$JAWAHARLAL\,NEHRU\,TECHNOLOGICAL\,UNIVERSITY\,ANANTAPUR$

ACADEMIC REGULATIONS COURSE STRUCTURE AND DETAILED SYLLABI

PHARM. D

AND

PHARM. D (POST BACCALAUREATE)

PHARM. D (REGULAR SIX YEAR COURSE)

AND

PHARM. D (*POST BACCALAUREATE*) (REGULAR THREE YEAR COURSE)

(APPICABLE FOR THE BATCHES ADMITED FROM 2014-15)

Academic Regulations 2014 for Pharm. D and Pharm. D (Post Baccalaureate) (Regular)

(Effective for the students admitted into I year from the Academic Year 2014-2015 onwards)

1. Award of Pharm. D Degree

A student will be declared eligible for the award of the **Pharm. D** (Doctor of Pharmacy) Degree if he fulfills the following academic regulations:

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

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

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

- b) Pursue the course of study for not less than 06 academic years and is not more than 12 years.
- c) Students, who fail to fulfill all the academic requirements for the award of the degree within 12 academic years from the year of their admission, shall forfeit their seat in Pharm D. course and their admission is cancelled.
- 2. A student will be declared eligible for the award of the **Pharm. D** (*Post Baccalaureate*). Degree if he fulfills the following academic regulations:
 - a) Pharm. D (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

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

- b) Pursue the course of study for not less than 03 academic years and is not more than 06 years.
- c) Students, who fail to fulfill all the academic requirements for the award of the degree within 06 academic years from the year of their admission, shall forfeit their seat in Pharm. D (PB) course and their admission is cancelled.
- d) To add prefix 'Dr.' before the name of the candidate while awarding the degree 'Doctor of Pharmacy' vide regulation18 of the Pharm D regulation, 2008.
- 3. Examination.
 - a) Every year there shall be an examination to examine the students.
 - b) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination. Supplementary examination shall be conducted within a month after announcement of the regular examination results and the dates of which may be given on the date of declaration of the result.

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

TABLES

First Year examination :

S.No.	Name of Subject	Maximum	marks for Tl	neory	Maximum marks for Practicals			
		Examination	Sessional	Total	Examination	Sessional	Total	
1.1	Human Anatomy and Physiology	70	30	100	70	30	100	
1.2	Pharmaceutics	70	30	100	70	30	100	
1.3	Medicinal Biochemistry	70	30	100	70	30	100	
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100	
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100	
1.6	Remedial Mathematics/ Biology	70	30	100	70*	30*	100*	
				600			600 = 1100/1200*	

* for Biology.

Second Year examination :

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

Third Year examination :

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

Fourth Year examination (Including Pharm D Post Baccalaureate I Year):

S.No.	Name of Subject	Maximum 1	Maximum marks for Theory			Maximum marks for Practicals			
		Examination	Sessional	Total	Examination	Sessional	Total		
4.1	Pharmacotherapeutics- III	70	30	100	70	30	100		
4.2	Hospital Pharmacy	70	30	100	70	30	100		
4.3	Clinical Pharmacy	70	30	100	70	30	100		
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-		
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100		
4.6	Clinical Toxicology	70	30	100	-	-	-		
				600			400 = 1000		
For Ph	arm D Post Baccalaureat	e I Year							
4.7	Pharmacotherapeutics I & II	70	30	100	70	30	100		
				700			500= 1200		

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

Fifth Year examination (Including Pharm D Post Baccalaureate II Year):

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)

70 marks – Thesis work

Note: The entire class work be spread for the entire Academic Year along with Project work.

4. Attendance Requirements:

A student shall be eligible to appear for University examinations if he acquires a minimum of 80% of attendance in aggregate of all the subjects in a year.

- 4.1 Condonation of shortage of attendance in aggregate from 70% and above and below 80% in each year may be granted by the College Academic Committee, on medical grounds/valid reasons.
- 4.2 Shortage of Attendance below 70% in aggregate shall in NO case be condoned.
- 4.3 Students whose shortage of attendance is not condoned in any year are not eligible to take their end examination of that class and their registration shall stand cancelled.
- 4.4 A student will not be promoted to the next year unless he/she satisfies the attendance requirements of the present year, as applicable. They may seek readmission for that year when offered next.
- 4.5 A stipulated fee shall be payable towards condonation of shortage of attendance to the University.

5. Mode of examinations

- (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.
- (2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.
- (3) Practical examination shall also consist of a viva -voce (Oral) examination.
- (4) Clerkship examination Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the students. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

(6) Award of sessional marks and maintenance of records.-

- 1. A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm. D or as the case may be, Pharm. D (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.
- 2. There shall be at least three periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.
- 3. The sessional marks in practicals shall be allotted on the following basis:i. Actual performance in the sessional examination (20 marks);

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

7. Minimum marks for passing examination.-

A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects at the Pharm. D or as the case may be, Pharm. D (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in aggregate in all subjects shall be declared to have passed with distinction provided the student completes the course in 6 years for Pharm. D (Post Baccalaureate).

Pass class shall be awarded to such of the candidates who would have passed the examination in subsequent number of attempts after completion of 6/3 years of the course.

8. Eligibility for promotion to next year.—

All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than three subjects (excluding Remedial Mathematics/ Biology) shall debar him or her from promotion to the next year classes.

9. Internship.—

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

b. Every student has to undergo one year internship as per PCI (Pharmacy Council of India) norms for Pharm D (Appendix A).

10. Practical training

As per PCI norms for Pharm D (Appendix B)

11. Transitory regulations:

Candidates who have been detained for want of attendance or not fulfilled academic requirements or who have failed after having undergone the course in earlier regulations or have discontinued and wish to continue the course are eligible for admission into the unfinished year from the date of commencement of class work with the same or equivalent subjects as and when subjects are offered, subject to Section 1 and 2 and continue to be in the academic regulations then existing.

12. With-holding of results:

If the candidate has not paid dues to the university or if any case of in-discipline or malpractice is pending against him, the result of the candidate shall be withheld and he will not be allowed / promoted into the next higher semester. The issue of degree is liable to be withheld in such cases.

13. General:

- i. The academic regulations should be read as a whole for purpose of any interpretation.
- ii. Disciplinary action for Malpractice / improper conduct in examinations is appended
- iii. Where the words "he", "him", "his", occur in the regulations, they include "she", "her", "hers".
- iv. In the case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Vice-Chancellor is final.
- v. The University may change or amend the academic regulations or syllabi at any time and the changes or amendments shall be made applicable to all the students on roles with effect from the dates notified by the University.

