ANEEXURE 10

MANDATORY DISCLOSURE

"The information has been provided by the concerned institution on the onus of authenticity lies with the institution and not on AICTE."

1. **Name of the Institution:**

   GEETHANJALI COLLEGE OF PHARMACY

   Sy.31,Cheeryal (V), Keesara (M), Medchal Dist., Pin: 501301. Telangana

2. **Name and address of the Trust/ Society/ Company and the Trustees:**

   Teja educational society, Sy.31,Cheeryal (V), Keesara (M), Medchal Dist., Pin: 501301. Telangana

3. **Name and Address of the Vice Chancellor/ Principal/ Director:**

   Dr. M. RAVI KUMAR
   Geethanjali College Of Pharmacy
   Cheeryal (V), Keesara (M), Medchal Dist Pin: 501301. Telangana

4. **Name of the affiliating University**

   JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY
   Kukatpally, HYDERABAD-500 085

5. **Governance**

   a. **MEMBERS OF THE GOVERNING BODY :-** All the members of the Governing Body are professionals in various Fields with high educational qualifications and vast experience in administration. Such background will indeed give the desired direction to the Institutions sponsored by the Society. The profile of the members is as follows:-

   - **Mr. G. R. Ravinder Reddy, Chairman:** He is a post graduate in Civil Engineering and formerly a Senior Police Officer. He has graduated from

NIT, Warangal and has also completed his Post Graduation from the same Institution. Subsequently he joined the civil services and served the Police department for more than 20 years before taking up voluntary retirement. With an excellent education and vast field experience, he has a vision to develop the institution into a centre of learning, where discipline would be a hallmark.

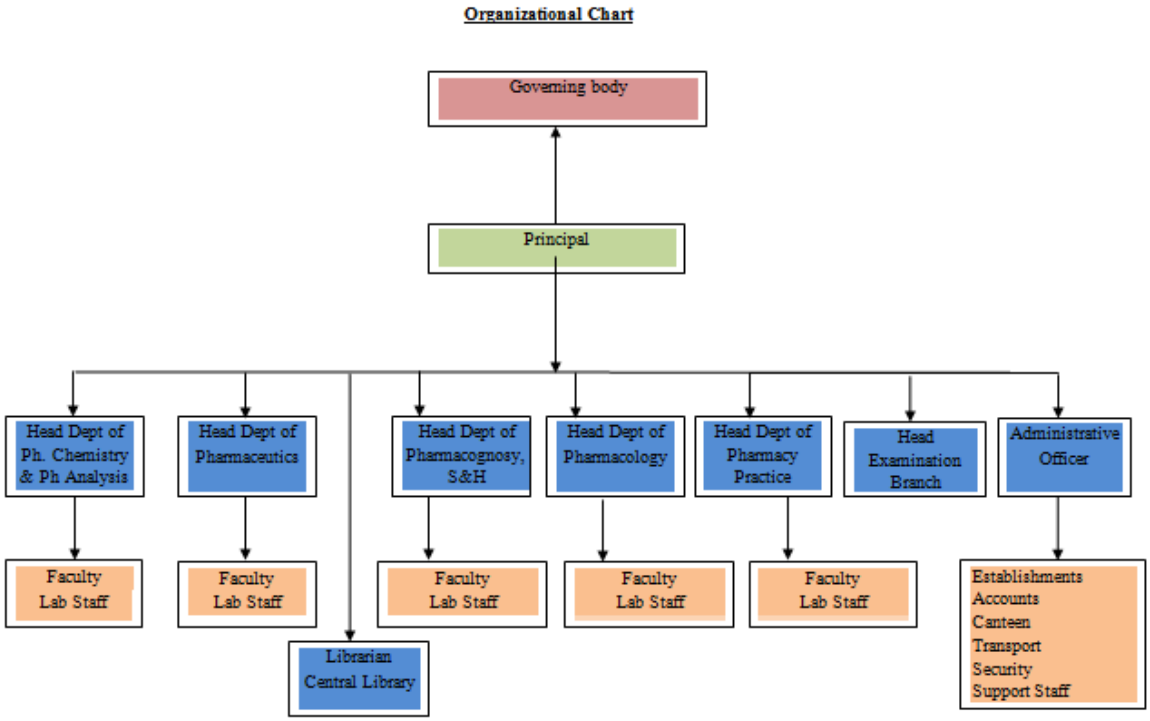
- **Dr. G. Sridevi, Member :** A dentist who graduated from the prestigious Osmania University will contribute immensely in adding new dimensions to the growth of the institution
- **Ms. A. Manjula Reddy,** Member
- **Ms.G.Madhumitha,** Member
- **Dr. S. Uday Kumar,** Member, Principal, GCET
- **Dr. J. Pardhasaradhi**, M.B.A., Ph.D., HOD, Dept of Finance, GCET
- **Dr. M.Ajitha**, Member, Asso.Prof. in Pharmaceutical Sciences, IST – **JNTUH-Nominee**
- **Dr. G.Jaganadh**, Member – Industry professional, Rashmi Pharmaceuticals
- **Dr. T. Mangilal**, Member-Professor, GCPK
- **Dr. P. Neeraja,** Member-Professor, GCPK
- **Dr. M. Ravi Kumar,** Principal –Member Secretary of GBC-GCPK

b. **Academic Advisory body: Frequency of meeting weekly**

S.No.	**Name**	**Designation**	**Nature**
1	Dr. M. Ravi Kumar	Professor & Principal	Coordinator
2	Dr. M. Srinivas	HOD, Pharmaceutical Chemistry	Member Incharge
3	Dr. B. Bhattacharya	HOD, Pharmacology	Member
4	Dr. T. Mangilal	HOD, Pharmaceutics	Member
5	Dr. Bharat Bhushan Mohapatra	HOD, Pharmacognosy	Member

6	Dr. R. Sivakumar	Incharge, Exam branch	Member
7	Dr. B. Rambabu	HOD, PharmD	Member

c. Organizational chart and processes:



d. Grievance redressal mechanism for faculty, staff and students: The college has a Grievance Redressal Committee to address grievances of staff and students. The students and staff having grievances may submit their grievances in writing to Grievances Redressal Committee. The Committee also takes note of complaints and suggestions dropped in the suggestions

boxes place at strategic locations. The grievances are examined and resolved by Grievance Redressal Committee. If the committee feels that the redressal of grievances requires some changes in policies, procedures, systems etc., the issues are discussed and resolved by College Academic Committee or Governing Body.

e. Grievance redressal committee in the institution and appointment of OMBUDSMAN by the University

S. No.	Names	Designation	Members
1	Dr. M. Ravi kumar	Principal	Coordinator
2	Sri. G. Ravindar Reddy	Secretary	Member
3	Dr. T.Mangilal	Professor	Member
4	Dr. B. Bhattacharya	Professor	Member
5	Dr. B. Rambabu	Professor	Member
6	Dr. S. Varalakshmi	Associate Professor	Member In charge
7	Mr. K. Abbulu	Associate Professor	Member
8	Mrs. D. Thirumala	Asst Professor	Member
9	Mr. Sarngapani	Social welfare officer	Member
10	Mr. M. Sathish Kumar	Asst Prof	Member
11	Prof. B. C. Jinaga	Former Rector, JNTUH. OMBUDSMAN	

f. Anti ragging Committee

S. No.	Name	Nature
1	Dr. T. Mangilal	Chair Person
2	Mr. K .Abbulu	Member
3	Dr. M. Srinivas	Member
4	Dr. B. Rambabu	Member

5	Dr. B. Bhattacharya	Member
6	Dr N. Anjaneyulu	Member
7	Dr. T. Siva prasad	Member
8	Mr. Guruva Reddy CI keesara	Member
9	Mr. M. Venkateswarlu, Physical educator	Member
10	Mr.Vishnu vardhan reddy	Member
11	Anantha chary, SI keesara	Member

g. Internal Complaint Committee (ICC)

S. No	Names	Designation	Members
1	Dr. R. Sivakumar	Professor	Coordinator
2	Mr. M. Sathish Kumar	Assistant Professor	Member
3	Mrs. Y. Swathi	Assistant Professor	Member
4	Mrs. P. Jyothirmayee	Assistant Professor	Member
5	Dr .MD. Abubaker	Assistant Professor	Member

h. SC/ST Cell

S. No	Name of the Faculty	Designation	Members
1	Dr. T. Mangilal	Professor	Chairman
2	Dr. J. Sunil	Associate Professor	Liaison Officer
3	Dr. S. Varalaxmi	Professor	Registrar
4	Mr. K Abbulu	Associate Professor	Member
5	Mrs. P. Jyothirmayee	Associate Professor	Member
6	Mrs. L Saritha	Assistant Professor	Member

I. Institutional Quality Improvement Committee

S. No	Names	Designation	Members
1	Dr. M. Ravi Kumar	Principal	Chairperson
2	Dr. M. Srinivas	Professor &HOD	Coordinator

3	Dr. R. Sivakumar	Professor	Member
4	Dr. T. Mangilal	Professor &HOD	Member
5	Dr. B. Battacharya	Professor &HOD	Member
6	Dr. R. Naga Kishore	Associate Professor	Member
7	Dr. P. Neeraja	Associate Professor	Member
8	Mrs. Pooja Agarwal	Assistant Professor	Member
9	Mr. G. R. Ravinder Reddy	Secretary, Teja Educational Society	Member
10	Mr. P. Ranadheer Reddy	Administration officer	Member
11	Dr. B. Rama Krishna chary	GMP Consultant	Member
12	Mr. K. Suryanarayana	M.D., Sterio Drugs Pvt Ltd	Member
13	Mr. M.D. Viqur Ahmed	Business	Parent Nominee

6. Programmes

a) Name of the Programmes approved by the AICTE

UG: B.Pharmacy

PG: M.Pharmacy- a) Pharmaceutics, b) Ph.Analysis, c) Ph. Regulatory Affairs

Pharm.D

Pharm.D P.B

b) Programme details

Name		B.Pharmacy	Pharm.D	Pharm.D P.B	M.Pharmacy		
					Pharmaceutics	Ph. analysis	Ph.regulatory affairs
Number of seats		100	30	10	15	15	15
Duration in Years		4	6	3	2	2	2
Cut off rank for admission during the last three years	2017-18	2795-57252	9614-70865	2092	1619-5866	869-6398	835-4903
	2018-19	9090-96866	9743-30151	484-4677	1142-3440	708-4133	967-4234
	2019-20	4483-57902	7039-21434	1210-3915	558-4970	488-4848	1837-3915

Fee (2019-20 A. Y)	**B.Pharm- 50,000/-, M.Pharm-110,000/-, Pharm.D-110,000/-**
Placement Facilities	**A Placement Officer is appointed who is in-charge of campus placements.**
Campus placement in last three years with salary.	• **32** students placed in different companies for the Academic year 2019-20 (current running batch) Median salaryRs**.3.95lakhs** per annum. • **49** students placed in different companies for the Academic year 2018-19 Median salaryRs**.4.25lakhs** per annum. • **31** students placed in different companies for the Academic year 2017-18

7. **Faculty:** Faculty & Student Ratio = 1:15 (UG) and 1:12(PG)

S.NO	FACULTY NAME	DESIGNATION
1	Dr. B. Bhattacharya	Professor
2	Dr. T. Mangilal	Professor
3	Dr. M. Srinivas	Professor
4	Dr. Bharat Bhushan Mohapatra	Professor
5	Dr. R. Sivakumar	Professor
6	Mr. K. Abbulu	Asso. Prof
7	Dr. B. Rambabu	Asso.Prof
8	Dr. N. Anjaneyulu	Professor
9	Dr. S. Varalakshmi	Asso. Prof
10	Dr. R. Naga Kishore	Asst. Prof
11	Mrs. P. Jyothirmaye	Asso. Prof
12	Mr. M. Sathish Kumar	Asst.Prof
13	Mrs. Ch. Sumalatha	Asst. Prof
14	Dr. P. Neeraja	Asso.Prof
15	Mrs. P. Aparna	Asst.Prof
16	Mr. J. Sunil	Asso.Prof
17	Mr. Y. Shiva kumar	Asst.Prof

18	Dr. Md. Abubakar	Asst.Prof
19	Mrs. M. Pravalika	Asst.Prof
20	Mrs. P. Madhuri	Asst.Prof
21	Mrs. V. Srivani	Asst.Prof
22	Mrs. D. Tirumala	Asst.Prof
23	Mr. M. Nagesh	Asst.Prof
24	Mrs. D. Savitha	Asst.Prof
25	Mrs. M. Santhoshi	Asst.Prof
26	Mrs. V. Shalini	Asst.Prof
27	Mrs. Pooja Agarwal	Asst.Prof
28	Mr. P. Nagaraju	Asst.Prof
29	Mrs. B. Sandhya	Asst.Prof
30	Mrs. R. Uma Devi	Asst.Prof
31	Mrs. T. Ramyakrishna	Asst.Prof
32	Mr. P. Shankaraiah	Asst.Prof
33	Mrs. D. Navya	Asst.Prof
34	Dr. Md. Mohasin Pasha	Asst.Prof
35	Mrs. S. Lahari	Asst.Prof
36	Mrs. T. Anoosha	Asst.Prof
37	Mrs. T. Vijaya kumari	Asst.Prof
38	Mrs. P. Umadevi	Asst.Prof
39	Mrs. Ch. Sowjanya	Asst.Prof
40	Mrs. B. Priyanka	Asst.Prof
41	Mr. K. Ganesh	Asst.Prof
42	Mrs. Y. Swathi	Asst.Prof
43	Mr. B. Chandulal	Asst.Prof

44	Mrs. V. Jyothirmayee	Asst. Prof
45	Mrs. L. Saritha	Asst.Prof
46	Mrs. S. Harshini	Asst.Prof
47	Mrs. B. Prathyusha	Asst.Prof
48	Mr. J. Naveen	Asst.Prof
49	Ms. B. Anitha	Asst.Prof
50	Mr. I. Nagaraju	Asst.Prof
51	Mr. J. Ramkishan	Asst.Prof
52	Mr. A. Srinivas	Asst.Prof
53	Mr. B. Kondal	Asst.Prof
54	Mrs. K. Swapna	Asst.Prof

8. Profile of Vice Chancellor/ Director/ Principal/ Faculty

Prof.Dr.M.Ravi Kumar has 29 years of rich teaching experience in various pharmacy colleges and currently heading a Pharmacy college in the capacity of the Principal.

