body' - Sukh and Suvidha. Understanding the Body as an instrument of 'I' (I being the doer, seer and enjoyer). Understanding the characteristics and activities of 'I' and harmony in 'I'. Understanding the harmony of I with the Body: Sanyam and Swasthya; correct appraisal of Physical needs, meaning of Prosperity in detail. Programs to ensure Sanyam and Swasthya.

Unit III:

Understanding Harmony in the Family and Society- Harmony in Human - Human Relationship : Understanding harmony in the Family- the basic unit

of human interaction. Understanding values in human-human relationship; meaning of Nyaya and program for its fulfillment to ensure Ubhay-tripti; **Trust (Vishwas) and Respect (Samman) as the foundational values of relationship.** Understanding the meaning of Vishwas; Difference between intention and competence. Understanding the meaning of Samman, Difference between respect and differentiation; the other salient values in relationship. Understanding the harmony in the society (society being an extension of family): Samadhan, Samridhi, Abhay, Sah-astitva as comprehensive Human Goals. Visualizing a universal harmonious order in society- Undivided Society (Akhand Samaj), Universal Order (Sarvabhaum Vyawastha)- from family to world family!

Unit IV:

Understanding Harmony in the Nature and Existence - Whole existence as Co-existence : Understanding the harmony in the Nature. Interconnectedness and mutual fulfillment among the four orders of nature- recyclability and self-regulation in nature. Understanding Existence as Co-existence (Sah-astitva) of mutually interacting units in all-pervasive space. Holistic perception of harmony at all levels of existence.

Unit V:

Implications of the above Holistic Understanding of Harmony on Professional Ethics : Natural acceptance of human values. Definitiveness of Ethical Human Conduct. Basis for Humanistic Education, Humanistic Constitution and Humanistic Universal Order. Competence in professional ethics:

a) Ability to utilize the professional competence for augmenting universal human order,

b) Ability to identify the scope and characteristics of people-friendly and eco-friendly production systems,

c) Ability to identify and develop appropriate technologies and management patterns for above production systems.

Case studies of typical holistic technologies, management models and production systems. Strategy for transition from the present state to Universal Human Order:

a) At the level of individual: as socially and ecologically responsible engineers, technologists and managers.

b) At the level of society: as mutually enriching institutions and organizations.

TEXT BOOKS

1. R R Gaur, R Sangal, G P Bagaria, 2009, A Foundation Course in Human Values and Professional Ethics.

2. Prof. KV Subba Raju, 2013, Success Secrets for Engineering Students, Smart Student Publications,3rd Edition.

EFERENCE BOOKS

1. Ivan Illich, 1974, Energy & Equity, The Trinity Press, Worcester, and HarperCollins, USA.
2. E.F. Schumacher, 1973, Small is Beautiful: a study of economics as if people mattered, Blond & Briggs, Britain.
3. A Nagraj, 1998, Jeevan Vidya ek Parichay, Divya Path Sansthan, Amarkantak.
4. Sussan George, 1976, How the Other Half Dies, Penguin Press. Reprinted 1986, 1991.
5. PL Dhar, RR Gaur, 1990, Science and Humanism, Commonwealth Purblishers.
6. A.N. Tripathy, 2003, Human Values, New Age International Publishers.
7. Subhas Palekar, 2000, How to practice Natural Farming, Pracheen(Vaidik) Krishi Tantra Shodh, Amravati.
8. Donella H. Meadows, Dennis L. Meadows, Jorgen Randers, William W. Behrens III, 1972, Limits to Growth – Club of Rome's report, Universe Books.
9. E G Seebauer & Robert L. Berry, 2000, Fundamentals of Ethics for Scientists & Engineers, Oxford University Press.
10. M Govindrajran, S Natrajan & V.S. Senthil Kumar, Engineering Ethichs (including Human Values), Eastern Economy Edition, Prentice Hall of India Ltd.

Relevant CDs, Movies, Documentaries & Other Literature:

1. Value Education website, http://www.uptu.ac.in
2. Story of Stuff, http://www.storyofstuff.com
3. Al Gore, An Inconvenient Truth, Paramount Classics, USA
4. Charlie Chaplin, Modern Times, United Artists, USA
5. IIT Delhi, Modern Technology – the Untold Story

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IV Year B.Pharm - II Sem	L	P	C
	4+1	-	4

(R80036) CLINICAL PHARMACY PRACTICE

Objective: To impart quality use of medicines & their therapeutics of various diseases management.Monitor adverse drug reaction,interpret selected laboratory results of specific disease states,retrieve, analyse, interpret and formulate drug or medicine information.

UNIT I

Basic concepts of Pharmacotherapy

a. Introduction to Clinical Pharmacy

b. Clinical Pharmacokinetics and individualization of Drug Therapy.

c. Special precautions in drugs usage during infancy and in the elderly (Pediatrics & Geriatrics).

d. Special precautions in drugs usage during pregnancy & lactation

e. Adverse Drug Reactions and Pharmacovigilance

f. The Basics of Drug Interactions

g. Interpretation of Clinical laboratory Tests.

UNIT II

Important Disorders of Organ Systems and their Management:

a. **Cardiovascular Disorders**: Hypertension, congestive heart failure, angina, acute myocardial infarction, cardiac arrhythmias.

b. **CNS Disorders**: Epilepsy, parkinsonism, schizophrenia depression.

UNIT III

Important Disorders of Organ Systems and their Management

a. **Respiratory Disease:** Asthma, COPD.

b. **Gastrointestinal Disorders:** Peptic Ulcer Disease, Ulcerative Colitis, Hepatitis, and Cirrhosis.

c. **Infectious Diseases**: Enteric Infections, sexually transmitted diseases, AIDS, Conjunctivits.

UNIT IV

Important Disorders of Organ Systems and their Management

a. **Endocrine Disorders:** Diabetes mellitus and Thyroid Disorders.

b. **Neoplastic Diseases**: Leukaemias, Hodgkin's disease,Lymphomas

UNIT V

a. Therapeutic Drug Monitoring, Concept of Essential Drugs, Drug and

Poison information, Drug induced diseases.

b. Commmunity Pharmacy practice, patient counselling, medication review ward round participation, drug utilization review.

Outcome: Know the pathophysiology of selected disease states and the rationale for drug therapy, their therapeutic approach in management of diseases. Understand the needs to identify the patient-specific parameters relevant in initiating drug therapy and its monitoring.

TEXT BOOKS

1. Roger, Walker, Clinical Pharmacy and Therapeutics.
2. G. Parthasarathi / Karin Nyfort-Hansu A text book of Clinical Pharmacy practice – Universities Press.
3. Dr. D.R Krishna, V. Klotz, Clinical pharmaco kinetics, Publ Springer Verlab.

REFERENCES

1. Laurence, DR and Bennet PN. Clinical Pharmacology, Scientific book agency.
2. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences, 20th edn.
3. Hamsten, Drug interaction, Kven Stockley.
4. J.K. Mehra, Drug interaction, Basic Bussiness Publ, Bombay.
5. Grahame smith and Aronson, Clinical pharmacology and drug therapy.
6. Richard A Helms, Text Book of Therapeutics Drug and Disease Management Hardbound.
4. Herfindal E T and Hirschman JL. Williams and Wilkins, Clinical Pharmacy and therapeutics.
5. Applied Therapeutics, The clinical uses of Drugs applied therapeutics INC.
6. Dr. A.R. Paradker, Hospital and Clinical Pharmacy, Nirali Prakashan.
7. D. Sudheer Kumar. Fundamentals of Clinical Pharmacy Practice-Pharm Med Press.
8. Katzung, B.G.Basic and Clinical Pharmacology, Prentice hall, International.
9. M Rowland and T N Tozer, "Clinical Pharmacokinetics" 2nd ed Lea & Febiger, NY.

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IV Year B.Pharm - II Sem

L	P	C
-	-	4

(R80079) PROJECT WORK & COMPREHENSIVE VIVA

1. Industrial Pharmacy / Technology
2. Clinical Pharmacy / Pharmacology
3. Pharmacognosy / Medical Chemistry
4. Pharmaceutical Analysis / Quality Assurance
5. Pharmaceutical Marketing
6. Herbal Drugs
7. Pharmainformatics
8. Computer aided drug design
9. Neutraceuticals
10. Nano Technology
11. Bio Technology
12. Pharmaco economics

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IV Year B.Pharm - II Sem

L	P	C
-	3	2

(R80080) NOVEL DRUG DELIVERY SYSTEMS AND REGULATORY AFFAIRS LAB

1. Preparation and Evaluation of Matrix Tablets
2. Formualtion and Evaluation of Film Coated Tablets.
3. Formualtion and Evaluation of Enteric Coated Tablets.
4. Prepartion and Evaluation of Transdermal Drug Delivery Systems.
5. Formulation and Evaluation of Mucoadhesive Delivery Systems.
6. Evaluation of Market SR Formualtions.
7. Preparation and evalution of Nano particles (Minimum two drugs)
8. Preparation and evaluation of Liposomes
9. Preparation and Evaluation of Alginate Beads.
10. Analytical Method Validation.
11. Assignment on Product development and filing to various regulatory agencies , FDA,MCC, EMEA,TGA.Etc (Ref.: www.fda.gov)

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IV Year B.Pharm - II Sem	L	P	C
	-	3	2

(R80081) PHARMACEUTICAL BIOTECHNOLOGY LAB

*** 3 hours on same day and 1 hour in the next day morning**

1. Isolation of antibiotic producing microorganisms from soil.
2. Immobilization of Enzymes / Cells using different methods and comparision of their efficacy.
3. Determination of minimum inhibitory concentration of the given antibiotic.
4. Standardization of Cultures.
5. Microbiological assay of Antibiotics by cup plate method.
6. Microbiological assay of Antibiotics by Turbidimetry method.
7. Production of alcohol by fermentation technique.
8. Sterility testing of Pharmaceutical products.
9. Isolation of mutants by gradient plate technique.
10. Preparation of bacterial vaccine and standardization.
11. Extraction of DNA.
12. Separation techniques: Various types of Gel electrophoresis, Centrifugation.

TEXT BOOKS

1. Dr. R.S. Gaud, G. D. Gupta - Pratical Biotechnology
2. Indian Pharmacoepia – 1997
3. F.C. Garg, Experimental microbiology

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IV Year B.Pharm - II Sem

L	P	C
-	3	2

(R80082) PHARMACEUTICAL ANALYSIS – II LAB

Experiments

1. Interpretation of IR Spectra of any two compounds.
2. Determination of λ_{max} of few bulk drugs.
3. Assay of any two bulk drugs and their formulations by UV-spectro photometry.
4. Assay of any two bulk drugs and their formulations by Colorimetric method.
5. Assay of Quinine Sulphate by Flourimetry
6. Ascending paper chromatography.
7. Radial paper chromatography.
8. Two dimensional paper chromatography
9. Thin layer chromatography.
10. Column chromatography
11. Determination of amino acids by Paper electrophoresis.
12. Gel electrophoresis (**Demonstration Only**).
13. HPLC (**Demonstration Only**).

BOOKS RECOMMENDED FOR REFERENCE:

PHARMACEUTICS

1. Cooper and Gunns "Tutorial Pharmacy" ed. S.J Carter, 6th edition, CBS Publisher, Delhi,
2. A N Martin, Arthur Cammarata, James Swarbrick, "Physical Pharmacy", 3rd edition, K M Varghese & Co., Bombay,
3. E Shotton and K Ridgway, "Physical Pharmaceutics" Oxford University Press, London,
4. "Remington's Pharmaceutical Sciences", ed. A R Gennaro, 18th ed, Mack Publishing Co.. P.A..
5. Leon Lachmen, H A Lieberman and J L Kanig, "The Theory and Practice of Industrial Pharmacy, 3rd ed. Lea & Febiger Philadelphia.
6. H C Ansel "Introduction to Pharmaceutical Dosage Forms", 3rd (Indian ed) K M Varghese & Co. Bombay .
7. Cooper and Gunn's "Dispensing for Pharmaceutical Students" ed S J Carter, 12th ed., CBS Publishers, Delhi.

रजिस्ट्री सं. डीएल (एन)-04/0007/2003--05 REGISTERED No. DL(N)—04/0007/2003—05

भारत का राजपत्र
The Gazette of India

साप्ताहिक/WEEKLY

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PUBLISHED BY AUTHORITY

सं॰ 19] नई दिल्ली, शनिवार, मई 10—मई 16, 2008 (वैशाख 20, 1930)
No. 19] NEW DELHI, SATURDAY, MAY 10—MAY 16, 2008 (VAISAKHA 20, 1930)

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4
[PART III—SECTION 4]
[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

सदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

''अरब बांगलादेश बैंक लिमिटेड'' शब्दों के स्थान पर ''एबी बैंक लिमिटेड'' शब्द होंगे।

आनन्द सिन्हा
कार्यपालक निदेशक

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 o f 1948).

(As approved by the Government of India, Ministry of Health vide, letter March, No.V.13013/1/2007-PMS, dated the 13th 2008 and notified by the Pharmacy Council of India).

No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.

   (2) They shall come into force from the date of their publication in the official Gazette.

2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3. Duration of the course. –

a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

4. Minimum qualification for admission to. –

a) Pharm.D. Part-I Course – A pass in any of the following examinations -

(1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:

Mathematics or Biology.

(2) A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

(3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

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b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
   i) Pharm.D. Programme – 30 students.
   ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

TABLES

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	**16**	**18**	**6 = (40)**

* For Biology

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Second Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	**17**	**9**	**6 = 32**

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	**16**	**15**	**5 = 36**

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Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	**15**	**12**	**6 = 33**

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	**8**	**20**	**4 = 32**

* Attending ward rounds on daily basis.

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Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

(i) Six months in General Medicine department, and

(ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or pharmacy college for the purpose of obtaining p ermission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination. – (1) Every year there shall be an examination to examine the students.

(2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.

(3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

TABLES

First Year examination :

S .No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	M edicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial M athematics/ Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

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Second Year examination :

S .No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical M icrobiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology -I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination :

S .No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology -II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	M edicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year examination :

S .No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research M ethodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

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Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

(i) Six months in General Medicine department, and

(ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or pharmacy college for the purpose of obtaining p ermission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination. – (1) Every year there shall be an examination to examine the students.

(2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.

(3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

TABLES

First Year examination :

S .No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	M edicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial M athematics/ Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

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Fifth Year examination :

S .No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug M onitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six M onths)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis .

** 30 marks – viva-voce (oral)
70 marks – Thesis work

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

12. Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

    (2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

    (3) Practical examination shall also consist of a viva –voce (Oral) examination.

    (4) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

13. Award of sessional marks and maintenance of records.— (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

    (2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

    (3) The sessional marks in practicals shall be allotted on the following basis:-

    (i) Actual performance in the sessional examination (20 marks);

    (ii) Day to day assessment in the practical class work, promptness, viva- voce record maintenance, etc. (10 marks).

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14. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.

15. Eligibility for promotion to next year.— All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

16. Internship.— (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquire s skills under the supervision so that he or she may become capable of functioning independently.

    (2) Every student has to undergo one year internship as per Appendix-C to these regulations.

17. Approval of examinations.— Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix–D to these regulations.

18. Certificate of passing examination.— Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

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CHAPTER-III
Practical training

19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

20. Project work.— (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

    (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

21. Objectives of project work.— The main objectives of the project work is to—

    (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

    (ii) develop the students in data collection, analysis and reporting and interpretation skills.

22. Methodology.— To complete the project work following methodology shall be adopted, namely:—

    (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;

    (ii) project topic shall be approved by the Head of the Department or Head of the Institution;

    (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;

    (iv) project work shall be approved by the institutional ethics committee;

    (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

    (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

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23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.

(3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii)Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items:

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

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APPENDIX-A

(See regulation 8)

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

2. **Upon completion of the course the student shall be able to:**
   a. describe the structure (gross and histology) and functions of various organs of the human body;
   b. describe the various homeostatic mechanisms and the ir imbalances of various systems;
   c. identify the various tissues and organs of the different systems of the human body;
   d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
   e. appreciate coordinated working pattern of different organs of each system; and
   f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. **Course materials:**

   Text books

   a. Tortora Gerard J and Nicholas, P Principles of anatomy and physiology Publisher Harpercollins college New York.
   b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

   Reference books

   a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
   b. Chatterjee,C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
   c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
   d. *Gray's anatomy*. Publisher:Churchill Livingstone, London.