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TABLES

S.No.	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical	Lab	S.No.	Subjects codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
1.1	14T00101	Human Anatomy and Physiology	3	1	3		1.7	14T00107
1.2	14T00102	Pharmaceutics	2	1	3		1.8	14T00108
1.3	14T00103	Medicinal Biochemistry	3	1	3		1.9	14T00109
1.4	14T00104	Pharmaceutical Organic Chemistry	3	1	3		2.0	14T00110
1.5	14T00105	Pharmaceutical Inorganic Chemistry	2	1	3		2.1	14T00111
1.6	14T00106	Remedial Mathematics/ Biology	3	1	3*		2.2	14T00112*
		Total hours	16	6 = (40)	18			

FIRST YEAR :

* For Biology

SECOND YEAR:

S.No	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical	Lab	S.No	Subjects Codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
2.1	14T00201	Pathophysiology	3	1	-	-		-
2.2	14T00202	Pharmaceutical Microbiology	3	1	3	~	2.7	14T00207
2.3	14T00203	Pharmacognosy & Phytopharmaceuticals	3	1	3	~	2.8	14T00208
2.4	14T00204	Pharmacology-I	3	1	-	-		-
2.5	14T00205	Community Pharmacy	2	1	-	-		-
2.6	14T00206	Pharmacotherapeutics-I	3	1	3	~	2.9	14T00209
		Total Hours	17	6 = 32	9			

THIRD YEAR:

S.N O	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical	Lab	S.No	Subjects Codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
3.1	14T00301	Pharmacology-II	3	1	3	 ✓ 	3.7	14T00307
3.2	14T00302	Pharmaceutical Analysis	3	1	3	~	3.8	14T00308
3.3	14T00303	Pharmacotherapeutics- II	3	1	3	~	3.9	14T00309
3.4	14T00304	Pharmaceutical Jurisprudence	2	-	-	-		-
3.5	14T00305	Medicinal Chemistry	3	1	3	✓	4.0	
3.6	14T00306	Pharmaceutical Formulations	2	1	3	~	4.1	14T00310
		Total hours	16	5 = 36	15			

S.N 0.	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Tutorial	No. of hours of Practical/ Hospital Posting	Lab	S.No	Subjects Codes
(1)	(2)	(3)	(4)	(5)	(6)		(7)	(8)
4.1	14T00401	Pharmacotherapeutics- III	3	1	3	✓	4.7	14T00407
4.2	14T00402	Hospital Pharmacy	2	1	3	✓	4.8	14T00408
4.3	14T00403	Clinical Pharmacy	3	1	3	~	4.9	14T00409
4.4	14T00404	Biostatistics & Research Methodology	2	1	-	-		-
4.5	14T00405	Biopharmaceutics & Pharmacokinetics	3	1	3	•	4.10	14T00410
4.6	14T00406	Clinical Toxicology	2	1	-	-		-
		Total hours	15	6 = 33	12			
For Pl	narm D Post Ba	accalaurate	1	1	1	1	1	
4.11	14T00410	Pharmacotherapeutics I & II	3	1	3	√	4.12	14T00411
			18	7=39				

FOURTH YEAR (Including Pharm D Post Baccalaureate I Year):

S.N o.	Subjects Codes	Name of Subject	No. of hours of Theory	No. of hours of Seminar	No. of hours of Hospital posting*
(1)	(2)	(3)	(4)	(5)	(6)
5.1	14T00501	Clinical Research	3	1	-
5.2	14T00502	Pharmacoepidemiology and Pharmacoeconomics	3	1	-
5.3	14T00503	Clinical Pharmacokinetics & Therapeutic Drug monitoring	2	1	-
5.4		Clerkship *	-	1	-
5.5		Project work (Six Months)	-	-	20
		Total hours	8	4 = 32	20

FIFTH YEAR(Including Pharm D Post Baccalaureate II Year):

* Attending ward rounds on daily basis.

SIXTH YEAR:

Internship or residency training include postings in specialty units. Student should independently provide the clinical pharmacy services to the allotted wards which include:

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other specialty departments

RULES FOR DISCIPLINARY ACTION FOR MALPRACTICE / IMPROPER CONDUCT IN EXAMINATIONS

	Nature of Malpractices/Improper conduct	Punishment
	If the candidate:	
1. (a)	Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, Cell phones, pager, palm computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)	Expulsion from the examination hall and cancellation of the performance in that subject only.
(b)	Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.	Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.
2.	Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already

	the examination (theory or practical) in which the candidate is appearing.	appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that Semester/year. The Hall Ticket of the candidate is to be cancelled and sent to the University.
3.	Impersonates any other candidate in connection with the examination.	The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination (including practicals and project work) already appeared and shall not be allowed to appear for examinations of the remaining subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.
4.	Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for one year from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
5.	Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.	Cancellation of the performance in that subject.
6.	Refuses to obey the orders of the Chief Superintendent/Assistant – Superintendent / any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in charge or any person on duty in or outside the examination hall of any injury to his person or to any of his relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the College campus or engages in any other act which in the opinion of	In case of students of the college, they shall be expelled from examination halls and cancellation of their performance in that subject and all other subjects the candidate(s) has (have) already appeared and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The candidates also are debarred and forfeit their seats. In case of outsiders, they will be handed over to the police and a police case is registered against them.

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	the officer on duty amounts to use of unfair means	
	or misconduct or has the tendency to disrupt the	
7	orderly conduct of the examination.	Emeration from the manipution half and
7.	Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.	Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for one year from class work and all University examinations. The continuation of the course by the candidate is subject to the academic regulations in connection with forfeiture of seat.
8.	Possess any lethal weapon or firearm in the examination hall.	Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat.
9.	If student of the college, who is not a candidate for the particular examination or any person not connected with the college indulges in any malpractice or improper conduct mentioned in clause 6 to 8.	Student of the colleges expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. Person(s) who do not belong to the College will be handed over to police and, a police case will be registered against them.
10.	Comes in a drunken condition to the examination hall.	cancellation of the performance in that subject and all other subjects the candidate has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that year.
11.	Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.	Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of that semester/year examinations.
12.	If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the University for further action to award suitable punishment.	

Malpractices identified by squad or special invigilators

- 1. Punishments to the candidates as per the above guidelines.
- 2. Punishment for institutions : (if the squad reports that the college is also involved in encouraging malpractices)
 - (i) A show cause notice shall be issued to the college.
 - (ii) Imposing a suitable fine on the college.
 - (iii) Shifting the examination centre from the college to another college for a specific period of not less than one year.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D - I YEAR Theory: 3 Hrs. /Week

(14T00101) HUMAN ANATOMY & PHYSIOLOGY (THEORY)

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

2. Upon completion of the course the student shall be able to:

- a. describe the structure (gross and histology) and functions of various organs of the human body;
- b. describe the various homeostatic mechanisms and their imbalances of various systems;
- c. identify the various tissues and organs of the different systems of the human body;
- d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
- e. appreciate coordinated working pattern of different organs of each system; and
- f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. Lecture wise

program: Topics

- 1 Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
- 2 Structure of cell its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4 a) Osseous system structure, composition and functions of the Skeleton. (done in practical classes -6hrs)
 - b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5 Haemopoetic System

- a) Composition and functions of blood
- b) Haemopoesis and disorders of blood components (definition of disorder)
- c) Blood groups
- d) Clotting factors and mechanism
- e) Platelets and disorders of coagulation