Qualifications:

P.D.F June 2008 from Eminent Services Corporation, Frederick, Maryland, U.S.A.

Ph.D August 2005 from Jawaharlal Nehru Technical University, Kukatpally, Hyderabad.

M.Pharm March 1990 Pharmaceutical Biotechnology, Department of Pharmaceutical sciences, Andhra University, Visakapattanam, AP

B.Pharm August 1987 Andhra University, Visakapattanam, A.P.

Teaching Experience

From March 1990 to July 1995 J.K.K.Natarajah College of pharmacy Tamil Nadu — Vice Principal

From August 1995 to December 1996 S.C.K. College of pharmacy, Tamil Nadu — Vice Principal

From December 1996 to August 1999 Nalanda College of pharmacy, Nalgonda — Vice Principal

From August 1999 to June 2005 Sultan-Ul-Uloom. College of pharmacy Hyderabad — Associate Professor.

From June 2005 to July 2008 Priyadharshini College of pharmaceutical Sciences, Hyderabad — Principal.

From July 2008 to October 2009 Geethanjali College of pharmacy, Hyderabad — Principal

From 2009 October to 2010 July in Al jabal al Garby University (formerly called as 7th of April University) Zawia, Libya — Professor

From 2010 August to till date in Geethanjali College of pharmacy, Hyderabad — Principal

Administrative Experience

Has rich administrative exposure and experience in various Pharmacy Colleges from the year 1990 to till date. And is actively involved in developing the institutions in all angles.

Examination Duty Experience

a) **Member in the Examination panels** of JNTU Hyd., Kakatiya University, Warangal, Dr. M.G.R.Medical University,

Tamilnadu, JNTU Anatapur, JNTU Kakinada, for Pharmaceutics,Pharmaceutical Biotechnology, Analysis, Regulatory Affairs for PhD, PG & UG courses

b) Panel member in PhD Research Review meeting, Research colloquium meetings,

c) paper Setter for PG, UG examinations. D

d) Guest speaker in UGC orientation programs & workshops. Chairman of sessions

Research Experience **:** 2 scholar was awarded Ph.D in Nov.2015 under his research Guidance in JNTU Anantapuram

3 research scholars have submitted their thesis in JNTUH, Hyderabad

 Currently guiding six research scholars for their PhD programs in JNTU Hyderabad & JNTU Anantapur

 Guided M.Tech students JNTUH for their project work

 Guided M.Sc. (Microbiology) & M.Sc (Technology) Students for their projects as Co-Guide.

 Guided scores of B.Pharm students for their B.Pharm final year project works in Indian and Foreign Universities

Isolation and Presentation **:** Isolated 3 new strains of Yeasts,

1. *Issatchenkia Orientails MTCC-6351,*
2. *Candida Pseudointermedia MTCC-6225*
3. *Candida Pseudointermedia MTCC-6352*

They were assigned above mentioned MTCC Numbers and stored in Culture Bank of microbial type culture Collection Centre, IMTECH, Chandigarh, India.

Publications & Research guidance : Authored a well received Text Book titled -

"Pharmaceutical Microbiology A Comprehensive Approach"

 Second edition of the book is in the press

Published **30** Research Papers in different **International Journals**

Published **45** research Papers in different
National Journals.

International Exposure : Attended "Bio US 2008" a Biotechnology Convention at
SANDIEGO, California State, USA. During 2008-May.

Worked as teaching faculty in Al-jabal-Al Garbhi University (formerly 7th of April University), Zawia, Libiya. During 2009october to 2010 July.

Worked as pharmacist in Hafar Al-Batin, Saudi Arabia during 2004

Experts duties : Judge for many scientific sessions and poster sessions in national level. seminars conducted by different pharmacy college in Gave guest lectures in Universities and other Pharmacy colleges. Expert in establishing new pharmacy labs and pharmacy colleges.

Professional membership in learned societies and organization

1. Life Member of association of pharmaceutical teachers of India (APTI).
2. Life Member of Indian pharmaceutical association (IPA).
3. Life Membership of Registered pharmacist.

9. Fee

Fee approved by AFRC:-

- B.Pharm. programme Rs. 50,000/-
- M.Pharm. Programme Rs. 110,000/-
- Pharm.D Programme Rs.90,000/-

Time schedule for payment of fee for the entire programme.:- At the time of admission.

No. of Fee waivers granted with amount and name of students.:- NIL

Number of scholarship offered by the institute, duration and amount:-

Merit scholarship of an amount Rs.10,000/- each is awarded from B.pharm.

of I, II, III, IV Year and for Pharm.D students.

Criteria for fee waivers/scholarship:- Not Applicable

Estimated cost of Boarding and Lodging in Hostels : No hostel facility

10. Admission

Number of seats sanctioned with the year of approval

No	Course Name	2019-20	2018-19	2017-18
1	B (PHARMACY)	100	100	100
2	M. PHARMCY(PHARMACEUTICS)	15	15	15
3	MPHARMACY(PHARMACEUTICAL ANALYSIS)	15	15	15
4	PHARM-D(PB)	10	10	10
5	M PHARM (REGULATORY AFFAIRES)	15	15	15
6	PHARMA D	30	30	30

Number of Students admitted under various categories each year in the last three years

B.Pharmacy

S.No	Past five Academic sessions	No. of Admissions
1	2016-2017	85
2	2017-2018	81
3	2018-2019	83
4	2019-2020	85

Pharm.D

S.No	Past five Academic sessions	No. of Admissions
1	2016-2017	25
2	2017-2018	25
3	2018-2019	21
4	2019-2020	25

Pharm.D (PB)

S.No	Past five Academic sessions	No. of Admissions
1.	2016-2017	04
2.	2017-2018	05
3.	2018-2019	01
4.	2019-2020	03

M.Pharmacy-Pharmaceutics

S.No	Past five Academic sessions	No. of Admissions
1	2016-2017	11
2	2017-2018	10
3	2018-2019	6
4	2019-2020	3

M.Pharmacy-Pharmaceutical Analysis

S.No	Past five Academic sessions	No. of Admissions
1	2016-2017	14
2	2017-2018	13
3	2018-2019	03
4	2019-2020	6

M.Pharmacy-Pharmaceutical Management & Regulatory Affairs

S.No	Past five Academic sessions	No. of Admissions
1	2016-2017	-
2	2017-2018	07
3	2018-2019	02
4	2019-2020	3

Year of Admission	**B.Pharmacy**			**PHARM-D**		
	CQ	MQ	spot	CQ	MQ	SPOT
2015-16	63	25	2	19	9	2
2016-17	53	24	10	14	5	4
2017-18	54	29	2	15	8	2
2018-19	48	26	8	17	4	0
2019-20	62	23	0	19	6	0

Year of Admission	PHARM-D(PB)		
	CQ	MQ	SPOT
2015-16	1	0	0
2016-17	4	0	0
2017-18	5	0	0
2018-19	1	0	0
2019-20	2	0	0

Year of Admission	M.PHARMACY (PH'CEUTICS)		
	CQ	MQ	SPOT
2015-16	10	1	0
2016-17	9	2	0
2017-18	8	2	0
2018-19	4	2	0
2019-20	0	2	0

Year of Admission	M.PHARMACY (PA)			M.PHARMACY (RA)		
	CQ	MQ	SPOT	CQ	MQ	SPOT
2015-16	15	3	0	11	0	0
2016-17	11	6	0	0	0	0
2017-18	11	4	0	6	1	0
2018-19	3	0	0	1	1	0
2019-20	0	6	0	3	0	0

11. Admission Procedure

a. Name and address of the Test Agency and its URL (website) :-
Type Of Test : EAMCET, ECET, PGCET & GPAT.
Test Agency : TELANGANA STATE COUNCIL OF HIGHER EDUCATION. URL : www.tsche.org

12. Criteria and Weightages for Admission

As per the the rank obtained in the EAMCET, ECET, PGCET & GPAT.

40 out of 160 marks in EAMCET conducted by State Government 60 out of 200 marks in ECET conducted by State Government

40 out of 160 marks in PGCET conducted by State Government This is amended time to time by the State Government.

In case of Management seats, the Government specified that the candidates shall qualify the EAMCET exam or obtain 50% marks in qualifying exam.

13. List of Applicants: Available

14. Results of Admission Under Management seats/Vacant seats: Available

15. Information of Infrastructure and Other Resources Available: Available

- **Library**

Sl. No.	Item	Titles(No)	Minimum Volumes(No)	Available	
				Title	No.
1	Number Of Books	150	1500 adequate coverage of a large number of standard text books and titles in all disciplines of pharmacy	1244	9760
2	Annual Addition of Books		150 books per year	84	605
3	Periodicals Hard Copies/Online		20 National10 International periodicals	47	47
4	CDS		Adequate Nos	50	430
5	Internet Browsing Facilities		Minimum ten Computers	Available	
6	Reprographic Facilities:PhotoCopierFaxScanner		010101	AvailableAvailableAvailable	
7	Library Automation and Computrized System (desirable)			Available	
8	Library timings			9.00 am to 5.00	

				pm	

- **Laboratory**

For each Laboratory

- ✓ **List of Major Equipment / Facilities** : ANNEXURE 1
- ✓ **List of Experimental Setup** : ANNEXURE 2

- Computing facilities

Name	**Required**	**Available**	
		No.	**Area in Sq.mts**
Computer Room	100 Sq.mts.	1	126
Computer (Latest Configuration)	1 system for every 10 students	115	0
Printers	1 printer for every 10 computers	7	0
Multi Media Projector	01	10	0
Generator (5KVA)	01	1	0
Internet Accessibility (in mbps & hrs)	64Mbps/24hrs	D-Ios-48 Sri Balaji Broadband-16	
Wi Fi connectivity to the campus	Yes	Reliance Jio	

Major software packages available **:** Microsoft Academic Alliance Kit (Including all major OS), TURBO C++, MS-OFFICE TOOL KIT, RED HAT LINUX, JAVA, WIN XP 2007. MS VISUAL STUDIO

Special purpose facilities available **:** YES (E-CLASS ROOM)

List of facilities available :-

Games and Sports Facilities :- Cricket, Volley Ball, Basket Ball, Carroms, Chess, Table Tennis etc.

Extra Curriculum Activities :- In addition to the academic activities such as mini projects, paper presentations, student seminars, number of other recreational activities are conducted through Fine Arts Club, Literary Club, Debating Club and Music Groups etc.,

Soft Skill Development Facilities: - We are providing the soft skill development facilities to the students to meet the current trends of the global market.

Teaching Learning process : The teacher learning process is effective as student centric methodology is being adopted. Teachers are encouraged to use Audio Visual Aids so that the learning process is effective.