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4. Lecture wise program

: Topics

1 Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)

2 Structure of cell – its components and their functions.

3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics

4 a) Osseous system - structure, composition and functions of the

b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5 Haemopoetic System

a) Composition and functions of blood
b) Haemopoesis and disorders of blood components (definition of d isorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation

6 Lymph

a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)

7 Cardiovascular system

a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

8 Respiratory system

a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9 Digestive system

a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

10 Nervous system
a) Definition and classification of nervous system
b) Anatomy, physiology and functional areas of cerebrum
c) Anatomy and physiology of cerebellum
d) Anatomy and physiology of mid brain
e) Thalamus, hypothalamus and Basal Ganglia
f) Spinal card: Structure & reflexes – mono-poly-planter
g) Cranial nerves – names and functions
h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11 Urinary system
a) Anatomy and physiology of urinary system
b) Formation of urine
c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
d) Clearance tests and micturition

12 Endocrine system
a) Pituitary gland
b) Adrenal gland
c) Thyroid and Parathyroid glands
d) Pancreas and gonads

13 Reproductive system
a) Male and female reproductive system
b) Their hormones – Physiology of menstruation
c) Spermatogenesis & Oogenesis
d) Sex determination (genetic basis)
e) Pregnancy and maintenance and parturition
f) Contraceptive devices

14 Sense organs
a) Eye
b) Ear
c) Skin
d) Tongue & Nose

15 Skeletal muscles
a) Histology
b) Physiology of Muscle contraction
c) Physiological properties of skeletal muscle and their disorders (definitions)

16 Sports physiology
a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
c) Drugs and athletics

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Require ments: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experime nts:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.
   (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.

(e) Digestive system.
(f) Urinary system.
(g) Nervous system.
(h) Special senses.
(i) Reproductive system.

10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastroenemius sciatic nerve preparation.
14. To record simple summation curve using gastroenemius sciatic nerve preparation.
15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.
17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

2. **Upon the completion of the course the student s hould be able to:**
   a. know the formulation aspects of different dosage forms;
   b. do different pharmaceutical caluculation involved in formulation;
   c. formulate different types of dosage forms; and
   d. appreciate the importance of good formulation for effectiveness.

3. **Course materials:**
   Text books
   a. Cooper and Gunns Dispensing for pharmacy students.
   b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

   Reference books
   a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
   b. Remington's Pharmaceutical Sciences.
   c. Register of General Pharmacy by Cooper and Gunn.
   d. General Pharmacy by M.L.Schroff.

4. **Lecture wise**
   programme: Topics

   1 a. Introduction to dosage forms - classification and definitions
   b. Prescription: definition, parts and handling
   c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
   2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
   3 Development of Indian Pharmacopoeia and introduction to o ther Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
   4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
   5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
   6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
10 Pharmaceutical calculations.
11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experime nts:

1. **Syrups**
   a. Simple Syrup I.P
   b. Syrup of Ephedrine Hcl NF
   c. Syrup Vasaka IP
   d. Syrup of ferrous Phosphate IP
   e. Orange Syrup
2. **Elixir**
   a. Piperizine citrate elixir BP
   b. Cascara elixir BPC
   c. Paracetamol elixir BPC
3. **Linctus**
   a. Simple Linctus BPC
   b. Pediatric simple Linctus BPC
4. **Solutions**
   a. Solution of cresol with soap IP
   b. Strong solution of ferric chloride BPC
   c. Aqueous Iodine Solution IP
   d. Strong solution of Iodine IP
   e. Strong solution of ammonium acetate IP

5. **Linime nts**
   a. Liniment of turpentine IP*
   b. Liniment of camphor IP
6. **Suspensions***
   a. Calamine lotion
   b. Magnesium Hydroxide mixture BP
7. **Emulsions***
   a. Cod liver oil emulsion
   b. Liquid paraffin emulsion
8. **Powders**♣
   a. Eutectic powder
   b. Explosive powder
   c. Dusting powder
   d. Insufflations
9. **Suppositories**♣
   a. Boric acid suppositories
   b. Chloral suppositories
10. **Incompatibilities**
    a. Mixtures with Physical
    b. Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing ♣ Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells.Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. **Objectives of the Subject** (Know, do, appreciate) :

   The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

   a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
   b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
   c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
   d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
   e. do the qualitative analysis and determination of biomolecules in the body fluids.

   Text books (Theory)

   a. Harpers review of biochemistry - Martin
   b. Text book of biochemistry – D.Satyanarayana
   c. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

   Reference books (Theory)

   a. Principles of biochemistry -- Lehninger
   b. Text book of biochemistry -- Ramarao
   c. Practical Biochemistry-David T.Plummer.
   d. Practical Biochemistry-Pattabhiraman.

3. **Lecture wise programme:**

   Topics

   1 **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

   2 **Enzymes**: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

   3 **Carbohydrate metabolis m**: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

4 **Lipid metabolis m:** Oxidation of saturated (β-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).

5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

6 **Protein and amino acid metabolis m:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

8 **Introduction to clinical chemistry: Cell**; composition; malfunction; Roll of the clinical chemistry laboratory.

9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
   a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
   b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
   c) Urine concentration test
   d) Urinary tract calculi. (stones)

10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
   a) Test for hepatic dysfunction-Bile pigments metabolism.
   b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
   c) Dye tests of excretory function.
   d) Tests based upon abnormalities of serum proteins.

11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

   Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1 Qualitative analysis of normal constituents of urine.*
2 Qualitative analysis of abnormal constituents of urine.*
3 Quantitative estimation of urine sugar by Benedict's reagent method.**
4 Quantitative estimation of urine chlorides by Volhard's method.**
5 Quantitative estimation of urine creatinine by Jaffe's method.**
6 Quantitative estimation of urine calcium by precipitation method.**
7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
8 Preparation of Folin Wu filtrate from blood.*
9 Quantitative estimation of blood creatinine.**
10 Quantitative estimation of blood sugar Folin- Wu tube method.**
11 Estimation of SGOT in serum.**
12 Estimation of SGPT in serum.**
13 Estimation of Urea in Serum.**
14 Estimation of Proteins in Serum.**
15 Determination of serum bilirubin**
16 Determination of Glucose by means of Glucoseoxidase.**
17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18 Study of factors affecting Enzyme activity. (pH & Temp.)**
19 Preparation of standard buffer solutions and its pH measurements (any two)*
20 Experiment on lipid profile tests**
21 Determination of sodium,calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives**: This course is designed to impart a very good knowledge about
   a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
   b. Some important physical properties of organic compounds;
   c. Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
   d. Some named organic reactions with mechanisms; and
   e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. **Course materials:**

   Text books

   a. T.R.Morrison and R. Boyd - Organic chemistry,
   b. Bentley and Driver-Text book of Pharmaceutical chemistry
   c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

   Reference books

   a. Organic chemistry – J.M.Cram and D.J.Cram
   b. Organic chemistry- Brown
   c. Advanced organic chemistry- Jerry March, Wiley
   d. Organic chemistry- Cram and Hammered, Pine Hendrickson

3. **Lecture wise programme**

   : Topics

   1 Structures and Physical properties:
      a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
      b. Acids and bases, Lowry bronsted and Lewis theories
      c. Isomerism

   2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.

   3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability

   4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

   5 Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN 2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen excha nge, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substituion in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

10 Elecrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.

11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.

14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

15 Oxidation reduction reaction.

16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through de monstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilde / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

2. **Upon completion of the course student shall be able to:**
   a. under stand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
   b. know the analysis of the inorganic pharmaceuticals their applications; and
   c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. **Course materials:**
   Text books
   a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
   b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
   c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

   Reference books
   a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
   b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
   c. Analytical chemistry principles by John H. Kennedy d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. **Lecture wise programme:**

   Topics

   1 Errors
   2 Volumetric analysis
   3 Acid-base titrations
   4 Redox titrations
   5 Non aqueous titrations
   6 Precipitation titrations
   7 Complexometric titrations
   8 Theory of indicators
   9 Gravimetry
   10 Limit tests
   11 Medicinal gases
   12 Acidifiers
   13 Antacids
   14 Cathartics
   15 Electrolyte replenishers

16 Essential Trace elements
17 Antimicrobials
18 Pharmaceutical aids
19 Dental Products
20 Miscellaneous compounds
21 Radio Pharmaceuticals

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. **Limit test (6 exercises)**
   a. Limit test for chlorides
   b. Limit test for sulphates
   c. Limit test for iron
   d. Limit test for heavy metals
   e. Limit test for arsenic
   f. Modified limit tests for chlorides and sulphates

2. **Assays (10 exercises)**
   a. Ammonium chloride- Acid-base titration
   b. Ferrous sulphate- Cerimetry
   c. Copper sulpahte- Iodometry
   d. Calcilugluconate- Complexometry
   e. Hydrogen peroxide – Permanganometry
   f. Sodium benzoate – Nonaqueous titration
   g. Sodium chloride – Modified volhard's method
   h. Assay of KI – KIO_3 titration
   i. Gravimetric estimation of barium as barium sulphate
   j. Sodium antimony gluconate or antimony potassium tartarate

3. **Estimation of mixture (Any two exercises)**
   a. Sodium hydroxide and sodium carbonate
   b. Boric acid and Borax
   c. Oxalic acid and sodium oxalate

4. **Test for identity (Any three exercises)**
   a. Sodium bicorbonate
   b. Barium sulphate
   c. Ferrous sulphate
   d. Potassium chloride

5. **Test for purity (Any two exercises)**
   a. Swelling power in Bentonite
   b. Acid neutralising capacity in aluminium hydroxide gel
   c. Ammonium salts in potash alum
   d. Adsorption power heavy Kaolin
   e. Presence of Iodates in KI

6. **Preparations (Any two exercises)**
   a. Boric acids
   b. Potash alum
   c. Calcium lactate
   d. Magnesium suphate

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives**: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

2. **Upon completion of the course the student shall be able to :** –
   a. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
   b. solve the problems of different types by applying theory; and
   c. appreciate the important applications of mathematics in pharmacy.

3. **Course materials:**

   Text books
   a. Differential calculus By Shantinarayan
   b. Text book of Mathematics for second year pre- university by Prof.B.M.Sreenivas

   Reference books
   a. Integral calculus By Shanthinarayan
   b. Engineering mathematics By B.S.Grewal
   c. Trigonometry Part-I By S.L.Loney

4. **Lecture wise programme :**

   Topics
   1 **Algebra :** Determinants, Matrices
   2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
   3 **Analytical Geometry :**Points, Straight line, circle, parabola
   4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
   5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
   6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
   7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting

BIOLOG Y :

1. **Scope and objectives**: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course materials:**

Text books

a. Text book of Biology by S.B.Gokhale
b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

a. A Text book of Biology by B.V.Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. **Lecture wise programme :**

Topic

PART – A

01 Introduction
2 General organization of plants and its inclusions
3 Plant tissues
4 Plant kingdom and its classification
5 Morphology of plants
6 Root, Stem, Leaf and Its modifications
7 Inflorescence and Pollination of flowers
8 Morphology of fruits and seeds
9 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

1 Study of Animal cell
2 Study animal tissues
3 Detailed study of frog
4 Study of Pisces, Raptiles, Aves
5 Genearal organization of mammals
6 Study of poisonous animals

1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
   a. describe the etiology and pathogenesis of the selected disease states;
   b. name the signs and symptoms of the diseases; and
   c. mention the complications of the diseases.

   Text books (Theory)
   a. Pathologic basis of disease by- Cotran, Kumar, Robbins
   b. Text book of Pathology- Harsh Mohan
   c. Text book of Pathology- Y.M. Bhinde

   Reference books (Theory)
   a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. **Detailed syllabus and lecture wise schedule :**

   Chapter

   1 **Basic principles of cell injury and Adaptation**
   a) Causes, Pathogenesis and morphology of cell injury
   b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

   2 **Inflammation**
   a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
   b) Repairs of wounds in the skin, factors influencing healing of wounds

   3 **Diseases of Immunity**
   a) Introduction to Tand B cells
   b) MHC proteins or transplantation antigens
   c) Immune tolerance
   - Hypersensitivity
     Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
   - Autoimmunity
     Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
   - Acquired immune deficiency syndrome (AIDS)

- Amylodosis

4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classificatio n of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5 Types of shock, mechanisms, stages and management

6 Biological effects of radiation

7 Environmental and nutritional diseases
   i) Air pollution and smoking- SO2,NO, NO2, and CO
   ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

8 Pathophysiology of common diseases
   a. Parkinsonism
   b. Schizophrenia
   c. Depression and mania
   d. Hypertension,
   e. Stroke (ischaemic and hemorrhage)
   f. Angina, CCF, Atherosclerosis, Myocardial infarction
   g. Diabetes Mellitus
   h. Peptic ulcer and inflammatory bowel diseases
   i. Cirrhosis and Alcoholic liver diseases
   j. Acute and chronic renal failure
   k. Asthma and chronic obstructive airway diseases

9 Infectious diseases :

Sexually transmitted diseases (HIV,Syphilis,Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

1 Chemical Mediators of inflammation
2 Drug Hypersensitivity
3 Cigarette smoking & its ill effects
4 Biological Effects of Radiation
5 Etiology and hazards of obesity
6 Complications of diabetes
7 Diagnosis of cancer
8 Disorders of vitamins
9 Methods in Pathology- Laboratory values of clinical significance
10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

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2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.
   This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. Its also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject :**
   Upon completion of the subject student shall be able to –
   a. know the anatomy, identification, growth factors and sterilization of microorganisms;
   b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
   c. do estimation of RNA and DNA and there by identifying the source ;
   d. do cultivation and identification of the microorganisms in the laboratory;
   e. do identification of diseases by performing the diagnostic tests; and
   f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

a. Vanitha Kale and Kishor Bhusari — Applied Microbiology ‖ Himalaya Publishing house Mumbai.
b. Mary Louis Turgeon — Immunology and Serology in Laboratory Medicines‖ 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
c. Harsh Mohan, — Text book of Pathology‖ 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

a. Prescot L.M., Jarley G.P Klein D.A —Microbiology‖ 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A.‖Bentley's Text Book of Pharmaceutics‖ B ailliere Tindals 24-28 London 1988
c. Forbisher — Fundamentals of Microbiology‖ Philidelphia W.B. Saunders.
d. Prescott L.M. Jarley G.P., Klein.D.A. — Microbiology.‖2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David male, — Immunology‖3rd edition 1996, Mosby-year book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.

4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.

5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.

6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.

7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.

9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B_2 and B_{12}. Standardisation of vaccines and sera.

10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1 Study of apparatus used in experimental microbiology*.
2 Sterilisation of glass ware's. Preparation of media and sterilisation.*
3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
4 Study of motility characters*.
5 Enumeration of micro-organisms (Total and Viable)*
6 Study of the methods of isolation of pure culture.*
7 Bio chemical testing for the identification of micro*-organisms.

8 Cultural sensitivity testing for some micro-organisms.*
9 Sterility testing for powders and liquids.*
10 Determination of minimum inhibitory concentration.*
11 Microbiological assay of antibiotics by cup plate method.*
12 Microbiological assay of vitamins by Turbidometric method**
13 Determination of RWC.**
14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories(other sterization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
   a. Report of recent microbial techniques developed in diagnosing some common diseases.
   b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occur ring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

2. **Upon completion of the course student shall be able to:**
   a. under stand the basic principles of cultivation, collection and storage of crude drugs;
   b. know the source, active constituents and uses of crude drugs; and
   c. appreciate the applications of primary and secondary metabolites of the plant.

3. **Course materials:**
   Text books
   a. Pharmacognosy by G.E. Trease & W.C.Evans.
   b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

   Reference books
   a. Pharmacognosy by Brady &Tyler.E.
   b. Pharmacognosy by T.E.Wallis.
   c. Pharmacognosy by C.S. Shah & Qadery.
   d. Pharmacognosy by M.A. Iyengar.

4. **Lecture wise programme:**
   Topics

1	Introduction.
2	Definition, history and scope of Pharmacognosy.
3	Classification of crude drugs.
4	Cultivation, collection, processing and storage of crude drugs.
5	Detailed method of cultivation of crude drugs.
6	Study of cell wall constituents and cell inclusions.
7	Microscopical and powder Microscopical study of crude drugs.
8	Study of natural pesticides.
9	Detailed study of various cell constituents.
10	Carbohydrates and related products.
11	Detailed study carbohydrates containing drugs.(11 drugs)
12	Definition sources, method extraction, chemistry and method of analysis of lipids.
13	Detailed study of oils.
14	Definition, classification, chemistry and method of analysis of protein.
15	Study of plants fibers used in surgical dressings and related products.
16	Different methods of adulteration of crude drugs.

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

General Require ments: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

1 Introduction of Pharmacognosy laboratory and experiments.
2 Study of cell wall constituents and cell inclusions.
3 Macro, powder and microscopic study of Datura.
4 Macro, powder and microscopic study of Senna.
5 Macro, powder and microscopic study of Cassia.cinnamon.
6 Macro, powder and microscopic study of Cinchona.
7 Macro, powder and microscopic study of Ephedra.
8 Macro, powder and microscopic study of Quassia.
9 Macro, powder and microscopic study of Clove
10 Macro, powder and microscopic study of Fennel.
11 Macro, powder and microscopic study of Coriander.
12 Macro, powder and microscopic study of Isapgol.
13 Macro, powder and microscopic study of Nux vomica.
14 Macro, powder and microscopic study of Rauwolfia.
15 Macro, powder and microscopic study of Liquorice.
16 Macro, powder and microscopic study of Ginger.
17 Macro, powder and microscopic study of Podophyllum.
18 Determination of Iodine value.
19 Determination of Saponification value and unsaponifiable matter.
20 Determination of ester value.
21 Determination of Acid value.
22 Chemical tests for Acacia.
23 Chemical tests for Tragacanth.
24 Chemical tests for Agar.
25 Chemical tests for Starch.
26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance.