6 Lymph

- a) Lymph and lymphatic system, composition, formation and circulation.
- b) Spleen: structure and functions, Disorders
- c) Disorders of lymphatic system (definition only)
- 7 Cardiovascular system
 - a) Anatomy and functions of heart
 - b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
 - c) Electrocardiogram (ECG)
 - d) Cardiac cycle and heart sounds
 - e) Blood pressure its maintenance and regulation

f) Definition of the following disorders

Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

- 8 Respiratory system
 - a) Anatomy of respiratory organs and functions
 - b) Mechanism / physiology of respiration and regulation of respiration
 - c) Transport of respiratory gases
 - d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.
- 9 Digestive system
 - a) Anatomy and physiology of GIT
 - b) Anatomy and functions of accessory glands of GIT
 - c) Digestion and absorption
 - d) Disorders of GIT (definitions only)
- 10 Nervous system
 - a) Definition and classification of nervous system
 - b) Anatomy, physiology and functional areas of cerebrum
 - c) Anatomy and physiology of cerebellum
 - d) Anatomy and physiology of mid brain
 - e) Thalamus, hypothalamus and Basal Ganglia
 - f) Spinal card: Structure & reflexes mono-poly-planter
 - g) Cranial nerves names and functions
 - h) ANS Anatomy & functions of sympathetic & parasympathetic N.S.
- 11 Urinary system
 - a) Anatomy and physiology of urinary system
 - b) Formation of urine
 - c) Renin Angiotensin system Juxtaglomerular apparatus acid base Balance
 - d) Clearance tests and micturition
- 12 Endocrine system
 - a) Pituitary gland
 - b) Adrenal gland
 - c) Thyroid and Parathyroid glands
 - d) Pancreas and gonads
- 13 Reproductive system
 - a)Male and female reproductive system
 - b) Their hormones Physiology of menstruation
 - c) Spermatogenesis & Oogenesis
 - d) Sex determination (genetic basis)
 - e) Pregnancy and maintenance and parturition
 - f) Contraceptive devices

14 Sense organs

- a) Eye
- b) Ear
- c) Skin
- d) Tongue & Nose

15 Skeletal muscles

- a) Histology
- b) Physiology of Muscle contraction
- c) Physiological properties of skeletal muscle and their disorders (definitions)
- 16 Sports physiology
 - a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
 - b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
 - c) Drugs and athletics

Text books

- a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
- b. Wilson K.J.W, Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

- a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
- b. Chatterjee, C.C. Human physiology. Volume 1&11. Publisher: medical allied agency, Calcutta.
- c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- d. Gray's anatomy. Publisher: Churchill Livingstone, London

Pharm. D – I YEAR

(14T00107) HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book (100pages), Stationary items, Blood lancet.

List of Experiments:

- 1. Study of tissues of human body
 - (a) Epithelial tissue.
 - (b) Muscular tissue.
- 2. Study of tissues of human body
 - (a) Connective tissue.
 - (b) Nervous tissue.
- 3. Study of appliances used in hematological experiments.
- 4. Determination of W.B.C. count of blood.
- 5. Determination of R.B.C. count of blood.
- 6. Determination of differential count of blood.
- 7. Determination of
 - (a) Erythrocyte Sedimentation Rate.
 - (b) Hemoglobin content of Blood.
 - (c) Bleeding time & Clotting time.
- 8. Determination of
 - (a) Blood Pressure.
 - (b) Blood group.
- 9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton.
 - (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.
 - (e) Digestive system.
 - (f) Urinary system.
 - (g) Nervous system.
 - (h) Special senses.
 - (i) Reproductive system.
- 10. Study of different family planning appliances.
- 11. To perform pregnancy diagnosis test.
- 12. Study of appliances used in experimental physiology.
- 13. To record simple muscle curve using gastroenemius sciatic nerve preparation.
- 14. To record simple summation curve using gastroenemius sciatic nerve preparation.
- 15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
- 16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.
- 17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition,

Publisher: B.S Shah Prakashan, Ahmedabad.

References

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune Anderson Experimental Physiology, Latest edition, Publisher: NA

	Sessional	Annual	
Identification	04	10	
Synopsis	04	10	
Major Experiment	07	20	
Minor Experiment	03	15	
Viva	02	15	
Max Marks	20	70	
Duration	03hrs	04hrs	

Scheme of Practical Examination:

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – I YEAR

(14T00102) PHARMACEUTICS (THEORY)

Theory: 2 Hrs. /Week

1. Scope and objectives: This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

2. Upon the completion of the course the student should be able to:

- a. know the formulation aspects of different dosage forms;
- b. do different pharmaceutical calculation involved in formulation;
- c. formulate different types of dosage forms; and
- d. appreciate the importance of good formulation for effectiveness.

3. Course materials:

Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

References

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Topics

- 1 a. Introduction to dosage forms classification and definitions
 - b. Prescription: definition, parts and handling
 - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
- 3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- 4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
- 5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- 6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.
- 7 Biphasic dosage forms: Suspensions and emulsions: Definition, advantages and disadvantages, classification, tests for the type of emulsion, formulation, stability and evaluation.
- 8 Suppositories and pessaries: Definition, advantages and disadvantages, types of bases, method of preparation, Displacement value and evaluation.

- 9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
- 10 Pharmaceutical calculations.
- 11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- 12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

Pharm. D – I YEAR

(14T00108) PHARMACEUTICS (PRACTICAL)

Practical: 3 Hrs. /Week

List of Experiments:

1. Syrups

- a. Simple Syrup I.P
- b. Syrup of Ephedrine Hcl NF
- c. Syrup Vasaka IP
- d. Syrup of ferrous Phosphate IP
- e. Orange Syrup

2. Elixir

- a. Piperizine citrate elixir BP
- b. Cascara elixir BPC
- c. Paracetamol elixir BPC

3. Linctus

- a. Simple Linctus BPC
- b. Pediatric simple Linctus BPC

4. Solutions

- a. Solution of cresol with soap IP
- b. Strong solution of ferric chloride BPC
- c. Aqueous Iodine Solution IP
- d. Strong solution of Iodine IP
- e. Strong solution of ammonium acetate IP

5. Liniments

- a. Liniment of turpentine IP*
- b. Liniment of camphor IP

6. Suspensions*

- a. Calamine lotion
- b. Magnesium Hydroxide mixture BP

7. Emulsions*

- a. Cod liver oil emulsion
- b. Liquid paraffin emulsion

8. Powders*

- a. Eutectic powder
- b. Explosive powder
- c. Dusting powder
- d. Insufflations

9. Suppositories*

- a. Boric acid suppositories
- b. Chloral suppositories

10. Incompatibilities

- a. Mixtures with Physical
- b. Chemical & Therapeutic incompatibilities
- * colourless bottles required for dispensing * Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessional	Annual	
Synopsis	05	15	
Major Experiment	10	25	
Minor Experiment	03	15	
Viva	02	15	
Max Marks	20	70	
Duration	03hrs	04hrs	

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – I YEAR

(14T00103) MEDICINAL BIOCHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the Subject: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. Objectives of the Subject (Know, do, appreciate) :

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to -

- a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
- c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- e. do the qualitative analysis and determination of biomolecules in the body fluids.

3. Lecture wise programme:

Topics

- 1 **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- 2 **Enzymes**: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- 3 **Carbohydrate metabolism**: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

- 4 **Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell**; composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 The kidney function tests: Role of kidney; Laboratory tests for normal function including
 - a) Urine analysis (macroscopic and physical examination, quantitative and Semi quantitative tests.)
 - b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
 - c) Urine concentration test
 - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
 - a) Test for hepatic dysfunction-Bile pigments metabolism.
 - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
 - c) Dye tests of excretory function.
 - d) Tests based upon abnormalities of serum proteins.
 - Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
 - Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)
- 13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium, potassium, chlorides and bicarbonates in the body fluids.