- post graduate courses give the following : Enclosed

16. Enrollment of students in the last 3 years: Enclosed

17. List of Research Projects/ Consultancy Works: Nil

18. LoA and subsequent EoA till the current Academic Year: Enclosed

19. Accounted audited statement for the last three years: Enclosed

20. Best Practices adopted, if any

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR (2019-20)

PHARM.D (Regular) and (PB) I YEAR

PHARM. D (Regular) and (Post Baccalaureate) I YEAR

Description	Period	Duration
Commencement of instruction	26th Aug. 2019	--
Dussehra Recess	7th to 12th oct. 2019	(1 w)
First mid examinations	11th to 16th Nov. 2019	(1 w)
Submission of First Mid Term Exam Marks to University on or before	23rd Nov. 2019	--
Parent-Teacher Meeting	14th Dec. 2019	--
Second mid examinations	3rd to 8th Feb. 2020	(1 w)
Submission of Second Mid Term Exam Marks to University on or before	16th Feb. 2020	--
Parent-Teacher Meeting	14th April 2020	--
Last date of Instruction	25th April 2020	(32 w)
Third mid examinations	27th April to 2nd May 2020	(1 w)
Preparation and Practical Examinations	4th to 16th May 2020	(2 w)
Submission of Third Mid Term Exam Marks to University on or before	9th May 2020	--
End / Supplementary Examinations	18th to 30th May 2020	(2 w)
Summer vacation	1st June to 4th July 2020	(5 w)

DIRECTOR
ACADEMIC & PLANNING, JNTUH

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR (2019-20)

PHARM. D (Regular) II, III, IV, V, VI YEARS and PHARM.D (PB) II & III YEARS

PHARM. D (Regular) II, III, IV, V YEAR and PHARM.D (PB) II YEAR

Description	Period	Duration
Commencement of instruction	1st July 2019	--
First mid examinations	16th to 21st Sept. 2019	(1 week)
Submission of First Mid Term Exam Marks to University on or before	30th Sept. 2019	--
Dussehra Recess	7th to 12th Oct.2019	(1 week)
Parent-Teacher Meeting	9th Nov. 2019	--
Supplementary Examinations	14th Oct. to 2nd Nov. 2019	(3 weeks)
Second mid examinations	30th Dec. 2019 to 4th Jan. 2020	(1 week)
Submission of Second Mid Term Exam Marks to University on or before	11th Jan. 2020	--
Parent-Teacher Meeting	8th Feb. 2020	--
Last date of Instruction	21st Mar. 2020	(32 weeks)
Third mid examinations	23rd to 28th Mar. 2020	(1 week)
Submission of Third Mid Term Exam Marks to University on or before	6th April 2020	--
Preparation and Practical Examinations	30th Mar. to 11th April 2020	(2 weeks)
End / Supplementary Examinations	13th to 25th April 2020	(2 weeks)
Summer vacation	26th April to 4th July 2020	(10 weeks)

PHARM. D (Regular) VI YEAR and PHARM.D (PB) III YEAR

Description	Period	Duration
Commencement of internship in general ward	1st July to 28th Dec. 2019	(6 months)
Report submission of internship in general ward	30th Dec. 2019	--
Commencement of internship in Specialty ward -1	31st Dec. 2019 to 29th Feb. 2020	(2 months)
Report submission of internship in Specialty ward -1	2nd Mar. 2020	--
Commencement of internship in Specialty ward – 2	3rd Mar. to 2nd May 2020	(2 months)
Report submission of internship in Specialty ward–2	4th May 2020	--
Commencement of internship in Specialty ward – 3	5th May to 4th July 2020	(2 months)
Report submission of internship in Specialty ward - 3	6th July 2020	--
Final viva of internship	8th July 2020	--

28.6.19

DIRECTOR

ACADEMIC & PLANNING, JNTUH

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

REVISED ACADEMIC CALENDAR (2019-20)

B. Pharmacy I Year I & II Semesters

I Sem

S. No	EVENT	DATE	Duration
1	Commencement of Instruction	26th Aug. 2019	--
2	Dussehra recess	7th to 19th Oct. 2019	2 weeks
3	First Mid Term Examinations	31st Oct. to 2nd Nov. 2019	--
4	Submission of First Mid Term Exam Marks to University on or before	8th Nov. 2019	--
5	Parent-Teacher Meeting	9th Nov. 2019	--
6	Last date of Instruction	24th Dec. 2019	--
7	Second Mid Term Examinations	27th to 30th Dec. 2019	16 weeks
8	Preparation Holidays and Practical Examinations	31st Dec. 2019 to 7th Jan 2020	1 week
9	Submission of Second Mid Term Exam Marks to University on or before	7th Jan. 2020	--
10	End Semester / Supplementary Examinations	8th to 25th Jan. 2020	2 weeks

II Sem

S. No	EVENT	DATE	Duration
1	Commencement of Instruction	27th Jan. 2020	--
2	First Mid Term Examinations	19th to 21st March 2020	--
3	Submission of First Mid Term Exam Marks to University on or before	28th March 2020	--
4	Parent-Teacher Meeting	11th April 2020	--
5	Last date of Instruction	13th May 2020	--
6	Second Mid Term Examinations	14th to 16th May 2020	16 weeks
7	Preparation Holidays and Practical Examinations	18th to 23rd May 2020	--
8	Submission of Second Mid Term Exam Marks to University on or before	23rd May 2020	--
9	End Semester / Supplementary Examinations	25th May to 6th June 2020	2 weeks
10	Summer Vacation	8th June to 4th July 2020	4 weeks

23.10.2019

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

REVISED ACADEMIC CALENDAR (2019-20)

FOR NON-AUTONOMOUS CONSTITUENT& AFFILIATED COLLEGES

B. TECH./B.PHARM. II, III & IV YEARS I & II SEMESTERS

I SEM

S. No	EVENT	DATE	Duration
1	Commencement of Instruction	15th July 2019	--
2	First Mid Term Examinations	12th to 14th Sept. 2019	--
3	Submission of First Mid Term Exam Marks to University on or before	20th Sept. 2019	--
4	Parent-Teacher Meeting	21st Sept. 2019	--
5	Dussehra recess	7th to 19th Oct. 2019	2 weeks
6	Last date of Instruction	20th Nov. 2019	17 weeks
7	Second Mid Term Examinations	21st to 23rd Nov. 2019	--
8	Preparation Holidays and Practical Examinations	25th to 30th Nov. 2019	1 week
9	Submission of Second Mid Term Exam Marks to University on or before	30th Nov. 2019	--
10	End Semester Examinations	2nd to 14th Dec. 2019	2 weeks

II SEM

S. No	EVENT	DATE	Duration
1	Commencement of Instruction	16th Dec. 2019	--
2	First Mid Term Examinations	10th to 12th Feb. 2020	--
3	Submission of First Mid Term Exam Marks to University on or before	19th Feb. 2020	--
4	Parent-Teacher Meeting	14th March 2020	--
5	Last date of Instruction	7th April 2020	16 weeks
6	Second Mid Term Examinations	8th to 11th April 2020	--
7	Preparation Holidays and Practical Examinations	13th to 18th April 2020	1 week
8	Submission of Second Mid Term Exam Marks to University on or before	18th April 2020	--
9	End Semester Examinations	20th April to 2nd May 2020	2 weeks
10	Summer Vacation	4th May to 4th July 2020	9 weeks

21.10.19

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
REVISED ACADEMIC CALENDAR (2019-20)
M.Tech. / M.Pharm. I Year - I & II Semesters

M.Tech. / M.Pharm. I Year - I Semester

S. No	EVENT	DATE	Duration
1	Commencement of Instruction	26th Aug. 2019	--
2	Dussehra recess	7th to 19th Oct. 2019	2 weeks
3	First Mid Term Examinations	31st Oct. to 2nd Nov. 2019	--
4	Submission of First Mid Term Exam Marks to University on or before	8th Nov. 2019	--
5	Parent-Teacher Meeting	9th Nov. 2019	--
6	Last date of Instruction	24th Dec. 2019	--
7	Second Mid Term Examinations	27th to 30th Dec. 2019	16 weeks
8	Preparation Holidays and Practical Examinations	31st Dec. 2019 to 7th Jan 2020	1 week
9	Submission of Second Mid Term Exam Marks to University on or before	7th Jan. 2020	--
10	End Semester / Supplementary Examinations	8th to 25th Jan. 2020	2 weeks

M.Tech. / M.Pharm. I Year - II Semester

S. No	EVENT	DATE	Duration
1	Commencement of Instruction	27th Jan. 2020	--
2	First Mid Term Examinations	19th to 21st March 2020	--
3	Submission of First Mid Term Exam Marks to University on or before	28th March 2020	--
4	Parent-Teacher Meeting	11th April 2020	--
5	Last date of Instruction	13th May 2020	--
6	Second Mid Term Examinations	14th to 16th May 2020	16 weeks
7	Practical Examinations	18th to 20th May 2020	--
8	Submission of Second Mid Term Exam Marks to University on or before	20th May 2020	--
9	Summer Vacation	21st May to 30th June 2020	6 weeks
10	End Semester / Supplementary Examinations	1st to 15th July 2020	2 weeks

Prabhakar 23.10.19
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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR (2019-20)

FOR NON-AUTONOMOUS CONSTITUENT & AFFILIATED COLLEGES

M.TECH./M.PHARMACY II YEAR - I & II SEMESTER

M.Tech./M. Pharmacy II Year - I Semester

S. No	EVENT	DATE	Duration
1.	Commencement of III Semester	15th July 2019	--
2.	Preparation of Project Work Proposals	10th Aug. 2019	4 weeks
3.	Project Work Review–I, Project approval (Part-I commencement)	13th to 19th Aug. 2019	--
4.	Last date for submission of list of approved students	20th Aug. 2019	--
5.	Comprehensive Viva-Voce	21st Aug. to 25th Oct. 2019	--
6.	Dussehra recess	7th to 12th Oct. 2019	1 week
7.	Last date for submission of Comprehensive Viva-Voce Marks	28th Oct. 2019	--
8.	Project Work Review -II (Phase-I)	11th to 14th Dec. 2019	--
9.	# Project Work Review -II(Phase-II)	27th to 30th Dec. 2019	--
10.	Last date for submission of PRC-II marks	2nd Jan. 2020	--
11.	**Part-I Duration**	13th Aug. to 14th Dec. 2019	**18 weeks**

M.Tech./M.Pharmacy II Year - II Semester

S. No	EVENT	DATE	Duration
1.	Commencement of IV Semester (Project Work Continuation)	16th Dec. 2019	--
2.	Project Work Review -III (Phase –I)	12th to 16th May 2020	--
3.	Last date for submission of Project Work Review-III (Phase-I) Marks	20th May 2020	--
4.	* Date of eligibility of thesis submission	20th May 2020	--
5.	Submission of Thesis and Project Viva –Voce Examination (Phase-I) follows	---	--
6.	**Part-II Duration**	16th Dec. 2019 to 16th May 2020	**22 weeks**
7.	# Project Work Review – III (Phase –II)	19th to 23rd Aug. 2020	--
8.	Last date for submission of Project Work Review –III (Phase-II) Marks	26th Aug. 2020	--
9.	Submission of Thesis and Project Viva –Voce Examination (Phase-II) follows	---	--

* After completion of 40 weeks from the date of approval of project work proposal and subject to approval of Project Work Review-III.

\# Phase-II will be conducted only for unsuccessful students in Phase –I

Note: 1 The unsuccessful students in Project Work Review-II (Phase-II) shall appear for Project Work Review-II at the time of Project Work Review-III. These students shall reappear for Project Work Review-III in the next academic year at the time of Project Work Review -II only after completion of Project Work Review -II, and then Project Work Review -III follows.

2 The unsuccessful students in Project Work Review -III (Phase-II) shall reappear for Project Work Review -III in the next academic year at the time of Project Work Review –II only.

3 The Project Viva-Voce External examination Marks must be submitted on the day of examination to the University.

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2017-18 Admitted Batch

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Advanced Physical Pharmaceutics	25	75	4	--	4
Core Course II	Modern Pharmaceutics-I	25	75	4	--	4
Core Course III	Applied Biopharmaceutics and Pharmacokinetics	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Techniques 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology and Pharmacoeconomics 2. Drug Regulatory Affairs 3. Herbal Cosmetic Technology 4. Pharmaceutical Validation 5. Pharmaceutical Management	25	75	4	--	4
Laboratory I	Advanced physical Pharmaceutics Lab	25	75	---	6	3
Laboratory II	Applied Biopharmaceutics and Pharmacokinetics Lab	25	75	--	6	3
Seminar I	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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	Modern Pharmaceutics-II	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Stability of Drugs and Dosage Forms	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Entrepreneurship management 5. Clinical Research And Pharmacovigilance	25	75	4	--	4
Laboratory III	Advanced Drug Delivery Systems Lab	25	75	---	6	3
Laboratory IV	Modern Pharmaceutics Lab	25	75	--	6	3
Seminar II	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm (Pharmaceutics/Pharmaceutical Technology)

ADVANCED PHYSICAL PHARMACEUTICS (Core course I)

Course 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.

Course 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.

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 and solid state decomposition.

UNIT - IV

Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

Characterization of API and excipients:

Differential Scanning Calorimetry: Principle, thermal transitions, advantages, disadvantages, instrumentation, applications, and interpretations

X Ray Diffraction methods: Origin of x-rays, applications, advantages, disadvantages, instrumentation, applications, and interpretations..

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.

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, Vallabha Prakashan Delhi - 2013

REFERENCE BOOKS:

1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICS – I (Core course II)

Course 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.

Course 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.

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, super disintegrants, 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.

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, Vallabha Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS (Core course III)

Course 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.

Course 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 evaluate the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

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.

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 Niazi Sarfaraz

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (Pharmaceutics/Pharmaceutical Technology)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (**Core Elective I)**

Course 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.

Course 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

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

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (Pharmaceutics/Pharmaceutical Technology)

INTELLECTUAL PROPERTY RIGHTS (Core Elective I)

Course 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.

Course Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

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

UNIT - IV

a. PCT Application procedure and review procedure
b. National phase application procedure for US& EU
c. Patent procecution procedure in US and EU
d. WIPO and its role in IPR
e. Hatch- Waxman provision for IPR

UNIT - V

a. Patent in validation process in India, US and Europe
b. IPR related to copyright, trade mark, trade secret and geographical indication.
c. Patent application writing
d. Claim construction and claims.

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, 5^{th} edition, by Guarino
9. Commercial Manual on Drugs and Cosmetics 2004, 2^{nd} 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. (Pharmaceutics/Pharmaceutical Technology)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Open Elective–I)

Course Objective:
This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT- I
Introduction to Pharmacoepidemiology:
Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT- II
Pharmacoepidemiological Methods:
Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT- III
Introduction to Pharmacoeconomics:
Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

UNIT- IV
Pharmacoeconomic evaluations:
Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost

Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT - V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of pharmacoeconomics.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm. (Pharmaceutics/Pharmaceutical Technology)

DRUG REGULATORY AFFAIRS (Open Elective–I)

Course 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.