2.4 PHARMACOLOGY – I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
   b. handle and carry out the animal experiments;
   c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
   d. correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher : Little Brown.Co
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical) :

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.

b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1. **General Pharmacology**
   a) Introduction, definitions and scope of pharmacology
   b) Routes of administration of drugs
   c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
   d) Pharmacodynamics
   e) Factors modifying drug effects
   f) Drug toxicity - Acute, sub- acute and chronic toxicity.
   g) Pre-clinical evaluations
   h) Drug interactions

   Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. **Pharmacology of drugs acting on ANS**
   a) Adrenergic and antiadrenergic drugs
   b) Cholinergic and anticholinergic drugs
   c) Neuromuscular blockers
   d) Mydriactics and miotics
   e) Drugs used in myasthenia gravis
   f) Drugs used in Parkinsonism

3. **Pharmacology of drugs acting on cardiovascular system**
   a) Antihypertensives
   b) Anti-anginal drugs
   c) Anti-arrhythmic drugs
   d) Drugs used for therapy of Congestive Heart Failure
   e) Drugs used for hyperlipidaemias

4. **Pharmacology of drugs acting on Central Nervous System**
   a) General anesthetics
   b) Sedatives and hypnotics
   c) Anticonvulsants
   d) Analgesic and anti- inflammatory agents
   e) *Psychotropic drugs*
   f) Alcohol and methyl alcohol
   g) CNS stimulants and cognition enhancers
   h) Pharmacology of local anaesthetics

5. **Pharmacology of Drugs acting on Respiratory tract**
   a) Bronchodilators
   b) Mucolytics
   c) Expectorants
   d) Antitussives
   e) NasalDecongestants

6. **Pharmacology of Hormones and Hormone antagonists**
   a) Thyroid and Antithyroid drugs
   b) Insulin, Insulin analogues and oral hypoglycemic agents
   c) Sex hormones and oral contraceptives
   d) Oxytocin and other stimulants and relaxants

7. **Pharmacology of autocoids and their antagonists**
   a) Histamines and Antihistaminics
   b) 5-Hydroxytryptamine and its antagonists
   c) Lipid derived autocoids and platelet activating factor

2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope**: In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know pharmaceutical care services;
   b. know the business and professional practice management skills in community pharmacies;
   c. do patient counselling & provide health screening services to public in community pharmacy;
   d. respond to minor ailments and provide appropriate medication;
   e. show empathy and sympathy to patients; and
   f. appreciate the concept of Rational drug therapy.

   Text Books:
   a. Health Education and Community Pharmacy by N.S.Parmar.
   b. WHO consultative group report.
   c. Drug store & Business management by Mohammed Ali & Jyoti.

   Reference books:
   a. Handbook of pharmacy – health care.Edt. Robin J Harman. The Pharmaceutical press.
   b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

   Special require ments:
   1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
   2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. **Scheme of evaluation (80 Marks)**

1. Synopsis	10
2. Major Experiment (Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)	30
3. Minor Experiment(Ability to measure B.P/ CBG / Lung function)	15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction a nd ability to tell the management)	15
5. Viva – Voce	10

4. **Lecture wise programme :**

Topics

1 **Definition, scope, of community pharmacy**
Roles and responsibilities of Community pharmacist

2 **Community Pharmacy Manage ment**
a) Selection of site, Space layout, and design
b) Staff, Materials- coding, stocking
c) Legal requirements
d) Maintenance of various registers
e) Use of Computers: Business and health care soft wares

3 **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.

4 **Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

5 **Pharmaceutical care**
Definition and Principles of Pharmaceutical care.

6 **Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels

7 **Patient medication adhe rence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8 **Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function and Cholesterol testing

9 **OTC Medication- Definition, OTC medication list & Counselling**

10 **Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents,
Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,
Syphilis, Gonorrhea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist

11 **Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to,
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.

12 **Essential Drugs concept and Rational Drug The rapy Role of community pharmacist**

13 **Code of ethics for community pharmacists**

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2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. discuss the controversies in drug therapy;
   i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
d. Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

3. **Detailed syllabus and lecture wise schedule :**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

3 **General prescribing guidelines for**
a. Paediatric patients
b. Geriatric patients
c. Pregnancy and breast feeding

4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial

5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamines, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Objectives of the Subject Upon completion of the subject student shall be able to:**
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
   b. carry out the animal experiments confidently,
   c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
   d. correlate and apply the knowledge therapeutically.

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 4^{th} edition, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16^{th} edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. and Dale, M.M. Pharmacology. 4^{th} edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9^{th} edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
   a) Anticoagulants
   b) Thrombolytics and antiplatelet agents
   c) Haemopoietics and plasma expanders

2. **Pharmacology of drugs acting on Renal System**
   a) Diuretics
   b) Antidiuretics

3. **Che motherapy**
   a) Introduction
   b) Sulfonamides and co-trimoxazole
   c) Penicillins and Cephalosporins
   d) Tetracyclins and Chloramphenicol
   e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
   f) Quinolines and Fluroquinolines
   g) Antifungal antibiotics
   h) Antiviral agents
   i) Chemotherapy of tuberculosis and leprosy
   j) Chemotherapy of Malaria
   k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
   l) Pharmacology of Anthelmintic drugs
   m) Chemotherapy of cancer (Neoplasms)

4 **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants

5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity

6. **The dynamic cell: The structures and functions of the components of the cell**

a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
c) DNA replication: General, bacterial and eukaryotic DNA replication.
d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

a) Gene structure: Organization and elucidation of genetic code.
b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.
Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events
Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.
The gene sequencing, mapping and cloning of human disease genes.
Introduction to gene therapy and targeting.
Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
4 Genes VIII by Lewin, B., (2004)
5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

List of Experime nts:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
    a) Analgesic property of drug using analgesiometer.
    b) Antiinflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	**20**	**70**
Duration	**3hrs**	**4hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. **Quality Assurance:**
   a. Introduction, sources of quality variation, control of quality variation.
   b. Concept of statistical quality control.
   c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
   d. GLP, ISO 9000.
   e. Total quality management, quality review and documentation.
   f. ICH- international conference for harmonization-guidelines.
   g. Regulatory control.

2. **Chromatography:**
   Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.
   a. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
   b. **TLC**: Introduction, principle, techniques, Rf value and applications.
   c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
   d. **Ion-exchange chromatography** : Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
   e. **HPLC**: Introduction, theory, instrumentation, and applications.
   f. **HPTLC**: Introduction, theory, instrumentation, and applications.
   g. **Gas Chromatography**: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
   h. **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis, and application.
   i. **Gel filtration** and **affinity chromatography**: Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

a. **Potentiometry**: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting e nd point, Karl Fischer titration.
b. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.
c. **Polarography**: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. **Absorption Spectroscopy:**

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.
  Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy**: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.

d. **Atomic Emission Spectroscopy** : Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.

f. **Mass Spectroscopy**: **(Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.

g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.

i. **Thermal Analysis**: Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experime nts:

1. Separation and identification of Amino Acids by Paper Chro matography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.

11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

Title of the Experiment:

1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
2 To study the effects of drugs on intestinal motility using frog's esophagus model*
3 To study the effects of drugs using rat uterus preparation.**
4 To study the anticonvulsant property of drugs (any one model).*
5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
6 To study the apomorphine- induced compulsive behaviour (stereotypy) in mice.*
7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
8 To study the antiinflammatory property of indomethacin against carrageenan- induced paw oedema.**
9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
11 To study the effect of anthelmintics on earthworms.
12 To study the taming effect of chlorpromazine.*
13 To study the effects of drugs on vas deferense of the male rat.**
14 To study the effect of drugs on pesticide toxicity using rats as model.
15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
   a. know the pathophysiology of selected disease states and the rationale for drug therapy
   b. know the therapeutic approach to management of these diseases;
   c. know the controversies in drug therapy;
   d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
   e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

   Text books (Theory)
   Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

   Reference books (Theory)
   a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
   b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
   c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Yo ung and Koda-Kimble MA]

3. **Detailed syllabus and lecture wise schedule :**
   Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

   1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis
   2 **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
   3 **Renal system**
   Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
   a. practice the Professional ethics;
   b. understand the various concepts of the pharmaceutical legislation in India;
   c. know the various parameters in the Drug and Cosmetic Act and rules ;
   d. know the Drug policy, DPCO, Patent and design act;
   e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
   f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
   g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

   Text books (Theory)

   Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

   Reference books (Theory)

   a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
   b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
   c. Reports of the Pharmaceutical enquiry Committee
   d. I.D.M.A., Mumbai. DPCO 1995
   e. Various reports of Amendments.
   f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
   g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. **Detailed syllabus and lecture wise schedule:**

   Title of the topic

   1. **Pharmaceutical Legislations** – A brief review.
   2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
   3. **Drugs and Cos metics Act, 1940,and its rules 1945.**
      Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
      Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB,DCC,CDL. Qualification and duties – Govt. analyst and Drugs Inspector.

4. **Pharmacy Act –1948.**
   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
   Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Curre nt).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationaship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

   A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti- infective agents
   a) Local anti- infective agents
   b) Preservatives
   c) Antifungal agents
   d) Urinary tract anti- infectives
   e) Antitubercular agents
   f) Antiviral agents and Anti AIDS agents
   g) Antiprotozoal agents
   h) Anthelmentics
   i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
   a) Antihypertensive agents
   b) Antianginal agents and vasodilators
   c) Antiarrhythmic agents
   d) Antihyperlipidemic agents
   e) Coagulants and Anticoagulants
   f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diureties
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.

b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.

c. Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.

d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.

e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.

f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.

g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.

h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.

i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the principle involved in formulation of various pharmaceutical dosage forms;
   b. prepare various pharmaceutical formulation;
   c. perform evaluation of pharmaceutical dosage forms; and
   d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

   Text books (Theory)
   a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
   b. Rowlings Text book of Pharmaceutics
   c. Tutorial Pharmacy – Cooper &Gun

   Reference books (Theory)
   a. Remington's Pharmaceutical Sciences
   b. USP/BP/IP

3. **Detailed syllabus and lecture wise schedule:**

   Title of the topic

   1. Pharmaceutical dosage form- concept and classification
   2. **Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
   3. **Caps ules**; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
   4. **Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
   5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
   6. **Ophthalmic preparations (Semi – Solids)**: Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
   7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experime nts :

1. **Manufacture of Tablets**
   - **a.** Ordinary compressed tablet-wet granulation
   - **b.** Tablets prepared by direct compression.
   - **c.** Soluble tablet.
   - **d.** Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parente rals**
   - **a.** Ascorbic acid injection
   - **b.** Calcium gluconate injection
   - **c.** Sodium chloride infusion.
   - **d.** Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
   - **a.** Tablets
   - **b.** Capsules
   - **c.** Injections
5. **Formulation of two liquid oral preparations and evaluation by assay**
   - **a.** Solution: Paracetamol Syrup
   - **b.** Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
   - **a.** Salicyclic acid and benzoic acid ointment
   - **b.** Gel formulation Diclofenac gel
7. **Cosmetic preparations**
   - **a.** Lipsticks
   - **b.** Cold cream and vanishing cream
   - **c.** Clear liquid shampoo
   - **d.** Tooth paste and tooth powders.
8. **Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology a nd mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. to discuss the controversies in drug therapy;
   i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5 Pain management including Pain pathways, neuralgias, headaches.
6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope**: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know various drug distribution methods;
   b. know the professional practice management skills in hospital pharmacies;
   c. provide unbiased drug information to the doctors;
   d. know the manufacturing practices of various formulations in hospital set up;
   e. appreciate the practice based research methods; and
   f. appreciate the stores management and inventory control.

   Text books: (latest editions)
   a. Hospital pharmacy by William .E. Hassan
   b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

   References:
   a. WHO consultative group report.
   b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
   c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. **Lecture wise programme :**

   Topics

   1 Hospital - its Organisation and functions

   2 Hospital pharmacy-Organisation and manage ment
   a) Organizational structure-Staff, Infrastructure & work load statistics
   b) Management of materials and finance
   c) Roles & responsibilities of hospital pharmacist

   3 The Budget – Pre paration and imple mentation

   4 Hospital drug policy
   a) Pharmacy and Therapeutic committee (PTC)
   b) Hospital formulary
   c) Hospital committees
   - Infection committee
   - Research and ethical committee

   d) developing therapeutic guidelines
   e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

a) Procurement & warehousing of drugs and Pharmaceuticals
b) Inventory control
   Definition, various methods of Inventory Control
   ABC, VED, EOQ, Lead time, safety stock
c) Drug distribution in the hospital
   i) Individual prescription method
   ii) Floor stock method
   iii) Unit dose drug distribution method
d) Distribution of Narcotic and other controlled substances
e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

a) Sterile formulations – large and small volume parenterals
b) Manufacture of Ointments, Liquids, and creams
c) Manufacturing of Tablets, granules, capsules, and powders
d) Total parenteral nutrition

7 Continuing professional development programs Education and training

8 Radio Pharmaceuticals – Handling and packaging

9 Professional Relations and practices of hospital pharmacist

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic ap proach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special require ments:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.

b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b. Ward round participation
   c. Adverse drug reaction management
   d. Drug information and poisons information
   e. Medication history
   f. Patient counseling
   g. Drug utilisation evaluation (DUE) and review (DUR)
   h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 **Research Methodology**

a) Types of clinical study designs:
Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

2 **Biostatistics**

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

2.3 **Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)

c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 **Statistical methods in epide miology**

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature

Retrieval Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
   a. Absorption of drugs from gastrointestinal tract.
   b. Drug Distribution.
   c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.

3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.

4. Multicompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration

5. Multiple – Dosage Regimens.
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model
   c. Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis- menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.
   a. Introduction.
   b. Bioavailability study protocol.
   c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed prod ucts of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, $t_{1/2}$, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half- life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

a. Biopharmaceutics and C linical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4^{th} edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
   a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
   b) Opiates overdose.
   c) Antidepressants
   d) Barbiturates and benzodiazepines.
   e) Alcohol: ethanol, methanol.
   f) Paracetamol and salicylates.
   g) Non-steroidal anti- inflammatory drugs.
   h) Hydrocarbons: Petroleum products and PEG.
   i) Caustics: inorganic acids and alkali.
   j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants :amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

References:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

APPENDIX-B

(See regulation 9)
CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.

2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
   a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
   b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

a) Tertiary care hospitals are desirable
b) Medicine[compulsory], and any three specialization of the following
   1. Surgery
   2. Pediatrics
   3. Gynecology and obstetrics
   4. Psychiatry
   5. Skin and VD
   6. Orthopedics

(iii)Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

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3) TEACHING STAFF REQUIREMENT

i) Staff Pattern : All faculty shall be full time. However part time perceptors in hospital shall be allowed.

ii) Subject wise specialisation of the Teaching Staff :

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

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iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	Three years experience in Teaching or Research at the level of Lecturer or equivalent.

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		iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	
3.	Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv) Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	i) Ten years experience in Teaching or Research. ii) Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i) Fifteen years experience in Teaching or Research. ii) Out of which five years must be as Professor or above in Pharmacy. Desirable : Administrative experience in responsible position. The maximum age for holding the post shall be 65 years.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

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v) Workload of Faculty : Professor – 8 hrs. per week Assistant Professor – 12 hrs. per week Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty :

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training –Minimum 3 months.

c) Training sites –Institutions running pharmacy practice or Programmes for atleast five years.

d) Trainer –Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF :

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

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5) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls alongwith eight laboratories as specified below should be provided for: —

1. Pharmaceutics and Pharmacokinetics Lab - 2
2. Life Science (Pharmacology, Physiology, Pathophysiology) - 2
3. Phytochemistry or Pharmaceutical Chemistry - 2
4. Pharmacy Practice - 2

Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum re quired Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone

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11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum re quired Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum re quired Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02

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4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum re quired Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum re quired Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01

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9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum re quired Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/ triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nesslers Cylinders	40

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

D. DEPARTMENT OF PHARMACEUTICS :

I. Equipment:

S.No	Name	Minimum re quired Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01

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20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/ stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum re quired Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

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E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum re quired Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

F. DEPARTMENT OF PHARMACY PRACTICE :

Equipment:

S.No.	Name	Minimum re quired Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1

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10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. **Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
2. **Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and the departme nt.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum re quired Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C
(See regulation 16)
INTERNSHIP

1) **SPECIFIC OBJECTIVES :**

i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.

iv) to demonstrate skills in monitoring of the National Health Programme s and schemes, oriented to provide preventive and promotive health care services to the community.

v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

vi) to communicate effectively with patients and the community.

2) **OTHER DETAILS :**

i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the P harmacy Council of India to be considered on merits.

ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

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iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii) Satisfactory completion of internship shall be determined on the basis of the following:-

(1)Proficiency of knowledge required for each case management SCORE 0-5

(2)The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3)Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4)Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

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Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology a nd mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. to discuss the controversies in drug therapy;
   i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5 Pain management including Pain pathways, neuralgias, headaches.
6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know various drug distribution methods;
   b. know the professional practice management skills in hospital pharmacies;
   c. provide unbiased drug information to the doctors;
   d. know the manufacturing practices of various formulations in hospital set up;
   e. appreciate the practice based research methods; and
   f. appreciate the stores management and inventory control.