Text books (Theory)

- a. Harpers review of biochemistry Martin
- b. Text book of biochemistry D.Satyanarayana
- c. Text book of clinical chemistry- Alex kaplan & Laverve L.Szabo

References (Theory)

- a. Principles of biochemistry -- Lehninger
- b. Text book of biochemistry -- Ramarao
- c. Practical Biochemistry-David T.Plummer.
- d. Practical Biochemistry-Pattabhiraman

Pharm. D – I YEAR

(14T00109) MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

Title of the Experiment:

- 1 Qualitative analysis of normal constituents of urine.*
- 2 Qualitative analysis of abnormal constituents of urine.*
- 3 Quantitative estimation of urine sugar by Benedict's reagent method.**
- 4 Quantitative estimation of urine chlorides by Volhard's method.**
- 5 Quantitative estimation of urine creatinine by Jaffe's method.**
- 6 Quantitative estimation of urine calcium by precipitation method.**
- 7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
- 8 Preparation of Folin Wu filtrate from blood.*
- 9 Quantitative estimation of blood creatinine.**
- 10 Quantitative estimation of blood sugar Folin-Wu tube method.**
- 11 Estimation of SGOT in serum.**
- 12 Estimation of SGPT in serum.**
- 13 Estimation of Urea in Serum.**
- 14 Estimation of Proteins in Serum.**
- 15 Determination of serum bilirubin**
- 16 Determination of Glucose by means of Glucoseoxidase.**
- 17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
- 18 Study of factors affecting Enzyme activity. (pH & Temp.)**
- 19 Preparation of standard buffer solutions and its pH measurements (any two)*
- 20 Experiment on lipid profile tests**
- 21 Determination of sodium, calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

- 1. Minimum & Maximum number of pages.
- 2. It shall be computer draft copy.
- 3. Reference(s) shall be included at the end.
- 4. Name and signature of the student.
- 5. Assignment can be a combined presentation at the end of the academic year.
- 6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessional	Annual	
Synopsis	05	15	
Major Experiment	10	25	
Minor Experiment	03	15	
Viva	02	15	
Max Marks	20	70	
Duration	03hrs	04hrs	

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – I YEAR

(14T00104) PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. Scope and objectives: This course is designed to impart a very good knowledge about

- a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
- b. Some important physical properties of organic compounds;
- c. Free radical/nucleophyllic [alkyl/ acyl/ aryl]/electrophyllic substitution, free radical/nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
- d. Some named organic reactions with mechanisms; and
- e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Lecture wise

Programme: Topics

- 1 Structures and Physical properties:
 - a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
 - b. Acids and bases, Lowry bronsted and Lewis theories
 - c. Isomerism
- 2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides,

Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.

- 3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
- 4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- 5 Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN₂ reactions. Stereochemistry and stearic hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.
- 6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity,E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- 8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

- 9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
- 10 Elecrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.
- 11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.
- 12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- 13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.
- 14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
- 15 Oxidation reduction reaction.
- 16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

Text books

- a. T.R.Morrison and R. Boyd Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finar- Organic chemistry, the fundamentals of chemistry

Reference books

- a. Organic chemistry J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown
- c. Advanced organic chemistry- Jerry March, Wiley
- d. Organic chemistry- Cram and Hammered, Pine Hendrickson

Pharm. D – I YEAR

(14T00110) PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

- 1. Acetanilde / aspirin (Acetylation)
- 2. Benzanilide / Phenyl benzoate (Benzoylation)
- 3. P-bromo acetanilide / 2,4,6 tribromo aniline (Bromination)
- 4. Dibenzylidene acetone (Condensation)
- 5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
- 6. Benzoic acid / salicylic acid (Hydrolysis of ester)
- 7. M-dinitro benzene (Nitration)
- 8. 9, 10 Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
- 9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
- 10. Benzophenone oxime
- 11. Nitration of salicylic acid
- 12. Preparation of picric acid
- 13. Preparation of O-chlorobenzoic acid from O-chlorotolune
- 14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carbohydrates, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D – I YEAR

(14T00105) PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory: 2 Hrs. /Week

1. Scope and objectives: This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

2. Upon completion of the course student shall be able to:

- a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
- b. know the analysis of the inorganic pharmaceuticals their applications; and
- c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. Lecture wise programme:

1. Errors

Errors in quantitative analysis, classification of errors, concept of accuracy and precision, treatment of analytical results.

2. Volumetric analysis

Principle of volumetric analysis, different methods of analysis, different methods for expressing concentrations of solutions, primary and secondary standards.

3. Acid-base titrations

Acid- base concepts, relative strength of acids and bases, law of mass action, common ion effect, ionic product of water, Henderson-Hasselbalch equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.

4. Redox titrations

Concepts of oxidation-reduction reactions, redox reactions, theory of redox titrations, redox indicators, iodometry and iodimetry, titrations involving cerric sulphate, potassium iodate, potassium bromate, potassium permanganate, titanous chloride.

5. Non aqueous titration

Theoretical basis, types of solvents, preparations and standardization of titrant solutions, titration of weak acid, weak bases and indicators. standardisation of perchloric acid, lithium and sodium methoxide, tetra butyl ammonium hydroxide.

6. Precipitation titrations

Introduction, types of precipitation titrations, end point detection.

7. Complexometric titrations

Introduction, principle, types of titrations, endpoint detection.

8. Theory of Indicators

9. Gravimetry

Basic concepts, Precipitation techniques, co-precipitation, post-precipitation, various steps involved in gravimetric analysis, pharmaceutical applications.

10. Limit tests

Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, lead and heavy metals.

11.Medicinal Gases

Preparation and uses of the following Oxygen, Carbon dioxide, Helium, Nitrogen and Nitrous Oxide.

Method of preparation, assay, storage conditions and uses of inorganic compounds listed in I.P belonging to the following categories.

12. Acidifiers

Dilute hydrochloric acid, Sodium phosphate, Ammonium chloride.

13. Antacids

Classification, Qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, Sodium bicarbonate, Potassium citrate, Aluminium hydroxide gel, Dried aluminium hydroxide gel, Magnesium hydroxide, Light and heavy magnesium trisilicate, light and heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.

14. Cathartics

Magnesium hydroxide, Magnesium sulphate, Magnesium carbonate and Sodium phosphate.

15. Electrolyte replenisher

- *Electrolytes used for replacement therapy*: Sodium chloride, Potassium chloride, Calcium gluconate,
- *Electrolytes used in the acid-base therapy* : Sodium acetate, Potassium acetate, Sodium bicarbonate, Potassium bicarbonate, Sodium citrate, Sodium lactate, Ammonium chloride. Electrolyte combination therapy, Compound sodium chloride solution, Sodium chloride injection and Oral rehydration salt.

16. Essential Trace elements

Definition, Physiological role of Iron, Copper, Zinc,

Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine.