Course Outcomes:

- 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.

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.

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. (Pharmaceutics and Pharmaceutical Technology)

HERBAL COSMETICS TECHNOLOGY (Open Elective I)

Course 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

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations herbal cosmetics.

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

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)

PHARMACEUTICAL VALIDATION (Open Elective –I)

Course Objective:
The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

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

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

UNIT - I
Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

UNIT - II
Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT - III
Qualification of analytical instruments: Electronic balance, Ph meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT - IV
Validation of Utility systems: Pharmaceutical Water System &pure steam, HVAC system, Compressed air and nitrogen.
Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT - V
Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Upǁ, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (Pharmaceutics/Pharmaceutical Technology)

PHARMACEUTICAL MANAGEMENT (Open Elective –I)

Course 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.

Course Outcomes:

- 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

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.

TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

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 2^{nd} 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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M.Pharm. (Pharmaceutics/Pharmaceutical Technology)

APPLIED BIOPHARMACEUTICS AND PHARMACOKINETICS LAB

List of experiments

1. Intrinsic dissolution (1 exp)
2. Analysis of dissolution by various data-kinetic modelling.
3. Dissolution of immediate release, sustained release and delayed release.
4. Evaluation of drug-protein binding analysis
5. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.
6. Calculation of K_a(absorption rate constant) absorption curve- Wagner nelson method , Loo-Riegel method.
7. Calculation of pharmacokinetics parameters of one compartment oral data and two compartment IV data.
8. Constuction of IVIVE from the data
9. Calculation of Urinary Pharmacokinetics
10. Permeation studies of Franz diffusion cell
11. Drug Release from semisolids by Agargel method or Franz diffusion cell.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICS / PHARMACEUTICAL TECHNOLOGY)

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2017-18 Admitted Batch

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Advanced Physical Pharmaceutics	25	75	4	--	4
Core Course II	Modern Pharmaceutics-I	25	75	4	--	4
Core Course III	Applied Biopharmaceutics and Pharmacokinetics	25	75	4	--	4
Core Elective I	1. Modern Pharmaceutical Analytical Techniques 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology and Pharmacoeconomics 2. Drug Regulatory Affairs 3. Herbal Cosmetics Technology 4. Pharmaceutical Validation 5. Pharmaceutical Management	25	75	4	--	4
Laboratory I	Advanced physical Pharmaceutics Lab	25	75	---	6	3
Laboratory II	Applied Biopharmaceutics and Pharmacokinetics Lab	25	75	--	6	3
Seminar I	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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	Modern Pharmaceutics-II	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Stability of Drugs and Dosage Forms	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Entrepreneurship management 5. Clinical Research And Pharmacovigilance	25	75	4	--	4
Laboratory III	Advanced Drug Delivery Systems Lab	25	75	---	6	3
Laboratory IV	Modern Pharmaceutics Lab	25	75	--	6	3
Seminar II	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

ADVANCED DRUG DELIVERY SYSTEMS (Core course - IV)

Course 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.

Course Outcomes:
Students will know the fabrication, design, evaluation and application of above drug delivery systems.

UNIT I
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

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 Aukunuru Jithan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

INDUSTRIAL PHARMACY (Core course - V)

Course 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

Course 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

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.

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.

REFERENCE 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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

MODERN PHARMACEUTICS - II (Core course - VI)

Course 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.

Course 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.

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

Cosmetics: Formulation approaches, preparation & method of manufacturing labeling& Q.C. of anti ageing products, sun screen lotion and fairness creams.

Nutraceuticals:

a) Introduction, source, manufacture, and analysis of glucosamine and cartinine.
b) Monographs: General and specific properties of glucosamine & cartinine.
c) 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.

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, Vallabh Prakashan Delhi - 2013

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

BIOSTATISTICS AND RESEARCH METHODOLOGY (Core Elective - II)

Course 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.

Course 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.

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

TEXT BOOKS:

1. Deepak Chawla Neena Sondhi, 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 R K Khanna bis and Suvasis Saha
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 (Pharmaceutics/ Pharmaceutical Technology)

STABILITY OF DRUGS AND DOSAGE FORMS (Core Elective - II)

Course 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

Course 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.

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.

REFERENCE BOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. 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's Cosmeticology; 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

SCREENING METHODS IN PHARMACOLOGY (Open Elective - II)

Course Objective: The students are 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.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

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 of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

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, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S. K. Kulkarni, Vallabh Prakashan, Delhi.

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/ Pharmaceutical Technology)

NANO BASED DRUG DELIVERY SYSTEMS (Open Elective - II)

Course 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.

Course 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

UNIT I – Introduction to Nanotechnology

- Definition of nanotechnology
- History of nanotechnology
- Unique properties of nanomaterials
- 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

RECOMMENDED BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in 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, Guozhong Gao, Imperial College Press(2004)

6. Nanochemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M. 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/ Pharmaceutical Technology)

NUTRACEUTICALS (Open Elective - II)

Course 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

Course Outcome: Helps the student to understand the importance of Neutraceuticals in various common problems with the concept of free radicals.

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, Allyltrisulfide.
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: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCES:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
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* Woodhead Publ. 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/ Pharmaceutical Technology)

ENTREPRENEURSHIP MANAGEMENT (Open Elective - II)

Course Objective: This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcome: On completion of this course it is expected that students will be able to understand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching And Organizing An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring, and evaluation.

UNIT IV

Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

TEXT AND REFERENCE BOOKS:

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R. D., and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G. G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Open Elective - II)

Course Objective: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing, and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT - I

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT - II

Clinical Trials: Types and Design: Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT - III

Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT- IV

Basic aspects, terminologies, and establishment of pharmacovigilance:

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT - V

Methods, ADR reporting and tools used in pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety Data.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
8. Textbook of PHarmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

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)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (Pharmaceutics/ Pharmaceutical Technology)

MODERN PHARMACEUTICS 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)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE) / (QUALITY ASSURANCE)

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2017-18 Admitted Batch

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Advanced Pharmaceutical Analysis	25	75	4	--	4
Core Course II	Food Analysis	25	75	4	--	4
Core Course III	Modern Pharmaceutical Analytical Techniques	25	75	4	--	4
Core Elective I	1. Pharmaceutical Validation 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Drug Regulatory Affairs 2. Pharmacoepidemiology and Pharmacoeconomics 3. Pharmaceutical Management 4. Herbal Cosmetics Technology 5. Pharmaceutical Formulation Technology	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	-	-6	3
Laboratory II	Advanced Pharmaceutical Analysis Lab	25	75	--	6	3
Seminar I	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**28**

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Advanced Instrumental Analysis	25	75	4	--	4
Core Course V	Quality Control and Quality Assurance	25	75	4	--	4
Core Course VI	Modern Bio analytical Techniques	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Spectral Analysis	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Stability of Drugs and Dosage Forms 3. Entrepreneurship management 4. Nano Based Drug Delivery Systems 5. Herbal & Cosmetics Analysis	25	75	4	--	4
Laboratory III	Advanced Instrumental Analysis Lab	25	75	-	6	4
Laboratory IV	Quality Control and Quality Assurance Lab	25	75	--	6	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

ADVANCED INSTRUMENTAL ANALYSIS (Core Course - IV)

Course Objectives: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization, and quantification of drugs. Instruments dealtare LC-MS, GC-MS, and hyphenated techniques.

Course 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.

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. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
b. **Super critical fluid chromatography**: Principles, instrumentation, pharmaceutical applications.
c. **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

Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method Development in CE,

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.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

QUALITY CONTROL AND QUALITY ASSURANCE (Core Course - V)

Course Objectives: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

UNIT I

a. **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
b. **Impurities in new drug products**: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical Procedures, limits of residual solvents, reporting levels of residual solvents

UNIT II

a. Concepts of Quality Assurance, Total Quality Management, Philosophy of GMP and cGMP
b. Guidelines for Quality Assurance of Human Blood Products and large volume parenterals.

UNIT III

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 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.

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 Vol. 1 and Vol. 2, WHO 2007)
3. GMP by Mehra

4. Pharmaceutical Process Validation by Berry and Nash
5. 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)

MODERN BIO-ANALYTICAL TECHNIQUES (Core course - VI)

Course Objectives: This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Course Outcomes: Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies

UNIT I

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

UNIT II

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental Methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT III

Bioanalysis and bioanalytical method validation:

a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

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.

UNIT V

a. **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).
b. **Drug Product Performance, In Vivo:** Purpose of Bioavailability Studies, Bioavailability and Bioequivalence Studies, Clinical Significance of Bioequivalence Studies.

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, New York. 1995.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jersey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38,Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines, Palmer

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

BIOSTATISTICS AND RESEARCH METHODOLOGY (Core Elective – II)

Course 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.

Course 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.

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

TEXT BOOKS:

1. Deepak Chawla Neena Sondhi, 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 G N Rao and N K 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 R K Khanna bis and Suvasis Saha
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 (PAQA/QA)
SPECTRAL ANALYSIS (Core Elective - II)

Course 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

Course 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.

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.

UNIT - III

Electrometric Techniques: Principle, instrumentation and applications of Potentiometer, Amperometer, Conductometer and Polarography.

UNIT - IV

a. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation, and Applications of fluorescence spectrophotometer.
b. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences, and applications.

UNIT - V

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

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

SCREENING METHODS IN PHARMACOLOGY (Open Elective - II)

Course Objective: The students are 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.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines, and regulations for screening new drug molecules on animals.

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 of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

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, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.

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 (PAQA/QA)

STABILITY OF DRUGS AND DOSAGE FORMS (Open Elective - II)

Course 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

Course 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.

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.

REFERENCE BOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. 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's Cosmeticology; 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

ENTREPRENEURSHIP MANAGEMENT (Open Elective - II)

Course Objective: This course is designed to impart knowledge and skills necessary to train the Students on entrepreneurship management.

Course Outcome: On completion of this course it is expected that students will be able to understand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

TEXT AND REFERENCE BOOKS:

1. Akhauri, M. M. P. (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R. D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G. G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII
6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

NANO BASED DRUG DELIVERY SYSTEMS (Open Elective – II)

Course 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.

Course 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

UNIT I – Introduction to Nanotechnology

- Definition of nanotechnology
- History of nanotechnology
- Unique properties of nanomaterials
- 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

RECOMMENDED BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in 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, Guozhong Gao, Imperial College Press(2004)

6. Nanochemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M. 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 (PAQA/QA)

HERBAL AND COSMETICS ANALYSIS (Open Elective - II)

Course Objectives: This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements; herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Course Outcomes: At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

UNIT I

Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

UNIT II

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.
Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

UNIT III

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT IV

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and biodrug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

UNIT V

Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr. S. H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics, and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

ADVANCED INSTRUMENTAL ANALYSIS 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)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PAQA/QA)

QUALITY CONTROL AND QUALITY ASSURANCE 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICAL ANALYSIS & QUALITY ASSURANCE) / (QUALITY ASSURANCE)

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2017-18 Admitted Batch

I Year – I Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course I	Advanced Pharmaceutical Analysis	25	75	4	--	4
Core Course II	Food Analysis	25	75	4	--	4
Core Course III	Modern Pharmaceutical Analytical Techniques	25	75	4	--	4
Core Elective I	1. Pharmaceutical Validation 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Drug Regulatory Affairs 2. Pharmacoepidemiology and Pharmacoeconomics 3. Pharmaceutical Management 4. Herbal Cosmetics Technology 5. Pharmaceutical Formulation Technology	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	-	-6	3
Laboratory II	Advanced Pharmaceutical Analysis Lab	25	75	--	6	3
Seminar I	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**28**

I Year – II Semester

Category	Course Title	Int. marks	Ext. marks	L	P	C
Core Course IV	Advanced Instrumental Analysis	25	75	4	--	4
Core Course V	Quality Control and Quality Assurance	25	75	4	--	4
Core Course VI	Modern Bio analytical Techniques	25	75	4	--	4
Core Elective II	1. Biostatistics And Research Methodology 2. Spectral Analysis	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Stability of Drugs and Dosage Forms 3. Entrepreneurship management 4. Nano Based Drug Delivery Systems 5. Herbal & Cosmetics Analysis	25	75	4	--	4
Laboratory III	Advanced Instrumental Analysis Lab	25	75	-	6	4
Laboratory IV	Quality Control and Quality Assurance Lab	25	75	--	6	2
Seminar II	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PAQA /QA)

ADVANCED PHARMACEUTICAL ANALYSIS (Core course–I)

Course 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.

Course Outcome: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

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
E. Amino Acids

UNIT - III

a. **Reference Standards:** Types, preparation methods and uses.

b. 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)
g. Carr – Price Reagent
h. 2,4 - DNP

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 Tests :** Types of Dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms, coated ,uncoated, enteric coated, gelatin capsules etc..

b. **Microbiological assays and Biological tests:** Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

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.)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PAQA / QA)

FOOD ANALYSIS (Core course–II)

Course Objective:
This course is designed to impart knowledge on analysis of food constituentsand finished food products. The course includes application of instrumentalanalysis in the determination of pesticides in variety of food products.