   Text books: (latest editions)
   a. Hospital pharmacy by William .E. Hassan
   b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

   References:
   a. WHO consultative group report.
   b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
   c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. **Lecture wise programme :**

   Topics

   1 Hospital - its Organisation and functions

   2 Hospital pharmacy-Organisation and manage ment
   a) Organizational structure-Staff, Infrastructure & work load statistics
   b) Management of materials and finance
   c) Roles & responsibilities of hospital pharmacist

   3 The Budget – Pre paration and imple mentation

   4 Hospital drug policy
   a) Pharmacy and Therapeutic committee (PTC)
   b) Hospital formulary
   c) Hospital committees
   - Infection committee
   - Research and ethical committee

   d) developing therapeutic guidelines
   e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

a) Procurement & warehousing of drugs and Pharmaceuticals
b) Inventory control
   Definition, various methods of Inventory Control
   ABC, VED, EOQ, Lead time, safety stock
c) Drug distribution in the hospital
   i) Individual prescription method
   ii) Floor stock method
   iii) Unit dose drug distribution method
d) Distribution of Narcotic and other controlled substances
e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

a) Sterile formulations – large and small volume parenterals
b) Manufacture of Ointments, Liquids, and creams
c) Manufacturing of Tablets, granules, capsules, and powders
d) Total parenteral nutrition

7 Continuing professional development programs Education and training

8 Radio Pharmaceuticals – Handling and packaging

9 Professional Relations and practices of hospital pharmacist

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic ap proach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special require ments:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b. Ward round participation
   c. Adverse drug reaction management
   d. Drug information and poisons information
   e. Medication history
   f. Patient counseling
   g. Drug utilisation evaluation (DUE) and review (DUR)
   h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

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4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 **Research Methodology**

a) Types of clinical study designs:
Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

2 **Biostatistics**

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

2.3 **Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)

c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 **Statistical methods in epide miology**

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature

Retrieval Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
   a. Absorption of drugs from gastrointestinal tract.
   b. Drug Distribution.
   c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.

3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.

4. Multicompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration

5. Multiple – Dosage Regimens.
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model
   c. Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis- menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.
   a. Introduction.
   b. Bioavailability study protocol.
   c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed prod ucts of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, $t_{1}/2$, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half- life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

a. Biopharmaceutics and C linical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4^{th} edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
   a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
   b) Opiates overdose.
   c) Antidepressants
   d) Barbiturates and benzodiazepines.
   e) Alcohol: ethanol, methanol.
   f) Paracetamol and salicylates.
   g) Non-steroidal anti- inflammatory drugs.
   h) Hydrocarbons: Petroleum products and PEG.
   i) Caustics: inorganic acids and alkali.
   j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants :amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

References:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. **Drug development process:**
   Introduction
   Various Approaches to drug discovery
   1. Pharmacological
   2. Toxicological
   3. IND Application
   4. Drug characterization
   5. Dosage form

2. **Clinical development of drug:**
   1. Introduction to Clinical trials
   2. Various phases of clinical trial.
   3. Methods of post marketing surveillance
   4. Abbreviated New Drug Application submission.
   5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
   6. Challenges in the implementation of guidelines
   7. Ethical guidelines in Clinical Research
   8. Composition, responsibilities, procedures of IRB / IEC
   9. Overview of regulatory environment in USA, Europe and India.
   10. Role and responsibilities of clinical trial personnel as per ICH GCP
       a. Sponsor
       b. Investigators
       c. Clinical research associate
       d. Auditors
       e. Contract research coordinators
       f. Regulatory authority
   11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
   12. Informed consent Process
   13. Data management and its components
   14. Safety monitoring in clinical trials.

References :

a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. **Pharmacoepidemiology :**

Definition and scope:
Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measure ment of outcomes in pharmacoepidemiology
Outcome measure and drug use measures
Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology
Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods
Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepide miological studies
Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology
Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. **Phrmacoeconomics:**

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation
Outcome assessment and types of evaluation
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**

Software and case studies

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5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

1. **Introduction to Clinical pharmacokinetics.**

2. **Design of dosage regimens:**
   Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. **Pharmacokinetics of Drug Interaction:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

4. **Therapeutic Drug monitoring:**
   a. Introduction
   b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   c. Indications for TDM. Protocol for TDM.
   d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. **Dosage adjustment in Renal and hepatic Disease.**
   a. Renal impairment
   b. Pharmacokinetic considerations
   c. General approach for dosage adjustment in Renal disease.
   d. Measurement of Glomerular Filtration rate and creatinine clearance.
   e. Dosage adjustment for uremic patients.
   f. Extracorporeal removal of drugs.
   g. Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics.**
   a. Introduction to Bayesian Theory.
   b. Adaptive method or Dosing with feed back.
   c. Analysis of Population pharmacokinetic Data.

7. **Pharmacogenetics**
   a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
   b. Genetic Polymorphism in Drug Transport and Drug Targets.
   c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

(See regulation 9)
CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.

2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
   a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
   b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

a) Tertiary care hospitals are desirable
b) Medicine[compulsory], and any three specialization of the following
   1. Surgery
   2. Pediatrics
   3. Gynecology and obstetrics
   4. Psychiatry
   5. Skin and VD
   6. Orthopedics

(iii)Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3) TEACHING STAFF REQUIREMENT

i) Staff Pattern : All faculty shall be full time. However part time perceptors in hospital shall be allowed.

ii) Subject wise specialisation of the Teaching Staff :

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

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iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	Three years experience in Teaching or Research at the level of Lecturer or equivalent.

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		iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	
3.	Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv) Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	i) Ten years experience in Teaching or Research. ii) Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i) Fifteen years experience in Teaching or Research. ii) Out of which five years must be as Professor or above in Pharmacy. Desirable : Administrative experience in responsible position. The maximum age for holding the post shall be 65 years.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

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v) Workload of Faculty : Professor – 8 hrs. per week Assistant Professor – 12 hrs. per week Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty :

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training –Minimum 3 months.

c) Training sites –Institutions running pharmacy practice or Programmes for atleast five years.

d) Trainer –Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF :

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

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5) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls alongwith eight laboratories as specified below should be provided for: —

1. Pharmaceutics and Pharmacokinetics Lab - 2
2. Life Science (Pharmacology, Physiology, Pathophysiology) - 2
3. Phytochemistry or Pharmaceutical Chemistry - 2
4. Pharmacy Practice - 2

Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum re quired Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone

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11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum re quired Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum re quired Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02

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4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum re quired Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum re quired Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01

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9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum re quired Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/ triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nesslers Cylinders	40

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

D. DEPARTMENT OF PHARMACEUTICS :

I. Equipment:

S.No	Name	Minimum re quired Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01

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20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/ stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum re quired Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum re quired Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and departme nt.

F. DEPARTMENT OF PHARMACY PRACTICE :

Equipment:

S.No.	Name	Minimum re quired Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1

10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. **Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
2. **Adequate numbe r of glassware commonly used in the laboratory should be provided in each laboratory and the departme nt.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum re quired Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C
(See regulation 16)
INTERNSHIP

1) **SPECIFIC OBJECTIVES :**

i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.

iv) to demonstrate skills in monitoring of the National Health Programme s and schemes, oriented to provide preventive and promotive health care services to the community.

v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

vi) to communicate effectively with patients and the community.

2) **OTHER DETAILS :**

i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the P harmacy Council of India to be considered on merits.

ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

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iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii) Satisfactory completion of internship shall be determined on the basis of the following:-

(1)Proficiency of knowledge required for each case management SCORE 0-5

(2)The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3)Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4)Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

APPENDIX-D

(See regulation 17)

CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

1. The Examining Authority shall be a statutory Indian University constituted by the Central Government/State Government/Union Territory Administration. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.

2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.

3. It shall provide:-
   (a) adequate rooms with necessary furniture for holding written examinations;
   (b) well-equipped laboratories for holding practical examinations;
   (c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examinations; and
   (d) such other facilities as may be necessary for efficient and proper conduct of examinations.

4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of presc ribed fee, if any, to the Examining Authority.

5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix–B.

6. In pursuance of sub–section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India, not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.

7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes in an approved institution.

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(ARCHNA MUDGAL)
Registrar cum Secretary
Pharmacy Council of India
New Delhi – 110002

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)

COURSE STRUCTURE AND SYLLABUS

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Applied Biopharmaceutics and Pharmacokinetics	25	75	4	--	4
Core Course II	Advanced Physical Pharmaceutics	25	75	4	--	4
Core Course III	Advanced Pharmaceutical Technology –I	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Technique 2. Intellectual Property Rights and Regulatory Affairs	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology, Pharmacoeconomics and Pharmacovigilance 2. Drug Regulatory Affairs (National & International) 3. Herbal Cosmetic Technology 4. Separation Methods 5. Pharmaceutical Management – I	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	4	--	4
Laboratory II	Advanced physical Pharmaceutics Lab	25	75	--	4	2
Seminar I	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Advanced Drug Delivery Systems	25	75	4	--	4
Core Course V	Industrial Pharmacy	25	75	4	--	4
Core Course VI	Advanced Pharmaceutical Technology II	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Pharmaceutical Management-II	25	75	4	--	4
Laboratory III	Advanced Drug Delivery Systems Lab	25	75	4	--	4
Laboratory IV	Advanced Pharmaceutical Technology Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	P	C
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review I	50	--	--	24	12
Total Credits			--	24	**16**

II Year - II Semester

Course Title	Int. marks	Ext. marks	L	P	C
Project work Review II	50	--	--	8	4
Project Evaluation (Viva-Voce)	--	150	--	16	12
Total Credits			--	**24**	**16**

Gautham College of Pharmacy

PRINCIPAL
Gautham College of Pharmacy

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS

Objective: The student shall learn about bioavailability, bioequivalence and factor affecting bioavailability. They also learn the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependant pharmacokinetics. They also understand about the drug interactions & problems, practice associated in pharmacokinetic parameters calculations.

UNIT I

1. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.
2. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.
3. **Bioavailability :**Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, InvitroInvivo Correlation analysis and Levels of Correlations.
4. **Bioequivalence:** Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT II

Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

a. Distribution: Apparent volume of distribution and its determination. factors affecting.
b. Metabolism: Metabolic rate constant, Factors affecting Metabolism
c. Elimination: Over all apparent elimination rate constant, and half life.
   All the above under the following conditions:
   1. Intravenous infusion
   2. Multiple dose injections
d. Noninvasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.
e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

Pharmacokinetics – Absorption: Rate constants – Zero order, first order,Models of experimental study of absorption (in silico, in vitro, in situ and in vivo) – Absorption half lives, method of residuals, Wagner – Nelson method, Loo - Reigleman method, Analysis of kinetics from urine samples. Pharmacokinetic parameters determination pertaining to: Multiple dosage oral administration

UNIT IV

Non-linear pharmacokinetics: Concepts of linear and non-linear pharmacokinetics, Michaelis-Menton kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, and non-linearity of pharmacological responses.

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V

Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

- Numerical problems associated with all units, if any.

Outcome: students will be able to express factors affecting the bioavailability and stability of dosage form; they also learn the bioequivalence studies and protocols for bioequivalent studies. They also

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHYSICAL PHARMACEUTICS

Objective: The students shall apply the principles of physical and chemical properties of particle science, polymer science and their use in pharmaceutical dosage forms. They also learn the compression and consolidation parameters for powders and granules. Students also learn about the rheology, disperse systems, dissolution and solubility related parameters for dosage forms.

UNIT I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive ,Hydrodynamically balanced and Transdermal Systems.

UNIT II

Physics of tablet compression: Basic principles of interactions,compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, drug release from suspension and emulsion formulations. Accelerated stability evaluation of physical stability. Microemulsions & multiple emulsions, types of viscometer-principle & working.

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

Outcome: The students will learn particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also practice the stability calculations, shelf life calculations and accelerated stability studies. They also understand the rheology, absorption related to liquids and semi-solid dosage forms with advances. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

TEXT BOOKS

1. Physical Pharmacy , 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman Vol.4
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II
4. Cartenson "Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

REFERENCE BOOKS

1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems

evaluate the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

TEXT BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by MiloGibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.
4. Basic biopharmaceutics, Sulnil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz

RECOMMENDED BOOKS

1. Bio-Pharmaceutics and Pharmacokinetics by V.Venkateshwarlu.
2. Pharmacokinetics.Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
3. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
4. Drug drug interactions, scientific and regulatory perspectives by Alber P. G

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHARMACEUTICAL TECHNOLOGY-I

Objectives: Students will know the preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

UNIT I

Preformulation studies: Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies (ICH)

UNIT II

Formulation development of solid dosage forms – I: New materials, excipients science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipients, co-processed materials, methods of preparation and evaluation.

UNIT III

Formulation development of solid dosage forms– II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.
Microencapsulation- types, methodology, problems encountered.

UNIT IV

Formulation development of soft and hard gelatin capsules : Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

Outcome: Students shall explain the preformulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical design in different formulations.

TEXT BOOKS

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Pharmaceutical statistics by Bolton

RECOMMENDED BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Core Elective I)

Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, MS, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation andoperation, detection, dramatization.
b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy

Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures

REFERENCES :

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors

4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth
12. Indian Pharmacopoeia 2007
13. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, AnneSchibli
14. Introduction to instrumental analysis by Robert. D. Braun

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm(Pharmaceutics/Pharmaceutical Technology)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS
(Core Elective I)

Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Intellectual Property Rights:

UNIT I
Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT II
a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT III
a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
b. Background, Salient Features and Impact of International Treaties / Conventions like
    1. Paris Convention, Berne convention
    2. World Trade Organization (WTO)
    3. World Intellectual Property Organization (WIPO)
    4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
    5. Patent Co-operation Treaty (PCT), Mandrid Protocol

Regulatory Affairs

Unit IV
a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

Unit V
a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10

Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students

RECOMMENDED BOOKS:
1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India

3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm. (Pharmaceutics/Pharmaceutical Technology)

PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE
(Optional Elective –I)

Objective: This course is designed to impart knowledge and skills in epidemiology, economics and vigilance of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

Unit-I

Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology Outcome measures and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Unit-II

Concept of risk in pharmacoepidemiology, Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross–sectional studies, cohort studies, case control studies, case–cohort studies, meta–analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Unit-III

Sources of data for pharmacoepidemiological studies Adhoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

Unit-IV

Pharmacoeconomics:

Definition, history, need of pharmacoeconomic evaluations Role in formulary management decisions.

Pharmacoeconomic evaluation Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

Applications of Pharmacoeconomics, Softwares used and case studies

Unit-V

a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, Mechanism, predisposing factors, causualilty assessment (different scales used)
c. Reporting, evaluation, monitoring and management of ADRs
d. Role of pharmacist in management of ADRs.

Outcome: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmocovigilance.

REFERENCES:

1. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
2. Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974 Edition. McGraw Hill.
3. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004
4. Goodman & Gilman's The Pharmcological basis of Thorapoutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.

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I Year – I Sem M.Pharm(Pharmaceutics/Pharmaceutical Technology)

DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)
(Optional Elective –I)

Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries

UNIT I
A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

UNIT II
The Drugs and Cosmetics Act, 1940 and Rules there under.Recent amendments to Drugs and Cosmetic Act and other relevant rules.
Drugs (Price Control) Order in force.Loan license (contract manufacture). Certification and licensing procedures.

UNIT III
A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV
Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V
Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.SFood & Drug Administration USDMF
b. CanadaTherapeutic Product Directorate DMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS& Health Care Products
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application(MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

TEXT AND REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; VallabhPrakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; VallabhPrakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M.Pharm (Pharmaceutics and Pharmaceutical Technology)

HERBAL COSMETICS TECHNOLOGY
(Optional Elective –I)

Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation

UNIT I

a) Introduction, historical background and present status of Herbal cosmetics
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Moulding, Packing. Raw materials used in preparation of herbal cosmetics
c) Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery
d) Quality, safety and efficacy of Herbal cosmetics

UNIT II

Skin care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT III

Hair care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like hair dyes, creams, Lotions, Jels, oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as *Acacia concinna* pods, Aloe Vera, Almond oil, Neem, *Citrus aurantium*peels, Henna, Turmeric, Liquorice, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

UNIT V

a) General Principles of Quality control and standardization of cosmetics-Raw material control, Packaging material control, finished product control, Shelf testing.
b) Natural colorants : Biological Source, coloring principles, chemical nature and usage of the following Annato, Cochineal, Caramel, Henna, Indigo, Madder, Saffron , Turmeric
c) Flavors and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Vanilla, Palmarosa, geranium oil

Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P.Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm(Pharmaceutics/Pharmaceutical Technology)

SEPARATION METHODS
(Optional Elective –I)

Objectives: The course is designed to import knowledge in the field of various separation techniques in the context of their applications both at laboratory and industry level. The techniques such as GC, HPLC, Electrophoresis etc. Methods allow qualitative and quantitative estimations and thus demand for the development and validation of methods.

UNIT: I

i. **Column Chromatography and Short column chromatography**: Column packing, sample loading, column development, detection.
ii. **Flash chromatography and Vacuum liquid chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.

UNIT-II

Sample Preparation - Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid-Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

UNIT: III

i. **HPLC:** Principles, basic parameters Retention factor, Capacity factor, Selectivity factor, plate number, plate height, resolution, peak shapes, band broadening, van Deemter equation and curve. Column selection and optimization, column problems, solvents, trouble shooting, sample preparation.
ii. **Method Development and validation:** Introduction, Forced Degradation Studies -Experimental Approach to Forced Degradation Studies. Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization and validation.