17. Antimicrobials

- Hydrogen Peroxide, Potassium Permanganate, Chlorinated Lime, Iodine, Boric Acid, Silver Nitrate, Selenium Sulphide.
- **18. Pharmaceutical Aids:** Sodium bisulphite, sodium metabisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methyl cellulose, purified water, water for injection and sterile water for injection.

19. Dental products

Anti-caries Agents: Role of Fluorides as anti-caries agents, Sodium fluoride.

Dentifrices: Calcium carbonate, dibasic calcium phosphate, Zinc chloride.

20. Miscellaneous compounds.

Sclerosing agents: Hypertonic saline, Sodium tetra decyl sulphate.

Expectorants: Potassium citrate and Potassium iodide.

Sedative: Potassium bromide.

Antidotes: Sodium nitrite, Sodium thiosulphate and Charcoal

Respiratory stimulant: Ammonium carbonate.

21. Radiopharmaceuticals.

Introduction, measurement of radioactivity, clinical applications and dosage, hazards and precautions.

Text books

- a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

References

- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- Analytical chemistry principles by John H. Kennedy
 d. I.P.1985 and 1996, Govt. of India, Ministry of health

Pharm. D – I YEAR

(14T00111) PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

1. Limit test (6 exercises)

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- a. Ammonium chloride- Acid-base titration
- b. Ferrous sulphate- Cerimetry
- c. Copper sulpahte- Iodometry
- d. Calcilugluconate- Complexometry
- e. Hydrogen peroxide Permanganometry
- f. Sodium benzoate Nonaqueous titration
- g. Sodium chloride Modified volhard's method
- h. Assay of KI KIO₃ titration
- i. Gravimetric estimation of barium as barium sulphate
- j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a. Sodium hydroxide and sodium carbonate
- b. Boric acid and Borax
- c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a. Sodium bicorbonate
- b. Barium sulphate
- c. Ferrous sulphate
- d. Potassium chloride

5. Test for purity (Any two exercises)

- a. Swelling power in Bentonite
- b. Acid neutralising capacity in aluminium hydroxide gel
- c. Ammonium salts in potash alum
- d. Adsorption power heavy Kaolin
- e. Presence of Iodates in KI

6. Preparations (Any two exercises)

- a. Boric acids
- b. Potash alum
- c. Calcium lactate
- d. Magnesium suphate

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, vivavoce and record maintenance).

Pharm. D – I YEAR

(14T00106) REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory: 3 Hrs. /Week

REMEDIAL MATHEMATICS:

1. Scope and objectives: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

2. Upon completion of the course the student shall be able to : -

- a. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
- b. solve the problems of different types by applying theory; and
- c. appreciate the important applications of mathematics in pharmacy.

3. Lecture wise programme :

Topics

- 1 Algebra : Determinants, Matrices
- 2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
- 3 Analytical Geometry : Points, Straight line, circle, parabola
- 4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
- 5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

Text books

- a. Differential calculus By Shantinarayan
- b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

References:

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

BIOLOGY:

1. Scope and objectives: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. Lecture wise programme :

Topic PART – A

- 1 Introduction
- 2 General organization of plants and its inclusions
- 3 Plant tissues
- 4 Plant kingdom and its classification
- 5 Morphology of plants
- 6 Root, Stem, Leaf and Its modifications
- 7 Inflorescence and Pollination of flowers
- 8 Morphology of fruits and seeds
- 9 Plant physiology
- 10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
- 11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

- 1 Study of Animal cell
- 2 Study animal tissues
- 3 Detailed study of frog
- 4 Study of Pisces, Raptiles, Aves
- 5 Genearal organization of mammals
- 6 Study of poisonous animals

Text books

a. Text book of Biology by S.B.Gokhale

b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

References:

a. A Text book of Biology by B.V.Sreenivasa Naidu

- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

Pharm. D – I YEAR

(14T00112) BIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week Title:

- 1. Introduction of biology experiments
- 2. Study of cell wall constituents and cell inclusions
- 3. Study of Stem modifications
- 4. Study of Root modifications
- 5. Study of Leaf modifications
- 6. Identification of Fruits and seeds
- 7. Preparation of Permanent slides
- 8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
- 9. Simple plant physiological experiments
- 10. Identification of animals
- 11. Detailed study of Frog
- 12. Computer based tutorials

Scheme of Practical Examination :

	Sessional	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, vivavoce and record maintenance.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm.D – II YEAR

(14T00201) PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope of the Subject: This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
- 2. Objectives of the Subject : Upon completion of the subject student shall be able to
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

3. Detailed syllabus and lecture wise schedule :

Chapter

1 **Basic principles of cell injury and Adaptation**

- a) Causes, Pathogenesis and morphology of cell injury
- b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

2 Inflammation

- a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
- b) Repairs of wounds in the skin, factors influencing healing of wounds

3 Diseases of Immunity

- a) Introduction to Tand B cells
- b) MHC proteins or transplantation antigens
- c) Immune tolerance
 - Hypersensitivity

Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs

- Autoimmunity

Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.

- Acquired immune deficiency syndrome (AIDS)
- Amylodosis
- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 5 Types of shock, mechanisms, stages and management
- 6 Biological effects of radiation

7 Environmental and nutritional diseases

- i) Air pollution and smoking- SO2,NO, NO2, and CO
- ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 8 Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and Alcoholic liver diseases
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :

Sexually transmitted diseases (HIV,Syphilis,Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhinde

References (Theory)

a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

4. Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
- 2. Reference(s) shall be included at the end.
- 3. Assignment can be a combined presentation at the end of the academic year
- 4. It shall be computer draft copy.
- 5. Name and signature of the student
- 6. Time allocated for presentation may be 8+2 Min

Pharm. D – II YEAR

(14T00202) PHARMACEUTICAL MICROBIOLOGY (THEORY) Theory: 3 Hrs. /Week

1. Scope of the Subject: Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future. This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. Its also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. Objectives of the subject:

Upon completion of the subject student shall be able to -

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do cultivation and identification of the microorganisms in the laboratory;
- d. do identification of diseases by performing the diagnostic tests; and
- e. appreciate the behavior of motility and behavioral characteristics of microorganisms.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

- 1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
- 2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- 4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria Total and Viable counting techniques.
- 5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.
- 6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive). Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- 8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.
- 9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B_2 and B_{12} . Standardisation of vaccines and sera.