Course Outcome: At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

UNIT - I

a. **Carbohydrates:** Classification and properties of foodcarbohydrates, General methods of analysis of foodcarbohydrates,
b. **Proteins**: Chemistry and classification of amino acids andproteins, Physico-Chemical properties of protein and theirstructure, general methods of analysis of proteins and amino acids

UNIT - II

Lipids: Classification, general methods of analysis, refining of fatsand oils; hydrogenation of vegetable oils, Determination ofadulteration in fats and oils,

UNIT - III

a. **Quality Control of Excipients:** Tests related to excipients such as bulk density, tapped density, particle size distribution, pH, moisture content, viscosity (dynamic), loss on drying, ash content, conductivity.
b. **Excipients of interest:** disintegrating agents, binders, emulsifiers, viscosity modifiers and preservatives including preservative challenge test.

UNIT - IV

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT - V

In process quality control tests carried on the following dosage forms

A. Tablets B. Capsules C. Parenterals D. Liquid Orals

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

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PAQA / QA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Core course III)

Course 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.

Course Outcome: 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.

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}C-NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PAQA / QA)

PHARMACEUTICAL VALIDATION (Core Elective I)

Course Objective:
The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

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

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

UNIT - I
Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

UNIT - II
Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT - III
Qualification of analytical instruments: Electronic balance, Ph meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT - IV
Validation of Utility systems: Pharmaceutical Water System &pure steam, HVAC system, Compressed air and nitrogen.
Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT - V
Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Upǁ, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PAQA / QA)

INTELLECTUAL PROPERTY RIGHTS (Core Elective –I)

Course 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.

Course Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

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), Madrid Protocol

UNIT - IV

a. PCT Application procedure and review procedure
b. National phase application procedure for US& EU
c. Patent prosecution procedure in US and EU
d. WIPO and its role in IPR
e. Hatch- Waxman provision for IPR

UNIT - V

b. Patent in validation process in India, US and Europe
c. IPR related to copyright, trade mark, trade secret and geographical indication.
d. Patent application writing
e. Claim construction and claims.

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
14. Pharmaceutical Regulatory affairs –selected topics. CVS subhramanyam and J Thimma settee. Delhi, Vallabha Prakasham, 2012

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm (PAQA / QA)

DRUG REGULATORY AFFAIRS (Open Elective I)

Course 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.

Course Outcomes:

- 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.

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.

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)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Open Elective –I)

Course Objective:
This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT- I

Introduction to Pharmacoepidemiology:

Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT- II

Pharmacoepidemiological Methods:

Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT- III

Introduction to Pharmacoeconomics:

Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

UNIT- IV

Pharmacoeconomic evaluations:

Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost

Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT - V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of pharmacoeconomics.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm (PAQA / QA)

PHARMACEUTICAL MANAGEMENT (Open Elective –I)

Course 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.

Course Outcomes:

- 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

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.

TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
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 thEdition Richard. H. Hall

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm (PAQA / QA)

HERBAL COSMETICS TECHNOLOGY (Open Elective I)

Course 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

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations herbal cosmetics.

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

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 FORMULATION TECHNOLOGY (Open Elective –I)

Course 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.

Course 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.

Unit - I:

Preformulation: Goals of preformulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.

Flow of Powders: Physical properties and importance. Angle of repose, Cars index, compressibility, bulk density, tapped density.

Unit - II:

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

Unit - III:

Tablets: Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.

Tablet coating: Types of coating, steps involved in coating process- pan coating and fluid bed coating and problems associated with coating.

Hard Gelatin Capsules: General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

Unit - IV:

Dissolution: Principles of dissolution, factors influencing dissolution, official methods and apparatus. Dissolution of immediate release, controlled release and delayed release products.

Unit - V:

Stability testing: Chemical degradation and preventive measures. Various stability testing conditions and use of stabilizers in packing

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

7. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

REFERENCE 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 (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.)
1. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
2. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
3. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
4. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
5. Calibration of glasswares
6. Calibration of pH meter
7. Calibration of UV-Visible spectrophotometer
8. Calibration of FTIR spectrophotometer
9. Calibration of HPLC instrument

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm (PAQA / QA)

ADVANCED PHARMACEUTICAL ANALYSIS 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 hydroxyl group.
6. Quantitative determination of amino group
7. Colorimetric determination of drugs by using different reagents
8. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides and steroids

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2017-18 Admitted Batch

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	Drug Regulatory Affairs	25	75	4	--	4
Core Course III	Modern Pharmaceutical Analytical Techniques	25	75	4	--	4
Core Elective I	1. Total Quality Management 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology and Pharmacoeconomics 2. Herbal Cosmetics Technology 3. Phytochemistry 4. Pharmaceutical Formulation Technology 5. Pharmaceutical Validation	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	--	6	3
Laboratory II	Pharmaceutical Management Lab	25	75	--	6	3
Seminar I	Seminar	100	--	--	4	2
Total Credits		**275**	**525**	**20**	**16**	**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. Stability of Drugs and Dosage Forms	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Advanced Drug Delivery Systems 5. Clinical Research and Pharmacovigilance	25	75	4	--	4
Laboratory III	Analytical Method Validation Lab	25	75	--	6	3
Laboratory IV	Pharmaceutical Market Research and Analysis Lab	25	75	--	6	3
Seminar II	Seminar	100	--	--	4	2
Total Credits		**275**	**525**	**20**	**16**	**28**

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	P	C
Comprehensive Viva-Voce	--	100	--	--	4
Project work Review II	100	--	--	24	12
Total Credits	**100**	**100**	--	24	**16**

II Year - II Semester

Course Title	Int. marks	Ext. marks	L	P	C
Project work Review III	100	--	--	8	4
Project Evaluation (Viva-Voce)	--	100	--	16	12
Total Credits	**100**	**100**	**--**	**24**	**16**

$ For Project review I, please refer 7.9 in R17 Academic Regulations

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PM & RA)

PHARMACEUTICAL MANAGEMENT-I (GENERAL & PERSONNEL) (Core course-I)

Course 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.

Course 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

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.

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)

DRUG REGULATORY AFFAIRS (Core course - II)

Course 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.

Course Outcomes:

- 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.

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.

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. (PM & RA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (Core course - III)

Course 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.

Course Outcome: 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.

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.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PM & RA)

TOTAL QUALITY MANAGEMENT (Core Elective I)

Course 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.

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.

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: Organization 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.

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.
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 Sadhan K.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
12. Total Quality Management, An integrated Approach by D. R. Kiran , BS Publications
13. Total Quality Management, 3rd edition by Joel E. Ross. CRC press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PM & RA)

INTELLECTUAL PROPERTY RIGHTS (Core Elective - I)

Course 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.

Course Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.

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), Madrid Protocol

UNIT - IV

a. PCT Application procedure and review procedure
b. National phase application procedure for US& EU
c. Patent prosecution procedure in US and EU
d. WIPO and its role in IPR
e. Hatch- Waxman provision for IPR

UNIT - V

a. Patent in validation process in India, US and Europe
b. IPR related to copyright, trade mark, trade secret and geographical indication.
c. Patent application writing
d. Claim construction and claims.

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
14. Pharmaceutical Regulatory affairs –selected topics. CVS subhramanyam and J Thimma settee. Delhi, Vallabha Prakasham, 2012

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PM & RA)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Open Elective – I)

Course Objective:
This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT- I
Introduction to Pharmacoepidemiology:
Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT- II
Pharmacoepidemiological Methods:
Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT- III
Introduction to Pharmacoeconomics:
Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

UNIT- IV
Pharmacoeconomic evaluations:
Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost

Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT - V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of pharmacoeconomics.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PM & RA)

HERBAL COSMETICS TECHNOLOGY (Open elective - I)

Course 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

Course Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations herbal cosmetics.

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

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)

PHYTOCHEMISTRY (Open Elective – I)

Course Objective: Helps the students to get exposed to natural product drug discovery and to perform quantitative and qualitative evaluation of herbal extracts. To understand the chemistry of important phytoconsitituents of different categories.

Course Outcome: On the basis of chemistry data of phytoconsitituents students will acquire knowledge on various types of phytoconstituents present in the plants.

UNIT - I

Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including prep and Flash column chromatography.

UNIT - II

Sources, Chemical structure, Identification tests, mechanism of action, SAR and uses of following Alkaloids

a) Caffeine

b) Quinine, Reserpine, Atropine, Vinca alkaloids

c) Morphine and brief account on its derivatives and analogues

UNIT - III

Sources, Chemical structure, Identification tests, mechanism of action SAR, uses and semi-synthetic derivatives of the following phytopharmaceuticals:

Camptothecin, Podophyllotoxin, Taxol, Digoxinand Artemisinine

UNIT - IV

Structure elucidation of the following compounds by spectroscopic

Techniques like UV, IR, NMR (1H, 13C)

a. Carvone, Citral, Menthol

b. Luteolin, Kaempferol

c. Nicotine, Caffeine

UNIT - V

Drug discovery and development: History of herbs as source of drugs and drug discovery. Sourcing and archiving Natural products for discovery. Evaluating natural products for therapeutic properties, identifying the biologically active Natural products, the lead structure selection process and structure development with suitable examples from the following source: artemesin, andrographolides.

RECOMMENDED/ REFERENCE BOOKS:

1. Phytochemical methods of chemical analysis by Harbone
2. Modern methods of plant analysis- peach & M.V. Tracey Vol. 1 to VII
3. Pharmacognosy & Phytochemistry of medical plants by Jean Brunton
4. Thin layer chromatography by Stahl
5. Chemistry of natural products by Atur Rahman
6. Comprehensive Medicinal Chemistry, Vol 1-6, Elsevier Publication
7. Medicinal Chemistry Drug Discovery by Donald J, Abrahm,

8. Plant drug analysis by Wagner
9. Clarke's isolation & identification of drugs by AC Mottal
10. Chromatography of Alkaloids by Varpoorte Swendson
11. Jenkins Quantitative pharmaceutical chemistry by AN Kenwell
12. Standardization of botanicals by V. Rajpal Vol 1 & 2
13. Medicinal chemistry and drug discovery by Burger's
14. Chemistry of Natural Products by S. V. Bhat, B. A. Nagasampagi, M. Sivakumar
15. Herbal Drugs: Quality and Chemistry by D. D. Joshi

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

I Year – I Sem M. Pharm. (PM & RA)

PHARMACEUTICAL FORMULATION TECHNOLOGY (Open Elective – I)

Course 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.

Course 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.

Unit - I:

Preformulation: Goals of preformulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle size distribution.

Flow of Powders: Physical properties and importance. Angle of repose, Cars index, compressibility, bulk density, tapped density.

Unit - II:

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

Unit - III:

Tablets: Types of tablets, granulation methods, highlighting operations such as mixing, drying, milling, blending, lubrication and compression.

Tablet coating: Types of coating, steps involved in coating process- pan coating and fluid bed coating and problems associated with coating.

Hard Gelatin Capsules: General principles and steps involved in the production of drug loaded hard gelatin capsules, filling operation, filling of powders, granules and pellets.

Unit - IV:

Dissolution: Principles of dissolution, factors influencing dissolution, official methods and apparatus. Dissolution of immediate release, controlled release and delayed release products.

Unit - V:

Stability testing: Chemical degradation and preventive measures. Various stability testing conditions and use of stabilizers in packing

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

7. Industrial Pharmacy - Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013

REFERENCE 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)

PHARMACEUTICAL VALIDATION (Open Elective – I)

Course Objective:
The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

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

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

UNIT - I
Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

UNIT - II
Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT - III
Qualification of analytical instruments: Electronic balance, Ph meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT - IV
Validation of Utility systems: Pharmaceutical Water System &pure steam, HVAC system, Compressed air and nitrogen.
Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT - V
Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Upll, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

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. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
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. Calibration of glasswares
7. Calibration of pH meter
8. Calibration of UV-Visible spectrophotometer
9. Calibration of FTIR spectrophotometer
10. Calibration of HPLC instrument

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS)

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2017-18 Admitted Batch

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	Drug Regulatory Affairs	25	75	4	--	4
Core Course III	Modern Pharmaceutical Analytical Techniques	25	75	4	--	4
Core Elective I	1. Total Quality Management 2. Intellectual Property Rights	25	75	4	--	4
Open Elective I	1. Pharmacoepidemiology and Pharmacoeconomics 2. Herbal Cosmetics Technology 3. Phytochemistry 4. Pharmaceutical Formulation Technology 5. Pharmaceutical Validation	25	75	4	--	4
Laboratory I	Modern Pharmaceutical Analytical Techniques Lab	25	75	--	6	3
Laboratory II	Pharmaceutical Management Lab	25	75	--	6	3
Seminar I	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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. Stability of Drugs and Dosage Forms	25	75	4	--	4
Open Elective II	1. Screening Methods in Pharmacology 2. Nano Based Drug Delivery Systems 3. Nutraceuticals 4. Advanced Drug Delivery Systems 5. Clinical Research and Pharmacovigilance	25	75	4	--	4
Laboratory III	Analytical Method Validation Lab	25	75	--	6	3
Laboratory IV	Pharmaceutical Market Research and Analysis Lab	25	75	--	6	3
Seminar II	Seminar	50	--	--	4	2
Total Credits				**20**	**16**	**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**

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PM & RA)

PHARMACEUTICAL MANAGEMENT - II (Core course - IV)
(PRODUCTION, MARKETING, FINANCE & PROJECT)

Course 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.

Course Outcome: Student will get knowledge about production management, production planning and control, design and development of packaging, marketing of pharmaceuticals.