UNIT-IV

i. **Gas Chromatography:** Principles, split-splitless injector, head space sampling, columns for GC, detectors, quantification, derivatization techniques.
ii. **Hyphenated techniques:** Introduction to GC-MS and LC-MS techniques and their applications.

UNIT-V

i. **Electrophoresis:** Capillary electrophoresis: Basic principle (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.
ii. **Counter current chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.

Outcome : The students should describe the separation techniques of choromatography (GC, HPLC) with principles, instrumentation, identification, development of methodology specific to the components of the mixure, including the method validation. The students should be able to explain the separation principles using the advanced techniques such as Flash chromatography and highphenated techniques.

REFERENCES:

1) 1. Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein

11) HPTLC by P.D. Seth
12) Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
13) Methods in Biotechnology, Natural Product Isolation by Richard Canell
14) Various Reviews and Research Papers

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I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL MANAGEMENT-I
(Optional Elective –I)

Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

Outcome:

- These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry..

TEXT AND REFERENCE BOOKS

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management "Global Perspectlve Helnz Welhrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.

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I Year – I SemM.Pharm (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.

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I Year – I Sem M.Pharm (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHYSICAL PHARMACEUTICS LAB

List of experiments

1. Determinates of molecular weight of some selected polymers.
2. Preparation and evaluation of solid dispersions (Immediate release and sustained release)
3. Accelerated stability testing of Aspirin Tablets
4. Stability evaluation of Aspirin at various pH and temperature conditions
5. Determination of Ist order and 2nd order rate constant. Half life by Acid / Alkali hydrolysis
6. Preparation and evaluation of multiple emulsions
7. Preparation and evaluation of β-cyclodextrin complexes of some drugs.
8. Generation of dissolution profiles of few dosage forms and application of the data into various kinetic equations. Calculation of Hixon-crowell dissolution rate constant
9. Preparation and dissolution study of paracetamol tablets and comparison with the marketed product.
10. Study of solubility and dissolution for few drugs and their respective salts.
11. Study of drug release from commercial suspension and emulsion dosage forms
12. Viscosity measurement of Newtonian and Non-Newtonian liquids
13. Evaluation of drug-protein binding analysis
14. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.

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M. Pharmacy (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)

COURSE STRUCTURE AND SYLLABUS

I Year – II Semester

Category	Course Title	marks	Ext. marks	L	P	C
Core Course IV	Advanced Drug Delivery Systems	25	75	4	--	4
Core Course V	Industrial Pharmacy	25	75	4	--	4
Core Course VI	Advanced Pharmaceutical Technology II	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Pharmaceutical Management-II	25	75	4	--	4
Laboratory III	Advanced Drug Delivery Systems Lab	25	75	4	--	4
Laboratory IV	Advanced Pharmaceutical Technology Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm (Pharmaceutics/Pharm Tech)

ADVANCED DRUG DELIVERY SYSTEMS

Objective: The students shall apply the pharmacokinetic and pharmacodynamic principles in the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

UNIT 1

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

a. Controlled release oral drug delivery systems
b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation and applications of the following

a. Implantable Therapeutic systems
b. Transdermal delivery systems
c. Ocular and Intrauterine delivery systems
d. Vaccine delivery : Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT III

Biochemical and molecular biology approaches to controlled drug delivery of

a. Bioadhesive drug delivery systems
b. Nasal drug delivery systems
c. Drug delivery to Colon

UNIT IV

Biochemical and molecular biology approaches to control drug delivery of

a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealed erythrocytes

UNIT V

Drug targeting to particular organs

a. Delivery to lungs
b. Delivery to the brain and problems involved
c. Drug targeting in neoplasams

Outcomes: Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

Text Books

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes..
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y.Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by AukunuruJithan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm(Pharmaceutics/Pharm Tech)

INDUSTRIAL PHARMACY

Objectives: The students shall learn the theory of unit operations, machinery, materials of constructions, qualification of equipments and its utility. The students shall also understand about the objectives and principles of GMP, TQM and effluent analysis and specifications. They also understand the regulatory basis for the validation of analytical methods related to solids, sterile and liquid dosage forms

UNIT I

Pharmaceutical unit operations: A detailed study involving machinery and theory of Pharmaceutical unit operations like milling, mixing, filtration, and drying.

UNIT II

a. Materials of construction of pharmaceutical equipment and packaging materials: Study of the principles, production techniques in the large scale production of tablets, capsules, suspensions, liquid pharmaceuticals, ophthalmic products and sterile products.

b. Qualification of equipment (IQ, OQ, PQ)

UNIT III

Production management: Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, material management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Total Quality Management (TQM)

UNIT IV

Effluent Testing and Treatment: Effluent analysis, specifications and preventive measures water of pollution, solid pollution, air pollution and sound pollution.

UNIT V

Validation: Regulatory basis, validation of analytical methods, and process, in solid dosage forms, sterile products, and liquid dosage forms.

Outcome: The students will explain the machinery involved in milling, mixing, filteration, drying and packing material constructions used in the production of pharmaceutical materials. They also learn salient features of GMP, TQM applicable in industry. They also understand the effluent treatments and prevent the pollution. They also should evaluate the validation of analytical methods and processes

Text Books

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Good Manufacturing Practice for Pharmaceuticals by Sidney H. willig.
3. Pharmaceutical Process validation by Robert A. Nash, Alfred H. Wachter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Pharmaceutical production management, C.V.S. Subrahmanyam, Vallabh Prakash.

Recommended Text Books

1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Bentley's Text book of Pharmaceutics by EA Rawlins.
4. CGMP, H.P.P. Sharma

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm(Pharmaceutics/Pharm Tech)

ADVANCED PHARMACEUTICAL TECHNOLOGY-II

Objective: The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control. The students also understand about the cosmetics and neutraceuticals.

UNIT I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

a. Pilot plant: Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.

b. Scale up: Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers, product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV

a. Cosmetics: Formulation approaches, preparation & method of manufacturing labeling& Q.C. of anti ageing products, sun screen lotion and fairness creams.

b. Nutraceuticals:

1. Introduction, source, manufacture and analysis of glucosamine and cartinine.
2. Monographs: General and specific properties of glucosamine &cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

b. Air handling systems: Study of AHUs, humidity & temperature control.

Outcomes: students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, aerosols, cosmetics and neutraceuticals.

Text Books

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.
4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
5. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
6. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

Recommended Books

1. Bentley`s Text Book of Pharmaceutics by EA Rawlins.

2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
5. Nutraceuticals, 2nd edition by Brian lock wood.
6. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – IISem M.Pharm (Pharmaceutics/Pharm Tech)

BIOSTATISTICS AND RESEARCH METHODS
(Core Elective- II)

Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.

Probability rules: Binomial, Poison and Normal distribution.

Hypothesis testing: Student't' test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

UNIT IV

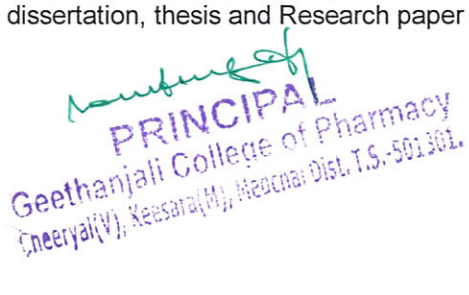
Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review,
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal
Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

UNIT V

The research report paper writing/ thesis writing
Different parts of the research paper

1. Title-Title of project with authors' name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology- subject, apparatus, instrumentation and procedure
5. Results – tables, graphs figure and statistical presentation
6. Discussion support or non-support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata
11. Importance of Spell check for entire projects
12. Uses of footnotes

Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper



Text Books

1. Deepak Chawla NeenaSondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)

Reference Books

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
9. Fundamentals of Biostatistics by Khan and Khanum
10. Research Methodology by RK Khanna bis and SuvasisSaha
11. Research methods and Quantity methods by G.N.Rao
12. A practical approach to PG dissertation.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm(Pharmaceutics/Pharm Tech)

SCREENING METHODS AND CLINICAL RESEARCH
(Core Elective- II)

Objective:- The students is going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs

UNIT I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological, anti-inflammatory, analgesic and anti-diabetic.

UNIT V

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Outcome: - The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, BerlinHeideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, VallabhPrakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm(Pharmaceutics/Pharm Tech)

STABILITY OF DRUGS AND DOSAGE FORMS
(Open Elective- II)

Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation

UNIT-I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT-II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT-III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.Factors affecting extraction of drugs.

UNIT-IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. .. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT-V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

Outcome: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

REFERENCE BOOKS :

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.

2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition.
3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore :Herry'sCosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W.Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm (Pharmaceutics/Pharm Tech)

NANO BASED DRUG DELIVERY SYSTEMS
(Open Elective- II)

Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

UNIT I – Introduction to Nanotechnology

a) Definition of nanotechnology
b) History of nanotechnology
c) Unique properties of nanomaterials
d) Role of size and size distribution of nanoparticles properties, classification.

UNIT II – Synthesis of Nanomaterials

a) Physical, chemical and biological Methods
b) Methods for sysnthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes , micelles, aquasomes and nanoemulsions

UNIT III – Biomedical applications of Nanotechnology

a) Nanotechnology products used for in vitro diagnostics
b) Improvements to medical or molecular imaging using nanotechnology
c) Targeted nanomaterials for diagnostic and therapeutic purpose

Unit IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

Unit V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

Recommended Books:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicologyin the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L.Arias,CRC press
3. Nano: The Essentials: Understanding Nanosicence and Nanotechnology, T.Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C.N.R.Rao, P.J.Thomas and G.U. Kulakarni, Springer(2007)
5. Nanostructures and Nanomaterilas: Synthesis, Properties and Application, GuozhongGao, Imperial College Press(2004)
6. Nanochemistry:A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridege, UK (2005)
7. Nanocomposite science and technology, pulickelM.Ajayan, Linda S.Schadler, paul V.Braun, Wiley-VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J.Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm (Pharmaceutics/Pharm Tech)

NUTRACEUTICALS
(Open Elective- II)

Objectives: The students will expose to characteristic features of various phytochemicals as neutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as neutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phytoestrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide,malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin

Synthetic antioxidants : Butylated hydroxy Toluene, Butylated hydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

Outcome: Helps the student to understand the importance of Neutraceuticals in various commom problems with the concept of free radicals

REFERENCES:

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* WoodheadPubl.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm (Pharmaceutics/Pharm Tech)

PHARMACEUTICAL MANAGEMENT-II
(Open Elective- II)

Objective: To know the pharmaceutical product management, planning, marketing accounts and finance. They also know the Inventory control, concept and techniques to improve production In packaging, marketing, sale and accounting

UNIT I

Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.

Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

UNIT II

Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment.Product management.E-Pharma Marketing.

UNIT III

Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.

Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

UNIT IV

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm's stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management.

Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance.

Introduction to financial management, financial planning and control, working capital management, management of fixed assets

Evaluation of investment decisions by payback period, accounting rate of return, net present value methods, break even analysis.

UNIT V

Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.

Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework.Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social.Risk analysis.

Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new issues, negotiations with FIs, FIIs, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

Outcome: Student will get knowledge about production management, production planning and control, design and development of packaging, marketing of pharmaceuticals.

Text and reference books

1. Financial Management by Johnson, R.W.; The Ronald Press.
2. Fundamental of Financial Management by Van Horne, J.C.; Prentice Hall of India (P) Limited.
3. Stock Exchange and Investment Analysis by Briston, R. J.
4. Indian Financial System by Khan, M. Y.; Tata McGraw Hill.
5. Tax Planning for Industrial Projects by Agarwal R. K.; Hind Law Publishers, New Delhi.
6. Project Management by Chaudhary, S.; Tata McGraw Hill.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner; CRS Publishers and Distributors, Delhi.
8. Financial Management by Gupta And Sharma I st Edition 1996.
9. Accounting for Management Planning and Control III rd Edition Richard M. Lynch
11. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
12. Business Organization and Management by Shukla M. C.; S. Chand and Company.
13. Business Organization and Management by Sherlakar S. A.; Himalaya.
14. Personnel Management by Filippo E. B.; McGraw Hill.
15. Marketing Management by Kotler Philip.; Prentice Hall of India.
16. Organizational Behavior by Rao and Narayan; Konark Publishers.
17. Personnel Management by Tripathi P. C.; S. Chand and Company.
18. Principle and Practice of Marketing in India by Memoria C. B.
19. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
20. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
21. Production and Operations Management by S.N.Chary

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm (Pharmaceutics/Pharm Tech)

ADVANCED DRUG DELIVERY SYSTEMS LAB

List of Experiments

1.	Study on diffusion of drugs through various polymeric membranes	(2 experiments)
2.	Formulation and evaluation of sustained release oral matrix tablet	(2 experiments)
3.	Formulation and evaluation of sustained release oral reservoir system.	(2 experiments)
4.	Formulation and evaluation of microspheres / microencapsules	(2 experiments)
5.	Study of in-vitro dissolution of various SR products in market	(2 experiments)
6.	Formulation and evaluation of transdermal films	(2 experiments)
7.	Formulation and evaluation mucoadhesive system	(2 experiments)
8.	Preparation and evaluation enteric coated pellets / tablets.	(2 experiments)

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm(PM&RA)

ADVANCED PHARMACEUTICAL TECHNOLOGY -II
(Open Elective – II)

Objective: The students shall know about the pilot plant scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also know about the filling of capsules, compression machines, sterilizers for formulation of parenterals and also know about the propellants, DPI, MDI and their quality control. The students also know about the cosmetics and neutraceuticals

UNIT I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

a. **Pilot plant:** Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.
b. **Scale up:** Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers, product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV

a. **Cosmetics:** Formulation approaches, preparation & method of manufacturing labeling& Q.C. of anti ageing products, sun screen lotion and fairness creams.
b. **Nutraceuticals:**

1. Introduction, source, manufacture and analysis of glucosamine and cartinine.
2. Monographs: General and specific properties of glucosamine &cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.
b. Air handling systems: Study of AHUs, humidity & temperature control.

Outcomes: Students will know about the scale up and pilot plant techniques used for all pharmaceutical dosage forms like tablets, capsules, parenterals, aerosols, cosmetics and neutraceuticals.

Text Books

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.
4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
5. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman
6. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

Recommended Books

1. Bentley's Text Book of Pharmaceutics by EA Rawlins.

2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm (Pharmaceutics/Pharm Tech)

ADVANCED PHARMACEUTICAL TECHNOLOGY LAB

List of Experiments

1. Preparation of four different types of semisolid forms and evaluation of their performance using in vitro diffusion method
2. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
3. Collecting samples of environment of aseptic room and counting the colonies
4. Validation of one unit operation (eg. Mixing) and development of protocol.
5. Comparative evaluation of different marketed products (tablets) of the same API
6. Dissolution studies of drug in three different bio relevant dissolution media
7. Stability study testing of tablet dosage forms (Any two products)

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE / QA
COURSE STRUCTURE AND SYLLABUS

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Separation Techniques	25	75	4	--	4
Core Course II	Advanced Pharmaceutical Analysis – I	25	75	4	--	4
Core Course III	Quality Control of Bulk Drugs and Formulations	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Technique 2. Intellectual Property Rights and Regulatory Affairs	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology, Pharmacoeconomics and Pharmacovigilance 2. Drug Regulatory Affairs (National And International) 3. Herbal Cosmetics Technology 4. Pharmaceutical Management – I 5. Advanced Physical Pharmaceutics	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	4	--	4
Laboratory II	Advanced Pharmaceutical Analysis-I Lab	25	75	--	4	2
Seminar I	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Advanced Pharmaceutical Analysis – II	25	75	4	--	4
Core Course V	Spectral Analysis	25	75	4	--	4
Core Course VI	Quality Assurance	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Pharmaceutical Product development and Management 5. Pharmaceutical Management-II	25	75	4	--	4
Laboratory III	Advanced Pharmaceutical Analysis – II Lab	25	75	4	--	4
Laboratory IV	Spectral Analysis Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	P	C
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review I	50	--	--	24	12
Total Credits			--	24	**16**

II Year - II Semester

Course Title	Int. marks	Ext. marks	L	P	C
Project work Review II	50	--	--	8	4
Project Evaluation (Viva Voce)	--	150	--	16	12
Total Credits			--	**24**	**16**

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

SEPARATION TECHNIQUES

Objective: The topics of various chromatographic methods from simple to advanced techniques are discussed in detail. The principles, instrumentation and method development parameters are discussed.

UNIT: I

a. **Column Chromatography and Short column chromatography**: Column packing, sample loading, column development, detection.
b. **Flash chromatography and Vacuum liquid chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.

UNIT-II

Sample Preparation - Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

UNIT: III

a. **HPLC:** Principles, basic parameters Retention factor, Capacity factor, Selectivity factor, plate number, plate height, resolution, peak shapes, band broadening, van Deemter equation and curve. Column selection and optimization, column problems, solvents, trouble shooting, sample preparation.
b. **Method Development and validation:** Introduction, Forced Degradation Studies -Experimental Approach to Forced Degradation Studies. Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization and validation.