10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

Text books (Theory)

- a. Vanitha Kale and Kishor Bhusari " Applied Microbiology " Himalaya Publishing house Mumbai.
- b. Mary Louis Turgeon "Immunology and Serology in Laboratory Medicines" 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- c. Harsh Mohan, "Text book of Pathology" 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

References (Theory)

- a. Prescot L.M., Jarley G.P Klein D.A "Microbiology" 2nd- edition Mc Graw Hill Company Inc
- b. Rawlins E.A."Bentley's Text Book of Pharmaceutics" B ailliere Tindals 24-28 London 1988
- c. Forbisher "Fundamentals of Microbiology" Philidelphia W.B. Saunders.
- d. Prescott L.M. Jarley G.P., Klein.D.A. "Microbiology."2nd edition WMC Brown Publishers, Oxford. 1993
- e. War Roitt, Jonathan Brostoff, David male, "Immunology"3rd edition 1996, Mosby-year book Europe Ltd, London.
- f. Pharmacopoeia of India, Govt of India, 1996.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D – II YEAR

(14T00207) PHARMACEUTICAL MICROBIOLOGY (PRACTICAL) Practical: 3 Hrs./Week

Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation.*
- 3 Staining techniques Simple staining ; Gram's staining ; Negative staining**
- 4 Study of motility characters*.
- 5 Enumeration of micro-organisms (Total and Viable)*
- 6 Study of the methods of isolation of pure culture.*
- 7 Bio chemical testing for the identification of micro*-organisms.
- 8 Cultural sensitivity testing for some micro-organisms.*
- 9 Sterility testing for powders and liquids.*
- 10 Determination of minimum inhibitory concentration.*
- 11 Microbiological assay of antibiotics by cup plate method.*
- 12 Microbiological assay of vitamins by Turbidometric method**
- 13 Determination of RWC.**
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.**
- * Indicate minor experiment & ** indicate major experiment

Assignments:

- 1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
- 2. Visit to milk dairies (Pasturization) and microbial laboratories(other sterization methods) & study the activities and equipment/instruments used and reporting the same.
- 3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

- 1. Minimum & Maximum number of pages.
- 2. It shall be computer draft copy.
- 3. Reference(s) shall be included at the end.
- 4. Name and signature of the student.
- 5. Assignment can be a combined presentation at the end of the academic year.
- 6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – II YEAR

(14T00203) PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory: 3 Hrs. /Week

1. Scope and objectives: This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

2. Upon completion of the course student shall be able to:

- a. understand the basic principles of cultivation, collection and storage of crude drugs;
- b. know the source, active constituents and uses of crude drugs; and
- c. appreciate the applications of primary and secondary metabolites of the plant.

3. Lecture wise programme:

Topics

- 1 Introduction.
- 2 Definition, history and scope of Pharmacognosy.
- 3 Classification of crude drugs.
- 4 Cultivation, collection, processing and storage of crude drugs.
- 5 Detailed method of cultivation of crude drugs.
- 6 Study of cell wall constituents and cell inclusions.
- 7 Microscopical and powder Microscopical study of crude drugs.
- 8 Study of natural pesticides.
- 9 Detailed study of various cell constituents.
- 10 Carbohydrates and related products.
- 11 Detailed study carbohydrates containing drugs.(11 drugs)
- 12 Definition sources, method extraction, chemistry and method of analysis of lipids.
- 13 Detailed study of oils.
- 14 Definition, classification, chemistry and method of analysis of protein.
- 15 Study of plants fibers used in surgical dressings and related products.
- 16 Different methods of adulteration of crude drugs.

Text books

- a. Pharmacognosy by G.E. Trease & W.C.Evans.
- b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

References:

- a. Pharmacognosy by Brady & Tyler.E.
- b. Pharmacognosy by T.E.Wallis.
- c. Pharmacognosy by C.S. Shah & Qadery.
- d. Pharmacognosy by M.A. Iyengar.

Pharm. D – II YEAR

(14T00208) PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical: 3 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box. List of experiments:

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia.cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil, sesame oil, shark liver oil, bees wax)
- 27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessional	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Pharm. D – II YEAR

Theory: 3 Hrs. /Week

(14T00204) PHARMACOLOGY - I (THEORY)

- 1. Scope of the Subject: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- 2. Objectives of the Subject : Upon completion of the subject student shall be able to (Know, do, appreciate)
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
 - b. handle and carry out the animal experiments;
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
- 3. correlate and apply the knowledge therapeutically.
- 4. Detailed syllabus and lecture wise schedule:

Title of the topic

1. General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics
- e) Factors modifying drug effects
- f) Drug toxicity Acute, sub- acute and chronic toxicity.
- g) Pre-clinical evaluations
- h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriactics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

3. Pharmacology of drugs acting on cardiovascular system

a) Antihypertensives

- b) Anti-anginal drugs
- c) Anti-arrhythmic drugs
- d) Drugs used for therapy of Congestive Heart Failure
- e) Drugs used for hyperlipidaemias

4. Pharmacology of drugs acting on Central Nervous System

- a) General anesthetics
- b) Sedatives and hypnotics
- c) Anticonvulsants
- d) Analgesic and anti-inflammatory agents
- e) Psychotropic drugs
- f) Alcohol and methyl alcohol
- g) CNS stimulants and cognition enhancers
- h) Pharmacology of local anaesthetics

5. Pharmacology of Drugs acting on Respiratory tract

- a) Bronchodilators
- b) Mucolytics
- c) Expectorants
- d) Antitussives
- e) NasalDecongestants

6. Pharmacology of Hormones and Hormone antagonists

- a) Thyroid and Antithyroid drugs
- b) Insulin, Insulin analogues and oral hypoglycemic agents
- c) Sex hormones and oral contraceptives
- d) Oxytocin and other stimulants and relaxants

7. Pharmacology of autocoids and their antagonists

- a) Histamines and Antihistaminics
- b) 5-Hydroxytryptamine and its antagonists
- c) Lipid derived autocoids and platelet activating factor

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Pharm. D – II YEAR

(14T00205) COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

- 1. Scope: In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counseling, health screening services for improved patient care in the community set up.
- 2. Objectives: Upon completion of the course, the student shall be able to
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counseling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU

with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.

2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Lecture wise programme :

Topics

- 1 Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist
- 2 Community Pharmacy Management
 - a) Selection of site, Space layout, and design
 - b) Staff, Materials- coding, stocking
 - c) Legal requirements
 - d) Maintenance of various registers
 - e) Use of Computers: Business and health care soft wares
- **3 Prescriptions** parts of prescription, legality & identification of medication related problems like drug interactions.
- 4 Inventory control in community pharmacy Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock

5 Pharmaceutical care

Definition and Principles of Pharmaceutical care.

6 Patient counseling

Definition, outcomes, various stages, barriers, Strategies to overcome barriers

Patient information leaflets- content, design, & layouts, advisory labels

7 **Patient medication adherence** Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8 Health screening services Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing

9 OTC Medication- Definition, OTC medication list & Counselling

10 Health Education

WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.

Commonly occurring Communicable Diseases, causative agents,

Clinical presentations and prevention of communicable diseases - Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,

Syphilis, Gonorrhea and AIDS

Balance diet, and treatment & prevention of deficiency disorders

Family planning – role of pharmacist

11 Responding to symptoms of minor ailments

Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.

12 Essential Drugs concept and Rational Drug Therapy Role of community pharmacist

13 Code of ethics for community pharmacists

Text Books:

- a. Community Pharmacy by H.P Tipnis
- b. Health Education and Community Pharmacy by N.S.Parmar.
- c. WHO consultative group report.
- d. Drug store & Business management by Mohammed Ali & Jyoti.

References:

- a. Handbook of pharmacy health care.Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review Edt. Leon Shargel. Lippincott Williams & Wilkins

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D – II YEAR

(14T00206) PHARMACOTHERAPEUTICS - I (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope of the Subject: This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly Pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives: At completion of this subject it is expected that students will be able to understand
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- 3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias
- Respiratory system : Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
 Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

3 General prescribing guidelines for

- a. Paediatric patients
- b. Geriatric patients
- c. Pregnancy and breast feeding
- 4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial

5 Introduction to rational drug use

Definition, Role of pharmacist. Essential drug concept. Rational drug formulations

Text Books

- a. Clinical Pharmacy and Therapeutics Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach Joseph T. Dipiro et al. Appleton & Lange.