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.

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
10. Management by Tripathi P. C. and Reddy P. N.; Tata McGraw Hill.
11. Business Organization and Management by Shukla M. C.; S. Chand and Company.
12. Business Organization and Management by Sherlakar S. A.; Himalaya.
13. Personnel Management by Filippo E. B.; McGraw Hill.
14. Marketing Management by Kotler Philip.; Prentice Hall of India.
15. Organizational Behavior by Rao and Narayan; Konark Publishers.
16. Personnel Management by Tripathi P. C.; S. Chand and Company.
17. Principle and Practice of Marketing in India by Memoria C. B.
18. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
19. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
20. Production and Operations Management by S.N.Chary

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PM & RA)

ANALYTICAL METHOD VALIDATION, COPY RIGHTS, AND TRADE MARKS (Core course - V)

Course 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

Course 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.

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.
Trademarks: The trademarks 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 trademarks, role of Indian trade mark office.

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PM & RA)

PHARMACEUTICAL MARKET RESEARCH AND ANALYSIS (Core course - VI)

Course 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.

Course 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.

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 analyze in relationship between various factors governing the market growth.

TEXT AND REFERENCE BOOKS:

1. Principles of Pharmaceutical Marketing by MICKEY SMITH
2. Principles and Practice of Drug Manufacturing Management by MD BURANDE
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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PM & RA)

BIOSTATISTICS AND RESEARCH METHODOLOGY (Core Elective – II)

Course 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.

Course 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.

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

TEXT BOOKS:

1. Deepak Chawla Neena Sondhi, 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 R K Khanna bis and Suvasis Saha
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)

STABILITY OF DRUGS AND DOSAGE FORMS (Core Elective – II)

Course 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

Course 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

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.

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REFERENCE BOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. 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's Cosmeticology; 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PM & RA)

SCREENING METHODS IN PHARMACOLOGY (Open Elective - II)

Course Objective:
The students are 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.

Course Outcome:
The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

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 of cardiac and anti-diabetic activities.

UNIT V
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

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, Berlin Heideleberg.
3. Handbook of experimental pharmacology by S. K. Kulkarni, Vallabh Prakashan, Delhi.

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 (PM & RA)

NANO BASED DRUG DELIVERY SYSTEMS (Open Elective - II)

Course 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.

Course 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

UNIT I – Introduction to Nanotechnology

- Definition of nanotechnology
- History of nanotechnology
- Unique properties of nanomaterials
- 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

RECOMMENDED BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in 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, Guozhong Gao, Imperial College Press(2004)

6. Nanochemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M. 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)

Course 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

Course Outcome: Helps the student to understand the importance of Neutraceuticals in various common problems with the concept of free radicals.

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, Allyltrisulfide.
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: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCES:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
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* Woodhead Publ. 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 (PM & RA)

ADVANCED DRUG DELIVERY SYSTEMS (Open Elective – II)

Course 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.

Course Outcomes: Students will know the fabrication, design, evaluation and application of above drug delivery systems.

UNIT I

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

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 Aukunuru Jithan

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
I Year – II Sem M. Pharm (PM & RA)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Open Elective – II)

Course Objective:
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing, and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

Course Outcomes: Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT- I
Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT- II
Clinical Trials: Types and Design: Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT- III
Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT- IV
Basic aspects, terminologies, and establishment of pharmacovigilance:
History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT- V

Methods, ADR reporting and tools used in pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety
data.

REFERENCES:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
8. Textbook of PHarmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, PharmaMed Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
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

All India Council for Technical Education

(A Statutory body under Ministry of HRD, Govt. of India)

Nelson Mandela Marg,Vasant Kunj, New Delhi-110070 Website: www.aicte-india.org

APPROVAL PROCESS 2019-20

Extension of Approval (EoA)

F.No. South-Central/1-4261522431/2019/EOA

Date: 25-Apr-2019

To,

The Principal Secretary
(Higher Education) Govt. of Telangana,
D Block, 117 Telangana Secretariat,
Hyderabad

Sub: Extension of Approval for the Academic Year 2019-20

Ref: Application of the Institution for Extension of approval for the Academic Year 2019-20

Sir/Madam,

In terms of the provisions under the All India Council for Technical Education (Grant of Approvals for Technical Institutions) Regulations 2018 notified by the Council vide notification number F.No.AB/AICTE/REG/2018 dated 31/12/2018 and norms standards, procedures and conditions prescribed by the Council from time to time, I am directed to convey the approval to

Permanent Id	1-16381801	**Application Id**	1-4261522431
Name of the Institute	GEETHANJALI COLLEGE OF PHARMACY	**Name of the Society/Trust**	TEJA EDUCATIONAL SOCIETY
Institute Address	CHEERYAL-VILLAGE, KEESARA-MANDAL, RANGA REDDY-DISTRICT, ANDHRA PRADESH, 501301-PINCODE, HYDERABAD, RANGAREDDI, Telangana, 501301	**Society/Trust Address**	2-1-88/1,ANAND NAGAR X-ROAD,BANDLAGUDA VILLAGE,NAGOLE,HYDERABAD,RANGAREDDI,Andhra Pradesh,500068
Institute Type	Unaided - Private	**Region**	South-Central

Opted for Change from Women to Co-Ed and vice versa	No	**Change from Women to Co-Ed and vice versa Approved or Not**	NA
Opted for Change of Name	No	**Change of Name Approved or Not**	NA
Opted for Change of Site/Location	No	**Change of Site/Location Approved or Not**	NA
Opted for Conversion from Degree to Diploma or vice versa	No	**Conversion for Degree to Diploma or vice versa Approved or Not**	NA
Opted for Organization Name Change	No	**Change of Organization Name Approved or Not**	NA
Opted for Merger of Institution	No	**Merger of Institution Approved or Not**	NA
Opted for Introduction of New Program/Level	No	**Introduction of Program/Level Approved or Not**	NA

To conduct following Courses with the Intake indicated below for the Academic Year 2019-20

Program	Shift	Level	Course	FT/PT+	Affiliating Body (Univ/Body)	Intake Approved for 2019-20	NRI Approval Status	PIO / FN / Gulf quota/ OCI/ Approval Status
Pharmacy	1st	POST GRADUATE	Pharmaceutical Management And Regulatory Affairs	FT	Jawaharlal Nehru Technological University, Hyderabad	15	NA	NA
Pharmacy	1st	UNDER GRADUATE	Pharmacy	FT	Jawaharlal Nehru Technological University, Hyderabad	100	NA	NA

Pharmacy	1st	POST GRADUATE	Pharmaceutics	FT	Jawaharlal Nehru Technological University, Hyderabad	15	NA	NA
Pharmacy	1st	POST GRADUATE	Pharmaceutical Analysis	FT	Jawaharlal Nehru Technological University, Hyderabad	15	NA	NA
Pharmacy	1st	POST GRADUATE	Pharm.D.	FT	Jawaharlal Nehru Technological University, Hyderabad	30	NA	NA
Pharmacy	1st	POST GRADUATE	Pharm.D. (Post Baccalaureate)	FT	Jawaharlal Nehru Technological University, Hyderabad	10	NA	NA

+FT –Full Time,PT-Part Time

In case of any differences in content in this Computer generated Extension of Approval Letter, the content/information as approved by the Executive Council / General Council as available on the record of AICTE shall be final and binding.

Strict compliance of Anti-Ragging Regulation: - Approval is subject to strict compliance of provisions made in AICTE Regulation notified vide F. No. 37-3/Legal/AICTE/2009 dated July 1, 2009 for Prevention and Prohibition of Ragging in Technical Institutions. In case Institution fails to take adequate steps to Prevent Ragging or fails to act in accordance with AICTE Regulation or fails to punish perpetrators or incidents of Ragging, it will be liable to take any action as defined under clause 9(4) of the said Regulation.

It is mandatory to comply all the essential requirements as given in APH 2019-20(appendix 6)

NOTE: If the State Government / UT / DTE / DME has a reservation policy for admission in Technical Education Institutes and the same is applicable to Private & Self-financing Technical Institutions, then the State Government / UT/ DTE / DME shall ensure that 10 % of Reservation for EWS would be operational from the Academic year 2019-20 without affecting the percentage reservations of SC/ST/OBC/General . However, this would not be applicable in the case of Minority Institutions referred to the clause (1) of Article 30 of Constitution of India.

Prof. A.P Mittal
Member Secretary, AICTE

Copy to:

1. **The Director Of Technical Education**, Telangana**

2. **The Registrar**,**
   Jawaharlal Nehru Technological University, Hyderabad

3. **The Principal / Director,**
   Geethanjali College Of Pharmacy
   Cheeryal-Village, Keesara-Mandal, Ranga Reddy-District, Andhra Pradesh, 501301-Pincode,
   Hyderabad,Rangareddi,
   Telangana,501301

4. **The Secretary / Chairman,**
   Teja Educational Society
   2-1-88/1,Anand Nagar X-Road,Bandlaguda Village,Nagole.
   Hyderabad,Rangareddi,
   Andhra Pradesh,500068

5. **The Regional Officer,**
   All India Council for Technical Education
   First Floor, old BICARD Building
   Jawaharlal Nehru Technological University
   Masab Tank, Hyderabad-500076

6. **Guard File(AICTE)**

30.4.19
PRINCIPAL
Geethanjali College of Pharmacy
Cheeryal (V), Keesara (M), Medchal Dist. (T.S)-501 301

INDIAN INCOME TAX RETURN ACKNOWLEDGEMENT

[Where the data of the Return of Income in Form ITR-1 (SAHAJ), ITR-2, ITR-3, ITR-4 , ITR-5, ITR-6,ITR-7 transmitted electronically with digital signature]

Assessment Year 2018-19

PERSONAL INFORMATION AND THE DATE OF ELECTRONIC TRANSMISSION

Name			PAN
TEJA EDUCATIONAL SOCIETY			AAATT7624B
Flat/Door/Block No	Name Of Premises/Building/Village		Form No. which has been electronically transmitted: ITR-7
SY NO.33 AND 34			
Road/Street/Post Office	Area/Locality		
CHERIYAL VILLAGE	KEESARA MANDAL		Status: AOP/BOI
Town/City/District	State	Pin/ZipCode	Aadhaar Number/Enrollment ID
R R DIST	TELANGANA	501301	

Designation of AO(Ward/Circle): CENTRAL CIRCLE 7 | Original or Revised: ORIGINAL

E-filing Acknowledgement Number: 353249101291018 | Date(DD/MM/YYYY): 29-10-2018

COMPUTATION OF INCOME AND TAX THEREON

1	Gross total income				1	0
2	Deductions under Chapter-VI-A				2	0
3	Total Income				3	0
3a	Current Year loss, if any				3a	0
4	Net tax payable				4	0
5	Interest and Fee Payable				5	0
6	Total tax, interest and Fee payable				6	0
7	Taxes Paid	a Advance Tax	7a	0		
		b TDS	7b	69643		
		c TCS	7c	33601		
		d Self Assessment Tax	7d	0		
		e Total Taxes Paid (7a+7b+7c +7d)			7e	103244
8	Tax Payable (6-7e)				8	0
9	Refund (7e-6)				9	103240
10	Exempt Income	Agriculture		0	10	0
		Others		0		

This return has been digitally signed by SRIDEVI GADDAM in the capacity of SECRETARY

having PAN AEIPG7169Q from IP Address 124.123.108.69 on 29-10-2018 at R R DIST

Dsc Sl No & issuer 1401087876CN=(n)Code Solutions CA 2014,2.5.4.51=#13133330312c20474e464320496e666f746f776572,STREET=Bodakdev\, S G Road\, Ahmedabad,ST=Gujarat,2.5.4.17=#1306333830303534,OU=Certifying Authority,O=Gujarat Narmada Valley Fertilizers and Chemicals

DO NOT SEND THIS ACKNOWLEDGEMENT TO CPC, BENGALURU

CODE NO.	: D-31		
NAME OF ASSESSEE	: TEJA EDUCATIONAL SOCIETY		
PAN	: AAATT7624B		
OFFICE ADDRESS	: SY NO.33 AND 34, CHERIYAL VILLAGE, KEESARA MANDAL, R R DIST, TELANGANA-501301		
STATUS	: AOP (TRUST)	ASSESSMENT YEAR	: 2018 - 2019
WARD NO	: CENTRAL CIRCLE 7	FINANCIAL YEAR	: 2017 - 2018
D.O.I.	: 09/09/2002		
EMAIL ADDRESS	: mallesham1975@gmail.com		
NATURE OF BUSINESS	: SOCIETY		
METHOD OF ACCOUNTING	: MARCANTILE SYSTEM		
NAME OF BANK	: CANARA BANK		
IFS CODE	: CNRB0004926		
ADDRESS	: SPECIALISED MID-CORPORATE,HYD ABID ROA		
ACCOUNT NO.	: 0606201021972		
RETURN	: ORIGINAL (FILING DATE : 29/10/2018 & NO. : 353249101291018)		

COMPUTATION OF TOTAL INCOME

		NIL
INCOME NOT FORMING PART OF APPLICATION OF INCOME		
AGGREGATE OF INCOME REFERRED TO IN SECTIONS 11, 12 AND SECTIONS 10(23C)(IV), 10(23C)(V), 10(23C)(VI) AND 10(23C)(VIA) DERIVED EXCLUDING VOLUNTARY CONTRIBUTION	373501492	
INCOME BEFORE APPLICATION OF INCOME	373501492	
LESS : APPLICATION OF INCOME		
AMOUNT APPLIED TO CHARITABLE OR RELIGIOUS PURPOSES - REVENUE ACCOUNT	390048222	NIL
		NIL
GROSS TOTAL INCOME		NIL
TOTAL INCOME		NIL