UNIT-IV

a. **Gas Chromatography:** Principles, split-splitless injector, head space sampling, columns for GC, detectors, quantification, derivatization techniques.
b. **Hyphenated techniques:** Introduction to GC-MS and LC-MS techniques and their applications.

UNIT-V

a. Electrophoresis: Capillary electrophoresis: Basic principle (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.
b. **Counter current chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.

Outcome: The students will learn the every aspect of separation methods, also sample preparation and method validation process. They will come out with full knowledge of various methods including the instrumentation, handling and uses.

REFERENCES:

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
13) Methods in Biotechnology, Natural Product Isolation by Richard Canell
14) Various Reviews and Research Papers

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS – I

Objective: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB etc. in the determination of the pharmaceuticals are also discussed.

UNIT I

Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods

UNIT II

A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl

UNIT III

Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

a. MBTH (3-methyl-2-benzothiazolone hydrazone)
b. F.C. Reagent (Folin-Ciocalteu)
c. PDAB (*para*-Dimethyl Amino Benzaldehyde)
d. 2, 3, 5 - *tri*Phenyltetrazolium salt
e. 2,6 *di* -ChloroquinoneChlorimide
f. *N* - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)

UNIT-IV

a. **Atomic Absorption Spectrometry (AAS):** Principle, instrumentation, sample automization techniques, interferences. Elemental analysis such as determination of Sodium, Potassium, Calcium, Chlorine, Bromine and Iodine.
b. **Radio chemical methods including RIA:** Radio Active Isotopes, tagging of compounds, Labeled Reagents, Isotope dilution Analysis, Scintillation counter, RIA.

UNIT-V

a. **Dissolution Method Development:** Physical and Chemical Properties of API, Dissolution Apparatus Selection, Dissolution Medium Selection, Key Operating Parameters, Method Optimization, Validation, Automated Systems.
b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

Outcome: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

TEXT BOOKS

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners

REFERENCES

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

QUALITY CONTROL OF BULK DRUGS & FORMULATIONS

Objective: The quality control aspects like in process quality control tests, impurity profiles, quality control of nutraceuticals and excipients.

UNIT I

Impurity Profiling of Pharmaceuticals: Sources of impurities, their effect on drug stability and therapeutic actions. Determination of impurities in bulk drugs and Formulations: Isolation, characterization and analytical methods.

UNIT II

In process quality control tests carried on the following dosage forms

A. Tablets B. Capsules C. Parenterals D. Liquid Orals

UNIT III

Quality Control of Excipients: Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), gelling temperature, swelling temperature, loss on drying, residue on ignition, conductivity, congealing range, readily carbonizable substances and readily oxidizable substances, melting point and melting range. Excipients of interest: disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT IV

Quality Control of Nutraceuticals: Vitamins (A, B_1, B_2, B_{12}, C, D, E and K), micro nutrients and health supplements including free radical scavengers.

UNIT V

Quality Control of Food Constituents: Carbohydrates, proteins and fats with emphasis in the determination of moisture, ash, nitrogen and physical constituents. Analytical methods for milk

TEXT BOOKS

1)Pharmaceutical Chemistry by Beckett and Stanlake
2)Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
3)Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
4)Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
5)Ahuja S, Alsante KM. Handbook of isolation and characterization of impurities in pharmaceuticals. Academic press, California, 2003

Outcome: The quality aspects bulk drugs, excipients nutraceuticals etc. and their control is clearly understood. The precautions to be taken during the process of manufacturing the formulations are also learned.

REFERENCE BOOKS

1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2) David Pearson. The Chemical Analysis of Foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.
3) Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
4) Indian Pharmacopoeia 2012

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I Year – I Sem M.Pharm (PAQA/QA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Core Elective-I)

Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.
b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

REFERENCES :

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors

4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia 2007
13) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14) Introduction to instrumental analysis by Robert. D. Braun

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS
(Core Elective-I)

Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Intellectual Property Rights:

UNIT I

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT II

a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).
b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT III

a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,
b. Background, Salient Features and Impact of International Treaties / Conventions like
   i. Paris Convention, Berne convention
   ii. World Trade Organization (WTO)
   iii. World Intellectual Property Organization (WIPO)
   iv. Trade Related Aspects of Intellectual Property Rights (TRIPS)
   v. Patent Co-operation Treaty (PCT), Mandrid Protocol

Regulatory Affairs

Unit IV

a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

Unit V

a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10

Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

RECOMMENDED BOOKS:

1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi

2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India
3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE
(Open Elective I)

Objective: This course is designed to impart knowledge and skills in epidemiology, economics and vigilance of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

Unit-I

Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology Outcome measures and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Unit-II

Concept of risk in pharmacoepidemiology, Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross–sectional studies, cohort studies, case control studies, case–cohort studies, meta–analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Unit-III

Sources of data for pharmacoepidemiological studies Adhoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

Unit-IV

Pharmacoeconomics: Definition, history, need of pharmacoeconomic evaluations Role in formulary management decisions.

Pharmacoeconomic evaluation Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

Applications of Pharmacoeconomics, Softwares used and case studies

Unit-V

a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, Mechanism, predisposing factors, causualilty assessment (different scales used)
c. Reporting, evaluation, monitoring and management of ADRs
d. Role of pharmacist in management of ADRs.

Outcome: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmocovigilance.

REFERENCES:

1. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
2. Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974 Edition. McGraw Hill.
3. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004
4. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hil

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)
(Open Elective I)

Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

UNIT I

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

UNIT II

The Drugs and Cosmetics Act, 1940 and Rules there under. Recent amendments to Drugs and Cosmetic Act and other relevant rules.

Drugs (Price Control) Order in force. Loan license (contract manufacture). Certification and licensing procedures.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe
   1) European Medicines Agency (EMEA/ National Authorities) EDMF
   2) European Directorate for Quality of Medicines CEP/COS & Health Care Products
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

Outcome:

1. Students will come to know the different competent regulatory authorities globally.
2. Students be aware of technical aspects pertaining to the marketing authoritization application(MAA)

The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals

TEXT AND REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA/QA)

HERBAL COSMETICS TECHNOLOGY
(Open Elective I)

Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation

UNIT I

a) Introduction, historical background and present status of Herbal cosmetics
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Moulding, Packing. Raw materials used in preparation of herbal cosmetics
c) Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery
d) Quality, safety and efficacy of Herbal cosmetics

UNIT II

Skin care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT III

Hair care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like hair dyes, creams, Lotions, Jels, oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as *Acacia concinna* pods, Aloe Vera, Almond oil, Neem, *Citrus aurantium*peels, Henna, Turmeric, Liquorice, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

UNIT V

a) General Principles of Quality control and standardization of cosmetics-Raw material control, Packaging material control, finished product control, Shelf testing.
b) Natural colorants : Biological Source, coloring principles, chemical nature and usage of the following Annato, Cochineal, Caramel, Henna, Indigo, Madder, Saffron , Turmeric
c) Flavors and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Vanilla, Palmarosa, geranium oil

Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P.Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PAQA&QA)

PHARMACEUTICAL MANAGEMENT-I
(Open Elective I)

Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

Outcome: These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.

Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.

Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry.

TEXT BOOKS AND REFERENCE BOOKS

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition I larry A. Smith.
10. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – I Sem M. Pharm (PAQA&QA)

ADVANCED PHYSICAL PHARMACEUTICS
(Optional Elective –I)

Objective: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

UNIT I

Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive ,Hydrodynamically balanced and Transdermal Systems.

UNIT II

Physics of tablet compression: Basic principles of interactions,compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

Kinetics and drug stability: Stability calculations, rate equations, complex order kinetics, Factors influencing stability, strategy of stability testing, method of stabilization, method of accelerated stability testing in dosage forms, temperature and humidity control, physical stability testing of pharmaceutical products. Photodecomposition, Method, solid state decomposition.

UNIT IV

Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, drug release from suspension and emulsion formulations. Accelerated stability evaluation of physical stability. Microemulsions & multiple emulsions, types of viscometer-principle & working.

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

UNIT V

Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

Outcome: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to *invitro/invivo* correlations.

TEXT BOOKS

1. Physical Pharmacy , 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman Vol.4
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II
4. Cartenson "Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, VallabhaPrakashan Delhi - 2013

REFERENCE BOOKS

1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems

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I Year – I Sem M.Pharm (PAQA/QA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I SemM.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS - I LAB

List of experiments

1. Determination of official compounds by Non-aqueous titrations
2. Determination of drugs containing di and trivalent metal ions by complexometric titrations
3. Determination of sulfa drugs by diazotization
4. Determination of Vitamin C by redox titration
5. Quantitative determination of hydroxy, carboxyl. amino and carbonyl groups present in drugs
6. Quantitative determination of suitable drugs using the reagents mentioned in Unit III
7. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides and steroids

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS-II

Objective: The principles and procedures for the calibration and validation belonging to different categories are discussed in detail. Bio analytical and Analytical method validation in the determination of the pharmaceuticals is also discussed.

UNIT-I

Calibration and qualification of equipment: Difference of definitions, calibration standards, calibration frequency, examples of calibration of pH meter, FTIR and a UV Spectrophotometer. Definition of qualification process involving DQ, IQ, OQ, CQ and PQ. Brief discussion on protocol of each.

UNIT-II

Validation methods of

i. Equipment and Processing Techniques for mixing, granulation, drying, compression, filtration and filling.
ii. Methods and equipment for sterilization, autoclaving and membrane filtration.
iii. Air handling equipment and facilities in zones
iv. Water purification systems, deionised and distilled water and water for injection

UNIT-III

Bioanalysis and bioanalytical method validation: Types of body fluids, requirement of analysis, matrix effects, sample preparation, non-biological analytical samples. Acceptance criteria in comparison to non-biological samples.

Automation and computer-aided analysis, LIMS: The concept of auto samplers and high throughput analysis, computer controlled instrumentation and networked laboratory. Peculiarities of laboratory information management systems (LIMS).

UNIT-IV

Pre-Formulation:

A consideration of following characteristics of medicinal agents in their dosage form:

Physical characteristics-

Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, wetting of solids, flow characteristics, compressibility and Partition coefficient.

Chemical Characteristics-

Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug - Excipient compatibility studies.

Regulatory Requirements - Impurities in New Drug Substances Q3A&New Drug Products.Q3B (R2).

UNIT-V

Analytical Method Validation

General principles of analytical method validation, Validation of following analytical Instruments - U.V/Visible spectrophotometers, FTIR,HPLC and GC. Dissolution test apparatus

Outcome: The students will get an idea on the process of calibration of instruments, their validation and method development process which are very essential for them to carry out their research works.

Text books:

1) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D.Sethi
3) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
4) Instrumental Methods of Chemical Analysis By B.K. Sharma
5) A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
6) Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba BarkhaNath Printers, Haryana, 2007

Reference books:

1) Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & Distributors, New Delhi, 1986
2) Quality Assurance of Pharmaceuticals (A Compendium of Guidelines and Selected Materials), Vol. I & II (Pharma. Book Syndicate, Book Street, Hyderabad)
3)Quantitative Chemical Analysis, Daniel C. Harris, 8th Edition, 2011
4) Indian Pharmacopoeia 2010
6) Journals like Indian Drugs, IJPS etc.

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I Year – II Sem M.Pharm (PAQA/QA)

SPECTRAL ANALYSIS

Objective: The students will acquire the knowledge about the various aspects of X-Ray diffraction methods, all types of IR methods, particle sizing methods, also DSC, DTA, TGA etc

UNIT-I

X-Ray diffraction methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal techniques, single crystal diffraction, power diffraction, structural elucidation and applications.

UNIT-II

a. **FT-NIR:** Principle (overtones, combinations, fermi resonance, interferences etc.),instrumentation (dispersion spectrometer and FT-NIR), advantage and disadvantage, qualitative and quantitative applications, including PAT and non-destructive analysis.

b. **ATR:** Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IR beam), advantages and disadvantages, pharmaceutical applications.

c. **FT-Raman**: Principle (absorption, diffraction, scattering and emission of wave, molecular interaction), instrumentation (Dispersive Raman, FT-Raman), advantage and disadvantage, pharmaceutical applications including detection of counterfeit

UNIT-III

Particle sizing: Light interaction methods: Rayleigh or static laser light scattering, photon correlation spectroscopy or dynamic laser light scattering, single particle light scattering, multi-angle light scattering.

UNIT-IV

a. **DSC:** Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.

b. **DTA**: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).

c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

UNIT-V

a. Scanning electron microscope (SEM): Principles, Instrumentation and applications.

b. Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

Outcome: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

References:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein
11. HPTLC by P.D. Seth
12. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan

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I Year – II Sem M.Pharm (PAQA/QA)

QUALITY ASSURANCE

Objective: The concepts of quality assurance and validation, the aspects of quality in the organization, personnel and the controls in packaging as well as manufacturing are explained.

UNIT I

a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
b. Preparation of audit, Conducting audit, Audit Analysis, Audit Report and Audit follow up

UNIT II

a. Organization and personnel, responsibilities, training hygiene
b. Premises: Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT III

a. Concepts of Validation: Types of validation, Master plan, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas.
b. Prevalidation activities, Protocol preparation, Protocol execution, Deviations and change controls, summary and certification. Revalidation

UNIT IV

a. Packaging and labeling controls, line clearance and other packaging materials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufacture and controls on dosage forms
a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling drying, compression, coating, disinfection, sterilization, membrane filtration etc.
c. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

Text Books

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material
3. Vol. 1 and Vol. 2, WHO 2007)
4. GMP by Mehra
5. Pharmaceutical Process Validation by Berry and Nash
6. How to Practice GMP's – P.P. Sharma

References Books

1. Basic Tests for Pharmaceutical Substances - WHO (1991)
2. The Drugs and Cosmetic Act 1940 by Vijay Malik
3. Q.A. Manual by D.H. Shah
4. SOP Guidelines by D.H. Shah
5. Quality Assurance Guide by OPPI
6. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally(Dec 26, 2006)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M.Pharm (PAQA/QA)

BIOSTATISTICS AND RESEARCH METHODOLOGY
(Core Elective- II)

Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

UNIT I
Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II
Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III
Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.
Probability rules: Binomial, Poison and Normal distribution.
Hypothesis testing: Student't' test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

UNIT IV
Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review,
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal
Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

UNIT V
The research report paper writing/ thesis writing
Different parts of the research paper
1. Title-Title of project with authors' name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology- subject, apparatus, instrumentation and procedure
5. Results – tables, graphs figure and statistical presentation
6. Discussion support or non-support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata
11. Importance of Spell check for entire projects
12. Uses of footnotes

Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

Text Books
1. Deepak Chawla NeenaSondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)

Reference Books

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
9. Fundamentals of Biostatistics by Khan and Khanum
10. Research Methodology by RK Khanna bis and SuvasisSaha
11. Research methods and Quantity methods by G.N.Rao
12. A practical approach to PG dissertation.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M.Pharm (PA&QA/QA)

SCREENING METHODS AND CLINICAL RESEARCH
(Core Elective- II)

Objective: The students is going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

UNIT I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III
Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological, anti-inflammatory, analgesic and anti-diabetic.

UNIT V
Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Outcome: The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:
1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, BerlinHeideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, VallabhPrakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:
1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M.Pharm (PA&QA/QA)

STABILITY OF DRUGS AND DOSAGE FORMS
(Open Elective- II)

Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation

UNIT-I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT-II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT-III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.Factors affecting extraction of drugs.

UNIT-IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. .. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT-V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

Outcome: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products

REFERENCE BOOKS :

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.

4. J. B. Wilkinson and R. J. Moore :Herry'sCosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W.Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M.Pharm(PA & QA/QA)

NANO BASED DRUG DELIVERY SYSTEMS
(Open Elective- II)

Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

UNIT I – Introduction to Nanotechnology
a) Definition of nanotechnology
b) History of nanotechnology
c) Unique properties of nanomaterials
d) Role of size and size distribution of nanoparticles properties, classification.

UNIT II – Synthesis of Nanomaterials
a) Physical, chemical and biological Methods
b) Methods for sysnthesis of
- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes , micelles, aquasomes and nanoemulsions

UNIT III – Biomedical applications of Nanotechnology
a) Nanotechnology products used for in vitro diagnostics
b) Improvements to medical or molecular imaging using nanotechnology
c) Targeted nanomaterials for diagnostic and therapeutic purpose

Unit IV
Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

Unit V
Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

Recommended Books:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicologyin the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L.Arias,CRC press
3. Nano: The Essentials: Understanding Nanosicence and Nanotechnology, T.Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C.N.R.Rao, P.J.Thomas and G.U. Kulakarni, Springer(2007)
5. Nanostructures and Nanomaterilas: Synthesis, Properties and Application, GuozhongGao, Imperial College Press(2004)
6. Nanochemistry:A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridege, UK (2005)
7. Nanocomposite science and technology, pulickelM.Ajayan, Linda S.Schadler, paul V.Braun, Wiley-VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J.Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M.Pharm(PA & QA/QA)

NUTRACEUTICALS
(Open Elective- II)

Objectives: the students will get exposed to characteristic features of various phytochemicals as Nutraceuticals in various diseased conditions and also know the role of antioxidants in free radical induced diseased conditions and will expose to various food laws and regulations.