References:

- a. Pathologic basis of disease Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

Pharm. D – II YEAR

(14T00209) PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical: 3 Hrs./Week Practicals

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 - 2000 words] should be submitted for evaluation.

Format of the assignment:

- 1. Minimum & Maximum number of pages.
- 2. Reference(s) shall be included at the end.
- 3. Assignment can be a combined presentation at the end of the academic year.
- 4. It shall be computer draft copy.
- 5. Name and signature of the student.
- 6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, vivavoce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D – III YEAR

(14T00301) PHARMACOLOGY - II (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the Subject: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamines, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. Objectives of the Subject Upon completion of the subject student shall be able to:

- a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
- b. carry out the animal experiments confidently,
- c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
- d. correlate and apply the knowledge therapeutically.

3. Detailed syllabus and lecture wise

schedule: Title of the topic

- 1. Pharmacology of Drugs acting on Blood and blood forming agents
 - a) Anticoagulants
 - b) Thrombolytics and antiplatelet agents
 - c) Haemopoietics and plasma expanders

2. Pharmacology of drugs acting on Renal System

- a) Diuretics
- b) Antidiuretics

3. Chemotherapy

- a) Introduction
- b) Sulfonamides and co-trimoxazole
- c) Penicillins and Cephalosporins
- d) Tetracyclins and Chloramphenicol
- e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
- f) Quinolines and Fluroquinolines
- g) Antifungal antibiotics
- h) Antiviral agents
- i) Chemotherapy of tuberculosis and leprosy
- j) Chemotherapy of Malaria
- k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
- 1) Pharmacology of Anthelmintic drugs
- m) Chemotherapy of cancer (Neoplasms)

4 Immunopharmacology

Pharmacology of immunosuppressants and stimulants

5. **Principles of Animal toxicology**

Acute, sub acute and chronic toxicity

6. The dynamic cell: The structures and functions of the components of the cell

- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
- c) DNA replication: General, bacterial and eukaryotic DNA replication.
- d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
- e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

References:

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
- 4 Genes VIII by Lewin, B., (2004)
- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

References (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Pharm. D – III YEAR

(14T00307) PHARMACOLOGY - II (PRACTICAL)

Practical: 3 Hrs. /Week

List of Experiments:

- 1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
- 2. Study of physiological salt solutions used in experimental pharmacology.
- 3. Study of laboratory appliances used in experimental pharmacology.
- 4. Study of use of anesthetics in laboratory animals.
- 5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
- 6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
- 7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
- 8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
- 9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
- 10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
- 11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
- 12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
- 13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical):

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill
 - livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

Scheme of Practical Examination:

	Sessional	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given	04	10
Graph or simulated experiment)		
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D – III YEAR

(14T00302) PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

1. Quality Assurance:

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- b. **TLC**: Introduction, principle, techniques, Rf value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- d. **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. HPLC: Introduction, theory, instrumentation, and applications.
- f. HPTLC: Introduction, theory, instrumentation, and applications.
- g. **Gas Chromatography**: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. Gel filtration and affinity chromatography: Introduction, technique, applications.

3. Electrometric Methods:

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry**: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. Conductometry: Introduction, conductivity cell, conductometric titrations and applications.

- c. **Polarography**: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. Spectroscopy:

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

- a. Absorption Spectroscopy:
 - Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy**: Vibrational transitions, frequency structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.
- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.
- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. Atomic Absorption Spectrometry: Introduction, Theory, types of electrodes, instrumentation and applications.
- d. Atomic Emission Spectroscopy: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
- e. NMR & ESR (introduction only): Introduction, theoretical aspects and applications.
- f. **Mass Spectroscopy**: (**Introduction only**) Fragmentation, types of ions produced mass spectrum and applications.
- g. **Polarimetry:** (Introduction only) Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h. **X-RAY Diffraction: (Introduction only)** Theory, reciprocal lattice concept, diffraction patterns and applications.
- i. Thermal Analysis: Introduction, instrumentation, applications, and DSC and DTA.

References:

- 1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
- 2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
- 3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
- 4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
- 5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
- 6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
- 7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
- 8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
- 9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
- 10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
- 11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
- 12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
- 13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
- 14. TLC by Stahl, Spring Verlay.
- 15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
- 16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
- 17. I.P.-1996, The Controller of Publications, New Delhi.
- 18. BPC- Dept. of Health, U.K. for HMSO.
- 19. USP Mack Publishing Co., Easton, PA.
- 20. The Extra Pharmacopoeia The Pharm. Press, London.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D – III YEAR

(14T00308) PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments:

- 1. Separation and identification of Amino Acids by Paper Chromatography.
- 2. Separation and identification of Sulpha drugs by TLC technique.
- 3. Effect of pH and solvent on the UV spectrum of given compound.
- 4. Comparison of the UV spectrum of a compound with that of its derivatives.
- 5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
- 6. Conductometric titration of mixture of acids with a strong base.
- 7. Potentiometric titration of a acid with a strong base.
- 8. Estimation of drugs by Fluorimetric technique.
- 9. Study of quenching effect in fluorimetry.
- 10. Colourimetric estimation of Supha drugs using BMR reagent.
- 11. Simultaneous estimation of two drugs present in given formulation.
- 12. Assay of Salicylic Acid by colourimetry.
- 13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
- 14. Determination of Na/K by Flame Photometry.
- 15. Determination of pKa using pH meter.
- 16. Determination of specific rotation.
- 17. Comparison of the IR spectrum of a compound with that of its derivatives.
- 18. Demonstration of HPLC.
- 19. Demonstration of HPTLC.
- 20. Demonstration of GC-MS.
- 21. Demonstration of DSC.
- 22. Interpretation of NMR spectra of any one compound.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – III YEAR

Theory: 3 Hrs. /Week

(14T00303) PHARMACOTHERAPEUTICS - II (THEORY)

1. Scope of the Subject: This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. Objectives of the Subject Upon completion of the subject student shall be able to -

- a. know the pathophysiology of selected disease states and the rationale for drug therapy
- b. know the therapeutic approach to management of these diseases;
- c. know the controversies in drug therapy;
- d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
- e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- 3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases -

Title of the topic

1. Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis

2 Musculoskeletal disorders

Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.

3 Renal system

Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

- **4 Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 Dermatology: Psoriasis, Scabies, Eczema, Impetigo

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

References (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

Pharm. D – III YEAR

(14T00309) PHARMACOTHERAPEUTICS - II (PRACTICAL)

Practical : 3 Hrs./Week

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 - 2000 words] should be submitted for evaluation.

Format of the assignment :

- 1. Minimum & Maximum number of pages.
- 2. Reference(s) shall be included at the end.
- 3. Assignment can be a combined presentation at the end of the academic year.
- 4. It shall be computer draft copy.
- 5. Name and signature of the student.
- 6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – III YEAR

(14T00304) PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

- 1. Scope of the Subject: (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
- 2. Objectives of the Subject: Upon completion of the subject student shall be able to (Know, do, and appreciate)
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

3. Detailed syllabus and lecture wise schedule: Title of the topic

- Title of the topic
- 1. **Pharmaceutical Legislations** A brief review.
- 2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
- 3. **Drugs and Cosmetics Act, 1940, and its rules 1945.** Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y. Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.