COMPUTATION OF TAX ON TOTAL INCOME

TAX ON RS. NIL		NIL
LESS TAX DEDUCTED AT SOURCE		
COLLECTION AT SOURCE FROM ALCOHOLIC LIQUOR FOR HUMAN CONSUMPTION	12605	
FEES FOR PROFESSIONAL OR TECHNICAL SERVICES	60225	
OTHER INTEREST	3454	
SALE OF IMMOVABLE PROPERTY	5964	
SALE OF VEHICLE	20996	103244
		-103244
REFUNDABLE		(103244)
TAX ROUNDED OFF U/S 288B		(103240)

For Teja Educational Society
G. Sridevi
SRIDEVI GADDAM
President

As per Form 26AS [File Creation Date: 16-09-2018] last imported on 16-09-2018 10:36 AM

Details of Tax Deducted at Source on Income other than Salary

Sl. No.	Tax Deduction Account Number (TAN) of the Deductor	Unique TDS Certificate No.	Name and address of the Deductor	Amount paid /credited	Date of Payment /Credit	Total tax deducted	Amount claimed for this year
194A : Other Interest							
1.	HYDC04738G		SOUTHERN POWER DISTRIBUTION COMPANY OF TELANGANA LIMITED	34540	30/06/2017	3454	3454
194IA : SALE OF IMMOVABLE PROPERTY							
1.	MUMA14385A		APTECH LIMITED	162000	23/05/2017	3240	3240
2.	MUMT11446B		TATA CONSULTANCY SERVICES LIMITED	136200	24/07/2017	2724	2724
			Total	**298200**		**5964**	**5964**
194J : Fees for professional or technical services							
1.	HYDD05371C		DIRECTOR OF EVALUATION JNT UNIVERSITY	2250	01/09/2017	225	225
2.	HYDV01011D		VEM TECHNOLOGIES PVT LTD	600000	31/03/2018	60000	60000
			Total	**602250**		**60225**	**60225**
			Grand Total	**934990**		**69643**	**69643**

Details of Tax Collected at Source on Income

Sl. No.	Tax Deduction and Tax Collection Account Number of the Collector	Name and address of the Collector	Amount received /debited	Date of receipt /debit	Total tax deducted	Amount claimed for this year
206CA : Collection at source from alcoholic liquor for human consumption						
1.	HYDV13560B	VENKATARAMANA MOTORS	1260490	30/08/2017	12605	12605
206CL : SALE OF VEHICLE						
1.	HYDJ00564E	JASPER INDUSTRIES PVT LIMITED	2099635	31/07/2017	20996	20996
		Grand Total	**3360125**		**33601**	**33601**

FORM NO. 10B

[*See* rule 17B]

Audit report under section 12A(b) of the Income-tax Act, 1961, in the case of charitable or religious trusts or institutions

We have examined the balance sheet of TEJA EDUCATIONAL SOCIETY , AAATT7624B [name and PAN of the trust or institution] as at 31/03/2018 and the Profit and loss account for the year ended on that date which are in agreement with the books of account maintained by the said trust or institution.

We have obtained all the information and explanations which to the best of our knowledge and belief were necessary for the purposes of the audit. In our opinion, proper books of account have been kept by the head office and the branches of the abovenamed trust visited by us so far as appears from our examination of the books, and proper Returns adequate for the purposes of audit have been received from branches not visited by us , subject to the comments given below:

In our opinion and to the best of our information, and according to information given to us , the said accounts give a true and fair view-

(i) in the case of the balance sheet, of the state of affairs of the above named trust as at 31/03/2018 and

(ii) in the case of the profit and loss account, of the profit or loss of its accounting year ending on 31/03/2018

The prescribed particulars are annexed hereto.

Place SECUNDERABAD

Date 29/10/2018

Name HARIBABU CHENNUPALLI

Membership Number 022361

FRN (Firm Registration Number) 0001064

Address PLOT NO:10,FLAT NO:201, A. R.RESIDENCY, RAVI CO-OP HOUSING SOCIETY, TRIMUL GHERRY, SECUNDERABAD-500015 TELANGANA

ANNEXURE

Statement of particulars

I. APPLICATION OF INCOME FOR CHARITABLE OR RELIGIOUS PURPOSES

1.	Amount of income of the previous year applied to charitable or religious purposes in India during that year (₹)		390048222
2.	Whether the trust has exercised the option under clause (2) of the Explanation to section 11(1) ? If so, the details of the amount of income deemed to have been applied to charitable or religious purposes in India during the previous year (₹)		No
3.	Amount of income **accumulated or set apart** for application to charitable or religious purposes, to the extent it does not exceed 15 per cent of the income derived from property held under trust **wholly** for such purposes. (₹)		No
4.	Amount of income eligible for exemption under section 11(1)(c) (Give details)		No
5.	Amount of income, in addition to the amount referred to in item 3 above, accumulated or set apart for specified purposes under section 11(2) (₹)		0
6.	Whether the amount of income mentioned in item 5 above has been invested or deposited in the manner laid down in section 11(2)(b) ? If so, the details thereof.		Not Applicable
7.	Whether any part of the income in respect of which an option was exercised under clause (2) of the Explanation to section 11(1) in any earlier year is deemed to be income of the previous year under section 11(1B) ? If so, the details thereof (₹)		Not Applicable
8.	Whether, during the previous year, any part of income accumulated or set apart for specified purposes under section 11(2) in any earlier year-		
	(a)	has been applied for purposes other than charitable or religious purposes or has ceased to be accumulated or set apart for application thereto, or	No
	(b)	has ceased to remain invested in any security referred to in section 11(2)(b)(i) or deposited in any account	No

		referred to in section 11(2)(b)(ii) or section 11(2)(b)(iii), or	
	(c)	has not been utilised for purposes for which it was accumulated or set apart during the period for which it was to be accumulated or set apart, or in the year immediately following the expiry thereof? If so, the details thereof	No

II. APPLICATION OR USE OF INCOME OR PROPERTY FOR THE BENEFIT OF PERSONS REFERRED TO IN SECTION 13(3)

1.	Whether any part of the income or property of the **trust** was lent, or continues to be lent, in the previous year to any person referred to in section 13(3) (hereinafter referred to in this Annexure as such person)? If so, give details of the amount, rate of interest charged and the nature of security, if any.	No
2.	Whether any part of the income or property of the trust was made, or continued to be made, available for the use of any such person during the previous year? If so, give details of the property and the amount of rent or compensation charged, if any.	No
3.	Whether any payment was made to any such person during the previous year by way of salary, allowance or otherwise? If so, give details	No
4.	Whether the services of the **trust** were made available to any such person during the previous year? If so, give details thereof together with remuneration or compensation received, if any	No
5.	Whether any share, security or other property was purchased by or on behalf of the trust during the previous year from any such person? If so, give details thereof together with the consideration paid	No
6.	Whether any share, security or other property was sold by or on behalf of the trust during the previous year to any such person? If so, give details thereof together with the consideration received	No
7.	Whether any income or property of the **trust** was diverted during the previous year in favour of any such person? If so, give details thereof together with the amount of income or value of property so diverted	No
8.	Whether the income or property of the trust was used or applied during the previous year for the benefit of any such person in any other manner? If so, give details	No

III. INVESTMENTS HELD AT ANY TIME DURING THE PREVIOUS YEAR(S) IN CONCERNS IN WHICH PERSONS REFERRED TO IN SECTION 13(3) HAVE A SUBSTANTIAL INTEREST

S. No	Name and address of the concern	Where the concern is a company, number and class of shares held	Nominal value of the investment(₹)	Income from the investment(₹)	Whether the amount in col. 4 exceeded 5 per cent of the capital of the concern during the previous year-say, Yes/No
Total					

Place SECUNDERABAD

Date 29/10/2018

Name HARIBABU CHENNUPALLI

Membership Number 022361

FRN (Firm Registration Number) 0001064

Address PLOT NO:10,FLAT NO:201, A. R.RESIDENCY, RAVI CO-OP HOUSING SOCIETY, TRIMUL GHERRY, SECUNDERABAD-500015 TELANGANA

Form Filing Details	
Revision/Original	Original

TEJA EDUCATIONAL SOCIETY

GEETHANJALI COLLEGE OF ENGINEERING & TECHNOLOGY

Sy.No.33 & 34, Cheeryal (V), Keesara (M).R.R.Dist.(T.S)-501 301

INCOME AND EXPENDITURE ACCOUNT FOR THE PERIOD ENDED 31.03.2018

	PARTICULARS	Rs		PARTICULARS	Rs
To	Staff Salaries	177,854,887			
To	EPF (Employer Share of Cont.)	8,151,013		**FEES RECEIPTS**	
To	ESI (Employer Share of Cont.)	805,566	By	Tuitions Fees	250,595,000
To	Telephone charges	277,525	By	Admission fees & Other fees	48,127,125
To	Printing & Stationery	8,403,778	By	Transportation Fee	31,151,780
To	Building Repairs & Maintenance	10,604,797	By	Other Income	1,327,192
To	College Miantenance Expenses	3,182,691	By	Grant Received from AICTE & SERB	700,000
To	Lab consumables & Repairs Maintenance	416,416	By	CSR-amount Received from	3,500,000
To	Seminars & Workshop	307,931		(Virchow Biotech Pvt.Ltd)	
To	Guest Hononorium	792,716			
To	Faculty Development Programe	30,246			
To	Student Technical Activities	337,408			
To	AICTE Grant Expenses (FDP & Seminars)	804,984			
To	R & D Project Expences (DST/SERB)	359,325			
To	Paper Publication Incentives	139,500			
To	NSS Unit Exp.	27,570			
To	Vehicle Repairs & Maintenance	1,560,942			
To	Training & Placement Exp.	6,557,689			
To	Sports & Games Expences	286,577			
To	Staff Welfare & Incentives	598,973			
To	Generator Repairs & Maintenance	1,275,088			
To	Electricity Charges	3,335,809			
To	Periodical & Subscriptions	18,114			
To	NBA Fee	59,000			
To	AICTE Fee	105,877			
To	JNTU Common Service Fee	5,091,278			
To	Student Merit Scholarship	407,218			
To	Postage & Telegrams	23,383			
To	Administrative Expences	1,276,657			
To	Legal Expenses	75,000			
To	Membership Registration fee	1,450,422			
To	Examination Expenses-(JNTU&Autonomous)	8,395,269			
To	Bank Charges	706,223			
To	Advertisement Charges	1,416,590			
To	Rates & Taxs	1,326,027			
To	Interest term Loan	7,989,641			
To	Interest on working Capital Loan	3,807,809			
To	Interest on Unsecured Loan	18,678,167			
	Hire Charges	1,628,845			
To	Security Charges	1,819,319			
To	Insurance Charges	217,226			
To	Insurance Charges on Vehicles	2,151,221			
To	Bus Repairs &Transport Maintenance	7,943,942			
To	Garden Maintanance	259,911			
To	College Functions & Celebrations Exp.	3,395,049			
To	Entertainment & Meeting Exp.	61,224			
To	Travelling & Conveyance Charges	1,696,264			
To	Internet & Website Charges	1,883,897			
To	Computer Peripherals &Maintenance	2,547,126			
To	Audit Fee	112,500			
To	Architect Fee	200,000			
To	Furniture Repairs & Maintenance	2,048,380			
To	Electrical Repairs & maintenance	1,380,579			
To	Depreciation	32,023,921			
To	Loss of income over Expenditure	(906,413)			
	Total	**335,401,097**			**335,401,097**

Geethanjali College of Engg. and Tech.

F.Y-2017-18

GEETHANJALI COLLEGE OF ENGINEERING & TECHNOLOGY

SCHEDULE - D - FIXED ASSETS FOR THE PERIOD 01.04.2017 to 31.03.2018

Sl. No.	DESCRIPTION	GROSS BLOCK				DEPRECIATION			NET BLOCK	
		AS AT 01.04.17	ADDITIONS DURING THE UPTO SEPT'17	ADDITIONS DURING THE AFTER SEPT'17	AS AT 31.03.18	for the March'18	UP TO April 2,017	AS AT 31.03.2018	31st March 2,018	31st March 2,017
1	Land	1,120,000	-	-	1,120,000	-	-	-	1,120,000	1,120,000
2	Buildings	183,870,572	3,678,218		187,548,790	10,024,820	87,300,586	97,325,406	90,223,384	96,569,985
3	Furniture & Fixtures	25,997,408	456,580	21,198	26,475,186	1,411,410	12,350,484	13,761,894	12,713,292	13,646,924
4	Text Books Library	15,052,203	386,502	1,400,585	16,839,290	988,235	6,256,647	7,244,882	9,594,408	8,795,556
5	Computers	46,605,005	592,824	9,104,750	56,302,579	6,407,460	41,071,104	47,478,564	8,824,015	5,533,901
6	Electrical & Lab Equip.	67,795,798	18,817,531	2,953,568	89,566,897	8,860,399	29,020,787	37,765,186	51,801,711	38,775,011
7	Vehicles	57,340,046	2,556,707		59,896,753	4,331,596	31,019,443	34,817,621	25,079,132	26,320,603
	TOTAL	**397,781,032**	**26,488,362**	**13,480,101**	**437,749,495**	**32,023,921**	**207,019,051**	**238,393,554**	**199,355,941**	**190,761,979**

Geethanjali College of Engg. and Tech.