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as neutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phytoestrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide,malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin

Synthetic antioxidants : Butylated hydroxy Toluene, Butylated hydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

Outcome: Helps the students to understand the importance of Nutraceuticals in various common health problems with the concepts of free radicals.

REFERENCES:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997)

6. G. Gibson and C.williams Editors *2000 Functional foods* WoodheadPubl.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M.Pharm (PAQA/QA)

PHARMACEUTICAL PRODUCT DEVELOPMENT AND MANAGEMENT
(Open Elective- II)

Objective: The students shall know the molecular optimization of APIs, different physical preformulation parameters, drug excipients compatibility studies, degradation kinetics, solid state stability and shelf life. They also know the equipment design and their qualification, USFDA guidelines for GLP, silent features of ISO, NABL and also environment health and safety.

UNIT I
Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT II
Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & Formulations). Solid state stability and shelf-life assignment.

UNIT III
Detailed study on Equipment Design, Installation, Operational and Performance Qualification

UNIT IV
a. US FDA Guidelines for GLP in non-clinical testing laboratories (only salient features will be covered)
b. Organization & Functioning of Accreditation bodies- ISO-9000, ISO-14000, NABL and OSHA (ISO 18000)

UNIT V
a. Environment Health and Safety (EHS): Hazards- Fire, mechanical, chemical and pharmaceutical, monitoring and prevention systems, industrial effluents testing and treatment, control of environmental pollution
b. Ware housing –Design, construction, maintenance and sanitation for materials and products – good warehousing practice

Outcome: students will have knowledge about preformulation studies, product stability, USFDA guidelines, environment health and safety and warehousing procedures.

Text books:

1. Ira R. Berry and R.A. Nash (eds) Pharmaceutical Process Validation, Marcel Dekker Inc, New York
2. Pharmaceutical Process Validation by Loftus and Nash..
3. Remington's Pharmaceutical Sciences, The science and practice of Pharmacy, 20th Edition, Vol. I&II,.
4. Quality Assurance of Pharmaceutical – A compendium of guidelines. – WHO publication..
5. Theory and practice of industrial practice of industrial pharmacy by Liberian and Lachman.

References:

1. GMP by Sidney Herbal, Willing.
2. Quality Assurance Guide Organization of Pharmaceutical products of India.
3. Drugs and Cosmetics Act 1969 and Rules 1945.
4. S.H. Willing M.M.T. Tuckerman, W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Decker Inc, M. New York.
5. P.P. Sharma, How to Practice GMP's Vandhana Publications, Agra
6. Lippincott Williams Wilkins, Philadelphia, 2000
7. Quality assurance guide supplied by Organization of Pharmaceutical procedure of India.
8. Basic tests for Pharmaceutical Substances, WHO, Geneva, All India traveler book seller, India, 1990.
9. Handbook of Environmental Health and Safety: Principles and Practices, Herman Koren, Michel S. Bisesi, National Environmental Health Association

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

PHARMACEUTICAL MANAGEMENT-II
(Open Elective- II)

Objective: To know the pharmaceutical product management, planning, marketing accounts and finance. They also know the Inventory control, concept and techniques to improve production In packaging, marketing, sale and accounting.

UNIT I

Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.

Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

UNIT II

Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment.Product management.E-Pharma Marketing.

UNIT III

Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.

Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

UNIT IV

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm's stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management.

Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance.

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Evaluation of investment decisions by payback period, accounting rate of return, net present value methods, break even analysis.

UNIT V

Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.

Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework.Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social.Risk analysis.

Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new issues, negotiations with FIs, FIIs, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

Outcome: Student will get knowledge about production management, production planning and control, design and development of packaging, marketing of pharmaceuticals.

Text and reference books

1. Financial Management by Johnson, R.W.; The Ronald Press.
2. Fundamental of Financial Management by Van Horne, J.C.; Prentice Hall of India (P) Limited.
3. Stock Exchange and Investment Analysis by Briston, R. J.
4. Indian Financial System by Khan, M. Y.; Tata McGraw Hill.
5. Tax Planning for Industrial Projects by Agarwal R. K.; Hind Law Publishers, New Delhi.
6. Project Management by Chaudhary, S.; Tata McGraw Hill.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner; CRS Publishers and Distributors, Delhi.
8. Financial Management by Gupta And Sharma I st Edition 1996.
9. Accounting for Management Planning and Control III rd Edition Richard M. Lynch
11. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
12. Business Organization and Management by Shukla M. C.; S. Chand and Company.
13. Business Organization and Management by Sherlakar S. A.; Himalaya.
14. Personnel Management by Filippo E. B.; McGraw Hill.
15. Marketing Management by Kotler Philip.; Prentice Hall of India.
16. Organizational Behavior by Rao and Narayan; Konark Publishers.
17. Personnel Management by Tripathi P. C.; S. Chand and Company.
18. Principle and Practice of Marketing in India by Memoria C. B.
19. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
20. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
21. Production and Operations Management by S.N.Chary

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PAQA/QA)

ADVANCED PHARMACEUTICAL ANALYSIS - II LAB

List of Experiments

1. Determination of bulk Drugs and formulations by UV-Visible, HPLC, GC etc. methods
2. Determination of total chloride in thiamine HCl
3. Detection and determination of preservatives, antioxidants and colourants in pharmaceutical preparations
4. Determination of chlorides and sulphates by Nephelo -Tubmidimetry
5. Determination of moisture content in sorbitol, sodium citrate, ampicillin etc.
6. Assays of official compounds by Flourimetry
7. Determination of compounds of sodium, potassium and calcium by Flame photometry.

(Note: Minimum of two experiments covering each of the above mentioned topics)

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I Year – II Sem M.Pharm (PAQA/QA)

SPECTRAL ANALYSIS LAB

List of Experiments

1. QC tests for tablets and capsules (minimum 3 experiments)
2. QC tests for oral liquids and parenterals (minimum 3 experiments)
3. Forced degradation studies of some drugs.
4. Interpretation of spectras by IR, NMR and MASS
5. Estimation of drugs by specified colorimetric reagents
6. Assay of drug formulations using UV-Spectrophotometer (Any four)
7. Demonstration of functional groups of the given samples by IR Spectrophotometer.
8. Physicochemical tests for water
9. Solubility studies of weakly acidic and weakly basic drugs.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)
COURSE STRUCTURE AND SYLLABUS

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Pharmaceutical Management –I (General and Personnel)	25	75	4	--	4
Core Course II	Total Quality Management	25	75	4	--	4
Core Course III	Drug Regulatory Affairs (National and International Aspects)	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Technique 2. Intellectual Property Rights and Regulatory Affairs	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology, Pharmacoeconomics and Pharmacovigilance 2. Herbal Cosmetics Technology 3. Advanced Pharmaceutical Technology –I 4. Industrial Pharmaceutics 5. Separation Techniques	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	4	--	4
Laboratory II	Pharmaceutical Management Lab	25	75	--	4	2
Seminar I	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Pharmaceutical Management –II (Production, Marketing, Finance and Project)	25	75	4	--	4
Core Course V	Analytical Method Validation and Copyrights and Trademarks	25	75	4	--	4
Core Course VI	Pharmaceutical Market Research and Analysis	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Advanced Drug Delivery Systems 5. Advanced Pharmaceutical Technology -II	25	75	4	--	4
Laboratory III	Analytical Method Validation Lab	25	75	4	--	4
Laboratory IV	Pharmaceutical Market Research and Analysis Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	P	C
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review I	50	--	--	24	12
Total Credits			--	24	**16**

II Year - II Semester

Course Title	Int. marks	Ext. marks	L	P	C
Project work Review II	50	--	--	8	4
Project Evaluation (Viva-Voce)	--	150	--	16	12
Total Credits			--	**24**	**16**

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

PHARMACEUTICAL MANAGEMENT-I (GENERAL & PERSONNEL)

Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect pharma professional.

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management.Introduction to budgeting, costing, accounting, auditing and budgetary control.Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed.Leadership; Styles and managing change.Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

Outcome:

- These topics are useful for the students to know how to manage a pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions &professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry

Text and reference books

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

TOTAL QUALITY MANAGEMENT

Objective: Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc.Which increases the knowledge of students in various quality control &regulatory aspects.

UNIT I

Concepts and Philosophy of TQM, GLP, GMP (orange guide).

UNIT II

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.)

UNIT III

Good manufacturing practices: Organisation and personnel, responsibilities, training, hygiene.
Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination.
Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP).
Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.
Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.,
Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials.
Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house.
Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities.
Finished products release, quality review, quality audits, batch release document.

UNIT IV

Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratoginicity.Animal pharmacokinetics and toxicokinetics.Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials.
Quality assurance standards as per ISO.

UNIT V

Globalization of drug industry, present status and scope of pharmaceutical industry in India.
WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

Outcome: Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA, WHO, ISO etc to become a perfect budding pharmacist.
It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

TEXT AND REFERENCE BOOKS

1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
2. Quality Assurance of Pharmaceuticals–A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.

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3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by SadhanK.Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance.
9. USP.
10. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
11. Quality assurance and quality management in pharmaceutical industry by Y.Anjaneyulu and Marayya

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL REGULATORY ASPECTS)

Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

UNIT I

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

UNIT II

The Drugs and Cosmetics Act, 1940 and Rules there under.Recent amendments to Drugs and Cosmetic Act and other relevant rules.

Drugs (Price Control) Order in force.Loan license (contract manufacture). Certification and licensing procedures.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations.

Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

CountryAuthority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS& Health Care Products
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application(MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

TEXT AND REFERENCE BOOKS

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; VallabhPrakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; VallabhPrakashan, New Delhi.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm(PM&RA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(Core Elective I)

Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection

b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds

c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

d. Counter – current extraction, solid phase extraction techniques, gel filtration

UNIT II

a. Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.

b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications

c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy

b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy

Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

REFERENCES :

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake

6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia 2007
13) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14) Introduction to instrumental analysis by Robert. D. Braun

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS
(Core Elective-I)

Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

Intellectual Property Rights:

UNIT I

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non-Obviousness, Utility, enablement and Best mode),

UNIT II

a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantages of Patent System, and future challenges. Indian Patents Act 1970, Definitions and Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and 4).

b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners

c. Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.

d. Patent filing procedure under PCT, advantages, patent search and literature

UNIT III

a. Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System,

b. Background, Salient Features and Impact of International Treaties / Conventions like

1. Paris Convention, Berne convention
2. World Trade Organization (WTO)
3. World Intellectual Property Organization (WIPO)
4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
5. Patent Co-operation Treaty (PCT), Mandrid Protocol

Regulatory Affairs

Unit IV

a. National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.

b. USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

Unit V

a. Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)

b. ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10

Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students

RECOMMENDED BOOKS:

1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
2. Draft manual of Patent Practice and Procedure -2008 , The Patent Office, India

3. Manual of Patent Office Practice and Procedure -2010
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
8. New drug approval process,5th edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org,wipo.int,patentlawlinks.com, hc-sc.gc.ca,ich.org,cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A.Potdar

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE
(Optional Elective –I)

Objective: This course is designed to impart knowledge and skills in epidemiology, economics and vigilance of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

Unit-I

Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology Outcome measures and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Unit-II

Concept of risk in pharmacoepidemiology, Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross–sectional studies, cohort studies, case control studies, case–cohort studies, meta–analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Unit-III

Sources of data for pharmacoepidemiological studies Adhoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

Unit-IV

Pharmacoeconomics: Definition, history, need of pharmacoeconomic evaluations Role in formulary management decisions.

Pharmacoeconomic evaluation Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

Applications of Pharmacoeconomics, Softwares used and case studies

Unit-V

a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, Mechanism, predisposing factors, causualilty assessment (different scales used)
c. Reporting, evaluation, monitoring and management of ADRs
d. Role of pharmacist in management of ADRs.

Outcome: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmocovigilance.

REFERENCES:

1. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
2. Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974 Edition. McGraw Hill.
3. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004
4. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed J G Hardman, L E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

HERBAL COSMETICS TECHNOLOGY
(Optional Elective-I)

Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation

UNIT I

a) Introduction, historical background and present status of Herbal cosmetics
b) Processes used in the manufacture of cosmetics-Emulsification, Mixing, compaction, Moulding, Packing. Raw materials used in preparation of herbal cosmetics
c) Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery
d) Quality, safety and efficacy of Herbal cosmetics

UNIT II

Skin care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT III

Hair care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like hair dyes, creams, Lotions, Jels, oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV

A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as *Acacia concinna* pods, Aloe Vera, Almond oil, Neem, *Citrus aurantium*peels, Henna, Turmeric, Liquorice, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

UNIT V

a) General Principles of Quality control and standardization of cosmetics-Raw material control, Packaging material control, finished product control, Shelf testing.
b) Natural colorants : Biological Source, coloring principles, chemical nature and usage of the following Annato, Cochineal, Caramel, Henna, Indigo, Madder, Saffron , Turmeric
c) Flavors and Perfumes : Sandal wood oil, Orange oil, Lemon oil, Vanilla, Palmarosa, geranium oil

Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

REFERENCES:

1. Cosmetics- Formulation, Manufacturing and Quality control –P.P.Sharma
2. Herbal Cosmetics Hand Book- H. Panda
3. Herbal Cosmetics by P.K Chattopadhyay
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm(PM&RA)

ADVANCED PHARMACEUTICAL TECHNOLOGY –I
(Optional Elective-I)

Objectives: Students will know the Preformulation studies, methodology, different excipients used in solid dosage forms and their evaluation. The students also know the optimization techniques and their applications in pharmaceutical industries.

UNIT 1

Preformulation studies: Goals of Preformulation, preformulation parameters, Polymorphs and Amorphous forms, selection of drugs- solubility, partition coefficient, salt forms, humidity, solid state properties, Particle Size Analysis (Laser Diffraction and Dynamic Light Scattering) drug-excipient compatibility, flow properties, format and content of reports of preformulation, preformulation stability studies (ICH)

UNIT II

Formulation development of solid dosage forms – I: New materials, excipients science - diluents, disintegrants, superdisintegrants, etc, evaluation of functional properties of excipients, co-processed materials, methods of preparation and evaluation.

UNIT III

Formulation development of solid dosage forms– II: Coating, coating machines, coating techniques in tablet technology for product development, computerization, inprocess control of tablets, formulation development and manufacture of powder dosage forms for internal use.

Microencapsulation- types, methodology, problems encountered.

UNIT IV

Formulation development of soft and hard gelatin capsules : Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, advances in capsule manufacture, machines, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

Outcome: Students shall know the preformulation parameters, ICH guidelines, drug excipients compatibility studies. Students also know about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also know the statistical design in different formulations.

TEXT BOOKS

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Pharmaceutical statistics by Bolton

RECOMMENDED BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

SEPARATION METHODS
(Optional Elective-I)

Objectives: The course is designed to import knowledge in the field of various separation techniques in the context of their applications both at laboratory and industry level. The techniques such as GC, HPLC, Electrophoresis etc. Methods allow qualitative and quantitative estimations and thus demand for the development and validation of methods.

UNIT: I

i. **Column Chromatography and Short column chromatography**: Column packing, sample loading, column development, detection.

ii. **Flash chromatography and Vacuum liquid chromatography:** Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.

UNIT-II

Sample Preparation - Analysis of drugs from formulations and biological samples including, selection of biological sample, extraction of drugs by various methods such as Liquid Liquid Extraction (LLE), Solid Phase Extraction (SPE) and Membrane filtration.

UNIT: III

i. **HPLC:** Principles, basic parameters Retention factor, Capacity factor, Selectivity factor, plate number, plate height, resolution, peak shapes, band broadening, van Deemter equation and curve. Column selection and optimization, column problems, solvents, trouble shooting, sample preparation.

ii. **Method Development and validation:** Introduction, Forced Degradation Studies -Experimental Approach to Forced Degradation Studies. Stability Indicating HPLC Method Development - Method Scope, Preliminary Requirements, Method Development Approach, Method Optimization and validation.

UNIT-IV

i. **Gas Chromatography:** Principles, split-splitless injector, head space sampling, columns for GC, detectors, quantification, derivatization techniques.

ii. **Hyphenated techniques:** Introduction to GC-MS and LC-MS techniques and their applications.

UNIT-V

i. **Electrophoresis:** Capillary electrophoresis: Basic principle (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.

ii. **Counter current chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.

Outcome : The students should describe the separation techniques of choromatography (GC, HPLC) with principles, instrumentation, identification, development of methodology specific to the components of the mixure, including the method validation. The students should be able to explain the separation principles using the advanced techniques such as Flash chromatography and highphenated techniques.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

11. HPTLC by P.D. Seth
12. Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
13. Methods in Biotechnology, Natural Product Isolation by Richard Canell
14. Various Reviews and Research Papers

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I Year – I Sem M.Pharm(PM&RA)

INDUSTRIAL PHARMACEUTICS
(Optional Elective-I)

Objective: This subject is to make the student achieve different parameters and factors that influence the dosage form design:

UNIT I

a. **Preformulation studies:** Goals of preformulation, preformulation parameters, methodology, solid state manipulation and characterization, solubility and partition coefficient, drug-excipient compatibility.
b. Advances in Pharmaceutical excipients. Excipients selection
c. Packaging development – selection of primary and secondary packaging materials and testing

UNIT II

Pharmaceutical unit operations: A detail study involving machinery and theory of pharmaceutical unit operations like mixing, filtration, drying, and sterilization.