Secretary

TEJA EDUCATIONAL SOCIETY

GEETHANJALI COLLEGE OF PHARMACY

Sy.No.33 & 34, Cheeryal (V), Keesara (M).R.R.Dist.(T.S)-501 301

INCOME AND EXPENDITURE ACCOUNT FOR THE PERIOD ENDED 31.03.2018

	PARTICULARS	Rs		PARTICULARS	Rs
To	Salaries Staff	32,227,168			
To	EPF (Employer Share of Cont.)	1,378,894		**FEES RECEIPTS**	
To	ESI (Employer Share of Cont.)	68,137	By	Tuitions Fees	30,304,300
To	Telephone charges	7,427	By	Admission fees & Other fees	3,541,502
To	Printing & Stationery	400,474	By	Transportation Fee	4,254,593
To	Building Repairs & College Maintanance	1,429,513			
To	Lab consumbles & Repairs Maintanance	348,610			
To	Computer Peripherals &Maintanance	288,083			
To	Hospital Intentionship Expences	2,475,000			
To	Vehicle.Repairs & Maintenance	254,760			
To	Insurance Charges on Vehicles	383,992			
To	Rates & Taxs	393,548			
To	Administrative Expenses	159,014			
To	Security Charges	294,963			
To	Electricity Charges	540,828			
To	Periodical & Subscriptions Journals	234,743			
To	JNTU Common Service Fee	1,474,336			
To	AICTE Fee	250,000			
To	PCI Fee	750,000			
To	Membership Registration fee	59,320			
To	JNTU Examination Fee Exp.	1,116,402			
To	Postage & Telegrams	5,088			
To	Bank Charges	24,664			
To	Advertisement Charges	207,800			
To	Buses Repairs &Transport Maintenance	1,322,210			
To	Garden Maintanance	58,132			
To	Functions & Celebrations Exp.	152,479			
To	Seminars & Workshop	42,490			
To	Student Merit Scholarship	46,000			
To	Generator Maintenance	610,795			
To	Furniture Repairs & Maintanance	4,665			
To	Electrical Repairs & maintanance	763,253			
To	Travelling & Conveyance	173,787			
To	Internet & Website Charges	211,834			
To	Depreciation	5,582,303			
To	Loss for the period	(15,640,317)			
	Total	**38,100,395**			**38,100,395**

Geethanjali College of Pharmacy

Authorised Signatory

1	Land	1,107,000	-	-	1,107,000	-	-	-	1,107,000	1,107,000
2	Buildings	38,511,028	5,455,668	-	43,966,696	3,090,950	13,057,198	16,148,148	27,818,548	25,453,830
3	Furniture & Fixtures	3,231,480	288,361	291,866	3,811,707	249,846	1,167,317	1,417,163	2,394,544	2,064,163
4	Text Books Library	3,752,553	25,708	205,967	3,984,228	264,570	1,235,546	1,500,116	2,484,112	2,517,007
5	Computers	3,365,629	454,500	227,000	4,047,129	548,979	3,018,664	3,567,643	479,486	346,965
6	Electrical & Lab Equip.	13,486,892	872,174	218,875	14,577,941	1,168,743	6,676,881	7,845,624	6,732,317	6,810,011
7	Vehicles	4,357,499	-	-	4,357,499	259,215	2,629,399	2,888,614	1,468,885	1,728,100
	TOTAL	**67,812,081**	**7,096,411**	**943,708**	**75,852,200**	**5,582,303**	**27,785,004**	**33,367,307**	**42,484,893**	**40,027,077**

Geethanjali College of Pharmacy

Authorised Signatory

TEJA EDUCATIONAL SOCIETY
GEETHANJALI COLLEGE OF ENGINEERING & TECHNOLOGY
Sy.No.33 & 34, Cheeryal (V), Keesara (M).R.R.Dist.(T.S)-501 301

BALANCE SHEET AS AT 31.03.2018

LIABILITIES		Rs	ASSETS		Rs
CAPITAL			**FIXED ASSETS**		
Corpus Fund		66,975,803	NET FIXED ASSETS(As per schedule)		199,355,941
Loss of Income over Expenditure		340,112	**CURRENT ASSETS**		
			Geethanjali College Of Pharmacy		96,688,564
LOAN FUNDS		197,095,364	Staff Salary Loans & advances		1,090,876
Unscured Loans			Prepaid Expences		1,354,722
Others Loan	197,095,364		Hire Charges Suspense		914,238
		58,656,055	TDS receiveble		282,353
Secured Loans			Canara Mutual Fund		200,000
ICICI Bank	6,971,895		Telephone & Other Deposits		1,571,871
Canara Bank	50,624,908		Consultancy Fee Receivable		151,270
H.D.F.C Bank	703,775		Tuition Fee Receivable		76,602,625
Kotech Mahindra Pvt.Ltd	355,477		**CURRENT ASSETS**		
		33,321,845			3,352,692
Canara Bank (OD A/c)			**CASH AND BANK**		
			Cash at Bank		62,388
CURRENT LIABILITIES		16,052,025	**CASH**		
Other Sundry Liabilities		139,595	Cash in hand		
Staff Salary deposits		50,000			
Canteen Deposit					
		8,996,741			
PROVISIONS					
		381,627,540			**381,627,540**

Geethanjali College of Engg. and Tech.

Secretary

TEJA EDUCATIONAL SOCIETY

SCHEDULE - D - FIXED ASSETS FOR THE PERIOD 01.04.2017 to 31.03.2018

Sl. No.	DESCRIPTION	GROSS BLOCK				DEPRECIATION			NET BLOCK	
		AS AT 01.4.17	ADDITIONS DURING THE UPTO SEPT'17	ADDITIONS DURING THE AFTER SEPT'17	AS AT 31.03.18	for the Yr March'18	UP TO April 2,017	AS AT 31.03.2018	31st March 2,018	31st March 2,017
1	Land	2,227,000	-	-	2,227,000	-	0	-	2,227,000	2,227,000
2	Buildings	222,381,600	9,133,886	-	231,515,486	13,115,770	100,357,784	113,473,554	118,041,932	122,023,816
3	Furniture & Fixtures	29,228,888	744,941	313,064	30,286,893	1,661,256	13,517,801	15,179,057	15,107,836	15,711,086
4	Text Books Library	18,804,756	412,210	1,606,552	20,823,518	1,252,805	7,492,193	8,744,998	12,078,520	11,312,563
5	Computers	49,970,634	1,047,324	9,331,750	60,349,708	6,956,439	44,089,768	51,046,207	9,303,501	5,880,866
6	Electrical & Lab Equip.	81,282,690	19,689,705	3,172,443	104,144,838	10,029,142	35,697,668	45,610,810	58,534,028	45,585,022
7	Vehicles	61,697,545	2,556,707	-	64,254,252	4,590,811	33,648,842	37,706,235	26,548,017	28,048,703
	TOTAL	465,593,113	33,584,773	14,423,809	513,601,695	37,606,224	234,804,055	271,760,861	241,840,834	230,789,056

For Teja Educational Society

G. Sridhar

President

TEJA EDUCATIONAL SOCIETY

Sy.No.33 & 34, Cheeryal (V), Keesara (M).R.R.Dist.(T.S)-501 301

INCOME AND EXPENDITURE ACCOUNT FOR THE PERIOD ENDED 31.03.2018

	PARTICULARS	Rs		PARTICULARS	Rs
To	Staff Salaries	210,082,055			
To	EPF -Employer Share	9,529,907		FEES RECEIPTS	
To	ESI - Employer Share	873,703	By	Tuitions Fees	280,899,300
To	Telephone charges	284,952	By	Admission fees & Other fees	51,668,627
To	Printing & Stationery	8,804,252	By	Transportation Fee	35,406,373
To	Building Repairs & Maintenance	12,034,310	By	Other Income	5,527,192
To	College Maintenance	3,182,691			
To	Lab consumbles & Repairs Maintenance	765,026			
To	Seminars & Workshop	350,421			
To	Guest Honorarium	792,716			
To	Faculty Development Programe	30,246			
To	Student Technical Activities	337,408			
To	AICTE Grant Expenses (FDP & Seminars)	804,984			
To	R & D Project Expences (DST/SERB)	359,325			
To	Paper Publication Incentives	139,500			
To	NSS Unit Exp.	27,570			
To	Vehicles Repairs & Maintenance	1,815,702			
To	Training & Placement Exp.	6,557,689			
To	Sports & Games Expences	286,577			
To	Staff Welfare & Incentives	598,973			
To	Generator Repairs & Maintenance	1,885,883			
To	Electricity Charges	3,876,637			
To	Periodical & Subscriptions	252,857			
To	NBA Fee	59,000			
To	AICTE Fee	355,877			
To	JNTU Common Service Fee	6,565,614			
To	PCI Fee	750,000			
To	Student Merit Scholarship	453,218			
To	Postage & Telegrams	28,471			
To	Administrative Expences	1,435,671			
To	Legal Expenses.	75,000			
To	Membership Registration fee	1,509,742			
To	Examination Expenses-(JNTU&Autonomous)	9,511,671			
To	Bank Charges	730,887			
To	Advertisement Charges	1,624,390			
To	Rates & Taxs	1,719,575			
To	Interest term Loan	7,989,641			
To	Interest on working Capital Loan	3,807,809			
To	Interest on Unsecured Loan	18,678,167			
To	Hire Charges	1,628,845			
To	Security Charges	2,114,282			
To	Insurance Charges	217,226			
To	Insurance Charges on Vehicles	2,535,213			
To	Bus Repairs &Transport Maintenance	9,266,152			
To	Garden Maintanance	318,043			
To	College Functions & Celebrations Exp.	3,547,528			
To	Entertainment & Meeting Exp.	61,224			
To	Travelling & Conveyance Charges	1,870,051			
To	Internet & Website Charges	2,095,731			
To	Hospital InternShip Expences	2,475,000			
To	Computer Peripherals &Maintenance	2,835,209			
To	Audit Fee	112,500			
To	Architect Fee	200,000			
To	Furniture Repairs & Maintenance	2,053,045			
To	Electrical Repairs & maintenance	2,143,832			
To	Depreciation	37,606,224			
To	Loss of income over Expenditure	(16,546,730)			
	Total	373,501,492			373,501,492

For Teja Educational Society

President

TEJA EDUCATIONAL SOCIETY

Sy.No.33 & 34, Cheeryal (V), Keesara (M).R.R.Dist.(T.S)-501 301

BALANCE SHEET AS AT 31.03.2018

LIABILITIES		Rs	ASSETS		Rs
CAPITAL			**FIXED ASSETS**		
Corpus Fund		66,975,803	NET FIXED ASSETS(As per schedule)		241,840,834
Loss of Income over Expenditure		(62,497,636)			
Opening	(45,950,906)		**OTHER CURRENT ASSETS**		
Current Year	(16,546,730)				
LOAN FUNDS			Canara Mutual Fund		200,000
Unscured Loans		197,095,364			
			Staff Salary advances &Loans		1,121,676
Others Loan	197,095,364				
			Prepaid Expences		1,354,722
Secured Loans		75,082,893			
ICICI Bank	6,971,895		Hire Charges Suspense		914,238
Canara Bank	67,051,746				
H.D.F.C Bank	703,775		TDS receiveble		282,353
Kotak Mahindra Pvt.Ltd	355,477				
			Telephone & Other Deposits		1,571,871
BANK OD A/C					
Canara Bank (O.D)		33,321,845	Consultancy Fee Receivable		151,270
			Tuition Fee Receivable		95,639,590
CURRENT LIABILITIES			**CURRENT ASSETS**		
Other Sundry Liabilities		22,245,352			
Staff Salary deposits		139,595			
Canteen Deposit		50,000	**CASH AND BANK**		
Other Provisions for Expenses		15,612,591	Cash at Bank		4,853,284
			CASH		
			Cash in hand		95,969
		348,025,807			**348,025,807**

For Teja Educational Society

President

TEJA EDUCATIONAL SOCIETY
GEETHANJALI COLLEGE OF PHARMACY
Sy.No.33 & 34, Cheeryal (V), Keesara (M).R.R.Dist.(T.S)-501 301
BALANCE SHEET AS AT 31.03.2018

LIABILITIES	Rs	ASSETS	Rs
CAPITAL		**FIXED ASSETS**	
Loss of Income over Expenditure	(62,837,748)	NET FIXED ASSETS(As per schedule)	42,484,893
Unscured Loans		**OTHER CURRENT ASSETS**	
Geethanjali College Of Engg.&Tech.	96,688,564	Staff Salary advances & Loans	30,800
Secured Loans		Tuition Fee Receivable	19,036,965
Canara Bank	16,426,838	**CURRENT ASSETS**	
CURRENT LIABILITIES			
Other Sundry Liabilities	6,193,327	**CASH AND BANK**	
		Cash at Bank	1,500,592
PROVISIONS	6,615,850		
		Cash in hand	33,581
	63,086,831		**63,086,831**

Geethanjali College of Pharmacy

RVR

Authorised Signatory