UNIT III

Formulation development of solid and powder dosage forms: Improved production techniques for tablets, new materials, processes, equipment improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development and computerization for in process quality control of tablets. Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

UNIT IV

Formulation development of soft and hard gelatin capsules : Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, the nature of the capsule shell and capsule, advances in capsule manufacture, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V

Optimization techniques in pharmaceutical formulation and processing: Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

Outcome:

- Different machinery used for various steps in manufacture of various dosage forms.
- Formulation and evaluation of hard and soft gelatin capsules and their advantages over other dosage forms

TEXT BOOKS

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. Pharmaceutical Dosage forms - Tablets (Vol I, II and III) by Lieberman, Lachman and Schwartz.
3. Pharmaceutical Dosage forms - Capsules (Vol I, II and III) by Avis, Lieberman and Lachman.
4. Pharmaceutical Dosage forms – Disperse systems (Vol I, II and III) by Avis, Lieberman and Lachman.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Hand book of Pharmaceutical excipients

RECOMMENDED BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Pharmaceutical Packaging Technology by UK Jain, DC Goupale S Nayak.

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I Year – I Sem M.Pharm (PM&RA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
9. Development and evaluation of drugs by derivative spectroscopy.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm (PM&RA)

PHARMACEUTICAL MANAGEMENT LAB

Practical work shall be carried out based on the theory syllabus.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M. Pharmacy (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)
COURSE STRUCTURE AND SYLLABUS

I Year – II Semester

Category	Course Title	marks	Ext. marks	L	P	C
Core Course IV	Pharmaceutical Management –II (Production, Marketing, Finance and Project)	25	75	4	--	4
Core Course V	Analytical Method Validation and Copyrights and Trademarks	25	75	4	--	4
Core Course VI	Pharmaceutical Market Research and Analysis	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Screening Methods & Clinical Research	25	75	4	--	4
Open Elective II	1. Stability of Drugs and Dosage Forms 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Advanced Drug Delivery Systems 5. Advanced Pharmaceutical Technology -II	25	75	4	--	4
Laboratory III	Analytical Method Validation Lab	25	75	4	--	4
Laboratory IV	Pharmaceutical Market Research and Analysis Lab	25	75	--	4	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**24**	**8**	**28**

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

PHARMACEUTICAL MANAGEMENT-II (PRODUCTION, MARKETING, FINANCE & PROJECT)

Objective: To know the pharmaceutical product management, planning, marketing accounts and finance. They also know the Inventory control, concept and techniques to improve production In packaging, marketing, sale and accounting.

UNIT I

Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.

Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

UNIT II

Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment.Product management.E-Pharma Marketing.

UNIT III

Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.

Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

UNIT IV

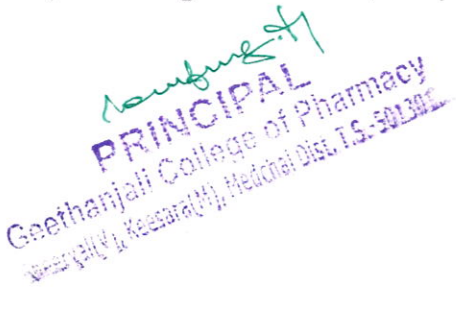
Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm's stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management.

Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance.

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Evaluation of investment decisions by pay back period, accounting rate of return, net present value methods, break even analysis.



UNIT V

Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.

Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework.Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social.Risk analysis.

Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new issues, negotiations with FIs, FIIs, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

Outcome: Student will get knowledge about production management, production planning and control, design and development of packaging, marketing of pharmaceuticals.

Text and reference books

1. Financial Management by Johnson, R.W.; The Ronald Press.
2. Fundamental of Financial Management by Van Horne, J.C.; Prentice Hall of India (P) Limited.
3. Stock Exchange and Investment Analysis by Briston, R. J.
4. Indian Financial System by Khan, M. Y.; Tata McGraw Hill.
5. Tax Planning for Industrial Projects by Agarwal R. K.; Hind Law Publishers, New Delhi.
6. Project Management by Chaudhary, S.; Tata McGraw Hill.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner; CRS Publishers and Distributors, Delhi.
8. Financial Management by Gupta And Sharma I st Edition 1996.
9. Accounting for Management Planning and Control III rd Edition Richard M. Lynch
11. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
12. Business Organization and Management by Shukla M. C.; S. Chand and Company.
13. Business Organization and Management by Sherlakar S. A.; Himalaya.
14. Personnel Management by Filippo E. B.; McGraw Hill.
15. Marketing Management by Kotler Philip.; Prentice Hall of India.
16. Organizational Behavior by Rao and Narayan; Konark Publishers.
17. Personnel Management by Tripathi P. C.; S. Chand and Company.
18. Principle and Practice of Marketing in India by Memoria C. B.
19. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
20. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
21. Production and Operations Management by S.N.Chary

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

ANALYTICAL METHOD VALIDATION, COPY RIGHTS AND TRADE MARKS

Objective: The students will know the validation guidelines, different methods of validation, implementation of validation. They also know about the law related to copyrights, trademarks and their implementation

UNIT I

Validation guidelines

1. ICH Q2A: Text on validation of analytical procedures: Definitions and terminology (March 1995)
2. ICH Q2B: Validation of analytical procedures: Methodology (June 1997)
3. FDA: (Draft) Guidance for Industry: Analytical procedures and methods validation
4. Pharmacopoeias: USP and European Pharmacopoeia

UNIT II

What methods to be validated?

Defined for:

- identification
- quantitative tests for content of impurities
- limit tests for control of impurities
- quantitative tests for active moiety in drug substances and drug products

Referred to:

- dissolution testing
- particle size determination (drug substance)

UNIT III

Implementation of Guidelines

- Standard protocols
- Set up as procedures
- Mutual agreement on tests
- Mutual agreement on criteria
- Mutual agreement on documentation

==> MUTUAL DEVELOPMENT PROCEDURES (MDP)

UNIT IV

Copyright: Law relating to copyright in India. Copyright Act, 1957and its amendments. Subject matter of copyright protection.Rights of owners of copyrights. Infringement of copyright, remedies against infringement of copyright. Authorities and institutions under the copyright Act.

Trade Marks: The trade marks legislation in India. Service marks, certification Marks, Collective marks, Distinctiveness of Trade Marks, Distinct Marks. Subject matter of Trade marks. Acquisition of registered Trade Mark. Register and conditions for Registration. Infringement of Trade marks.

UNIT V

Trade mark laws and governing of trade marks, role of Indian trade mark office.

Outcome: Students will get knowledge about ICH guidelines for validation, FDA drafts and techniques which are used for validation and their implementation. They also know the rights and laws related to copyrights and trademarks.

Text Books

1. Ira R.Berry and R.A. Nash (eds) Pharmaceutical Process Validation, Marcel Dekker Inc, New York
2. Pharmaceutical Process Validation by Loftus and Nash.
3. Remington's Pharmaceutical Sciences, The science and practice of pharmacy, 20th Edition, Vol.I&II.
4. Quality Assurance of Pharmaceuticals –A compendium of guidelines- WHO publication.

5. Theory and practice of industrial pharmacy by Liberian and Lachman.
6. Pharmaceutical Process validation by Berry and Nash.
7. Intellectual properties rights by GB Reddy.

Reference Books

1. GMP by Sidney Herbal, Willing.
2. Quality Assurance Guide - Organization of Pharmaceutical products of India.
3. Drugs and Cosmetics Act 1969 and Rules 1945.
4. S.H. Willing M.M.T.Tuckerman, W.S.Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Decker Inc, M.New York.
5. P.P. Sharma, How to practice GMP's Vandhana Publications, Agra
6. Lippincott Williams Wilkins, Philadelphia, 2000
7. Quality assurance guide supplied by Organization of Pharmaceutical procedure of India.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS

Objective: Students shall know the overview of global pharmaceutical market, growth calculations, innovator new drug evaluation, analysis of finished dosage forms and APIs. They also know about the pharmaceutical companies, R&D strengths, and case study of companies.

UNIT I

- Introduction and overview of global pharmaceutical market
- Growth calculations based on Therapeutic category vs regions
- Innovator new drug candidate evaluation and strategic development cycle.
- Calculation of market promotion data
- Patent extension strategies
- Return on investment and R&D pipeline

UNIT II

Analysis of finished dosage forms based on

- Therapy
- Product
- Companies
- Quantity
- Value
- Country wise
- Region wise etc

Analysis of Active Pharmaceutical Ingredients based on

- Product,
- Quantities
- Value

Critical evaluation of databases for the global market research

- IMS
- Newport
- Export data etc

UNIT III

Lead analysis of Innovator vis-à-vis with Therapeutic Category & Generic drug makers vis-à-vis with Therapeutic Category

UNIT IV

Pharmaceutical Companies Portfolio, financials, R&D strengths and pipeline strength analysis

UNIT V

Case studies- Pharma growth stories of companies
Market research using SAS programmes on market trends
Multi Variate Analysis programmes to analyse in relationship between various factors governing the market growth.

Outcome: Students will have knowledge about global market, growth calculations depending on regions, market promotion datas, patent extensions, analysis of finished dosage forms and APIs. They also study data base related to strategies of companies.

Text and Reference books

1. Principles of Pharmaceutical Marketing by MICKEY SMITH
2. Principles and Practice of Drug Manufacturing Management by MD BURANDE

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3. Pharmaceutical Market research and analysis by Donald R. Lehmann
4. Pharmaceutical Market in 21st Century by Mickey C. Smith
5. Pharmaceutical Marketing: A Practical Guide by Dimitris Dogramatzis
6. Strategic management of health care organizations by Linda E. Swayne, Walter Jack Duncan, Peter M. Ginter
7. Managing Health Care Business Strategy by George B. Moseley, III, George B. Moseley
8. Pharmaceutical Management by Sachin Atkar

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I Year – IISemM.Pharm(PM&RA)

BIOSTATISTICS AND RESEARCH METHODOLOGY
(Core Elective – II)

Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection.Stages of research, types of data and methods of data collections.Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.

Probability rules: Binomial, Poison and Normal distribution.

Hypothesis testing: Student't' test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

UNIT IV

Developing a research question, Resources for research question,
Literature Review: Traditional Qualitative Review,
Meta-Analysis—A Quantitative Review
Preparation of Research Proposal
Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison.Reliability and Validity of Measurements.

UNIT V

The research report paper writing/ thesis writing
Different parts of the research paper

1. Title-Title of project with authors' name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology- subject, apparatus, instrumentation and procedure
5. Results – tables, graphs figure and statistical presentation
6. Discussion support or non-support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata
11. Importance of Spell check for entire projects
12. Uses of footnotes

Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts.They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

Text Books

1. Deepak Chawla NeenaSondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)

Reference Books

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
9. Fundamentals of Biostatistics by Khan and Khanum
10. Research Methodology by RK Khanna bis and SuvasisSaha
11. Research methods and Quantity methods by G.N.Rao
12. A practical approach to PG dissertation.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

SCREENING METHODS AND CLINICAL RESEARCH
(Core Elective – II)

Objective: The students is going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

UNIT I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological, anti-inflammatory, analgesic and anti-diabetic.

UNIT V

Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Outcome: The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, BerlinHeideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, VallabhPrakashan, Delhi.
4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

Text Books

1. Deepak Chawla NeenaSondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt. Ltd)

Reference Books

1. Remington"s Pharmaceutical Sciences
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4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
9. Fundamentals of Biostatistics by Khan and Khanum
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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

STABILITY OF DRUGS AND DOSAGE FORMS
(Open Elective – II)

Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation

UNIT-I

Drug decomposition mechanisms:

1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
2. Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT-II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition
4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT-III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.Factors affecting extraction of drugs.

UNIT-IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. .. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT-V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.

Stability studies: Concept of stability studies.

a) cGMP& ICH guidelines for Accelerated stability Testing.

b) Interaction of containers & closure Compatibility Testing.

Outcome: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

REFERENCE BOOKS :

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.

2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore :Herry'sCosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
9. Drug stability: Principles and practices by Jens T. Carstensen
10. Stability Testing of Drug Products by W.Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

NANO BASED DRUG DELIVERY SYSTEMS
(Open Elective – II)

Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

UNIT I – Introduction to Nanotechnology

a) Definition of nanotechnology
b) History of nanotechnology
c) Unique properties of nanomaterials
d) Role of size and size distribution of nanoparticles properties, classification.

UNIT II – Synthesis of Nanomaterials

a) Physical, chemical and biological Methods
b) Methods for sysnthesis of

- Gold nanoparticles
- Magnetic nanoparticles
- Polymeric nanoparticles
- Self – assembly structures such as liposomes , micelles, aquasomes and nanoemulsions

UNIT III – Biomedical applications of Nanotechnology

a) Nanotechnology products used for in vitro diagnostics
b) Improvements to medical or molecular imaging using nanotechnology
c) Targeted nanomaterials for diagnostic and therapeutic purpose

Unit IV

Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

Unit V

Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

Recommended Books:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicologyin the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L.Arias,CRC press
3. Nano: The Essentials: Understanding Nanosicence and Nanotechnology, T.Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C.N.R.Rao, P.J.Thomas and G.U. Kulakarni, Springer(2007)
5. Nanostructures and Nanomaterilas: Synthesis, Properties and Application, GuozhongGao, Imperial College Press(2004)
6. Nanochemistry:A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridege, UK (2005)
7. Nanocomposite science and technology, pulickelM.Ajayan, Linda S.Schadler, paul V.Braun, Wiley-VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J.Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

NUTRACEUTICALS
(Open Elective – II)

Objectives: The students will expose to characteristic features of various phytochemicals as neutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as neutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phytoestrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide,malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α-Lipoic acid, melatonin

Synthetic antioxidants : Butylated hydroxy Toluene, Butylated hydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adultration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

Outcome: Helps the student to understand the importance of Neutraceuticals in various commom problems with the concept of free radicals.

REFERENCES:

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* WoodheadPubl.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

ADVANCED DRUG DELIVERY SYSTEMS
(Open Elective – II)

Objective: The students shall know the pharmacokinetic and pharmacodynamic on the basis of CDDS. They also know the design evaluation and application related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

UNIT 1

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

a. Controlled release oral drug delivery systems
b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation and applications of the following

a. Implantable Therapeutic systems
b. Transdermal delivery systems
c. Ocular and Intrauterine delivery systems
d. Vaccine delivery : Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT III

Biochemical and molecular biology approaches to controlled drug delivery of

a. Bioadhesive drug delivery systems
b. Nasal drug delivery systems
c. Drug delivery to Colon

UNIT IV

Biochemical and molecular biology approaches to control drug delivery of

a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealed erythrocytes

UNIT V

Drug targeting to particular organs

a. Delivery to lungs
b. Delivery to the brain and problems involved
c. Drug targeting in neoplasams

Outcomes: Students will know the fabrication, design, evaluation and application of above drug delivery systems.

Text Books

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes..
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y.Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by AukunuruJithan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year –II Sem M.Pharm(PM&RA)

ADVANCED PHARMACEUTICAL TECHNOLOGY -II
(Open Elective – II)

Objective: The students shall know about the pilot plant scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also know about the filling of capsules, compression machines, sterilizers for formulation of parenterals and also know about the propellants, DPI, MDI and their quality control. The students also know about the cosmetics and neutraceuticals

UNIT I

Pilot plant scale-up techniques used in pharmaceutical manufacturing

a. **Pilot plant:** Technology transfer from R&D to pilot plant to pilot scale considerations of steps involved with manufacture, layout design, facility, equipment selection of tablets, capsules, suspensions, emulsions & semisolids.
b. **Scale up:** Importance, Scale up process-size reduction, mixing, blending, granulation, compression, coating involved in tablets, capsules & liquid-liquid mixing.

UNIT II

Formulation development of parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers, product layout.

UNIT III

Pharmaceutical Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV

a. **Cosmetics:** Formulation approaches, preparation & method of manufacturing labeling& Q.C. of anti ageing products, sun screen lotion and fairness creams.
b. **Nutraceuticals:**

1. Introduction, source, manufacture and analysis of glucosamine and cartinine.
2. Monographs: General and specific properties of glucosamine &cartinine.
3. A brief overview of role of nutraceuticals in cancer prevention & cardio vascular disorders.

UNIT V

Aseptic processing operation

a. Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.
b. Air handling systems: Study of AHUs, humidity & temperature control.

Outcomes: Students will know about the scale up and pilot plant techniques used for all pharmaceutical dosage forms like tablets, capsules, parenterals, aerosols, cosmetics and neutraceuticals.

Text Books

1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.
4. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
5. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.
6. Scale up techniques – Pharmaceutical process by Michael Levin, Marcel Dekker

Recommended Books

1. Bentley`s Text Book of Pharmaceutics by EA Rawlins.

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2. Generic Drug Product Development by Leon Shargel.
3. Dispensing for Pharmaceutical Students by SJ Carter.
4. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – II Sem M.Pharm (PM&RA)

ANALYTICAL METHOD VALIDATION – LAB

Practical work shall be carried out based on the theory syllabus.

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I Year – II Sem M.Pharm (PM&RA)

PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS – LAB

Practical work shall be carried out based on the theory syllabus.

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