Constitution and Functions of DTAB, DCC, CDL.

Qualification and duties -Govt. analyst and Drugs Inspector.

4. Pharmacy Act -1948.

Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.Medicinal and Toilet Preparation Act –1955. Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.

- 5. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
- 6. Study of Salient Features of Drugs and magic remedies Act and its rules.
- 7. Study of essential Commodities Act Relevant to drugs price control Order.
- 8. Drug Price control Order & National Drug Policy (Current).
- 9. **Prevention Of Cruelty to animals Act-1960.**
- 10. Patents & design Act-1970.
- 11. Brief study of prescription and Non-prescription Products.

4. Assignments:

Format of the assignment

- 1. Minimum & Maximum number of pages
- 2. It shall be a computer draft copy
- 3. Reference(s) shall be included at the end.
- 4. Name and signature of the student
- 5. Assignment can be a combined presentation at the end of the academic year.
- 6. Time allocated for presentation may be 8+2 Min

Case studies relating to

- 1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
- 2. Various prescription and non-prescription products.
- 3. Medical and surgical accessories.
- 4. Diagnostic aids and appliances available in the market.

Text books (Theory)

Mithal, B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

Pharm. D – III YEAR

Theory: 3 Hrs. /Week

(14T00305) MEDICINAL CHEMISTRY (THEORY)

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationaship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

- 2. Anti-infective agents
 - a) Local anti-infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti-infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmentics
 - i) Antiscabies and Antipedicular agents
- 3. Sulphonamides and sulphones
- 4. Antimalarials
- 5. Antibiotics
- 6. Antineoplastic agents
- 7. Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators
 - c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
- 8. Hypoglycemic agents
- 9. Thyroid and Antithyroid agents
- 10. Diureties
- 11. Diagnostic agents
- 12. Steroidal Hormones and Adrenocorticoids

References:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.

- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wileyinterscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

Practical: 3 Hrs./Week

Pharm. D – III YEAR

(14T00310) MEDICINAL CHEMISTRY (PRACTICAL)

- 1. Assays of important drugs from the course content.
- 2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
- 3. Monograph analysis of important drugs.
- 4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – III YEAR

Theory: 2 Hrs. /Week

(14T00306) PHARMACEUTICAL FORMULATIONS (THEORY)

- 1. Scope of the Subject: Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
- 2. Objectives of the Subject: Upon completion of the subject student shall be able to (Know, do, appreciate)
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and
 - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

- 1. Pharmaceutical dosage form- concept and classification
- 2. **Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
- 3. **Capsules**; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
- 4. **Liquid orals**: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
- 5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

6. Semisolid preparations

- Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
- 8. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular etc.

Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy Cooper & Gun
- d. The design and manufacture of medicines by M. Aulton

References (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

Pharm. D – III YEAR

Practical: 3 Hrs./Week

(14T00310) PHARMACEUTICAL FORMULATIONS (PRACTICAL)

List of Experiments :

1. Manufacture of Tablets

- a. Ordinary compressed tablet-wet granulation
- **b.** Tablets prepared by direct compression.
- c. Soluble tablet.
- d. Chewable tablet.

2. Formulation and filling of hard gelatin capsules

3. Manufacture of parenterals

- **a.** Ascorbic acid injection
- **b.** Calcium gluconate injection
- **c.** Sodium chloride infusion.
- **d.** Dextrose and Sodium chloride injection/ infusion.

4. Evaluation of Pharmaceutical formulations (QC tests)

- **a.** Tablets
- **b.** Capsules
- c. Injections

5. Formulation of two liquid oral preparations and evaluation by assay

- a. Solution: Paracetamol Syrup
- **b.** Antacid suspensions- Aluminum hydroxide gel

6. Formulation of semisolids and evaluation by assay

- a. Salicyclic acid and benzoic acid ointment
- **b.** Gel formulation Diclofenac gel

7. Cosmetic preparations

- **a.** Lipsticks
- **b.** Cold cream and vanishing cream
- **c.** Clear liquid shampoo
- **d.** Tooth paste and tooth powders.

8. Tablet coating (demonstration)

Scheme of Practical Examination :

	Sessional	Annual	
Synopsis	05	15	
Major Experiment	10	25	
Minor Experiment	03	15	
Viva	02	15	
Max Marks	20	70	
Duration	03hrs	04hrs	

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – IV YEAR

Theory: 3 Hrs. /Week

(14T00401) PHARMACOTHERAPEUTICS - III (THEORY)

- 1. Scope : This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives: At completion of this subject it is expected that students will be able to understand
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

3. Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 Haematological system: Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine
- 7 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 8 Haematological system: Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 9 Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 10 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 11 Pain management including Pain pathways, neuralgias, headaches.
- 12 Evidence Based Medicine

Text Books

- a. Clinical Pharmacy and Therapeutics Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach Joseph T. Dipiro et al. Appleton & Lange

References:

- a. Pathologic basis of disease Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

Pharm. D – IV YEAR

Practical : 3 Hrs./Week

(14T00407) PHARMACOTHERAPEUTICS - III (PRACTICAL)

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation.

Each student should present medical cases they have observed and followed in the wards.

Assignments:

Students are required to submit written assignments on the topics given to them. hould cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

- 1. Minimum & Maximum number of pages
- 2. Reference(s) shall be included at the end.
- 3. Assignment can be a combined presentation at the end of the academic year
- 4. It shall be computer draft copy
- 5. Name and signature of the student
- 6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm.D – IV YEAR

Theory: 2 Hrs. /Week

(14T00402) HOSPITAL PHARMACY (THEORY)

- 1. Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counseling, and therapeutic drug monitoring for improved patient care.
- 2. Objectives: Upon completion of the course, the student shall be able to
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

3. Lecture wise

programme : Topics

1 Hospital - its organisation and functions

2 Hospital pharmacy-Organisation and management

- a) Organizational structure-Staff, Infrastructure & work load statistics
- b) Management of materials and finance
- c) Roles & responsibilities of hospital pharmacist

3 The Budget – Preparation and implementation

4 Hospital drug policy

- a) Pharmacy and Therapeutic committee (PTC)
- b) Hospital formulary
- c) Hospital committees
 - Infection committee
 - Research and ethical committee
- d) developing therapeutic guidelines

e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
 Definition, various methods of Inventory Control
 ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams

- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition
- 7 **Continuing professional development programs** Education and training
- 8 Radio Pharmaceuticals Handling and packaging
- 9 Professional Relations and practices of hospital pharmacist

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy health care. Edt. Robin J Harman. The Pharmaceutical press.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR Pharm. D – IV YEAR Practical : 3 Hrs./Week

(14T00408) HOSPITAL PHARMACY (PRACTICAL)

- 1. Assessment of drug interactions in the given prescriptions
- 2. Manufacture of parenteral formulations, powders.
- 3. Drug information queries.
- 4. Inventory control

List of Assignments:

- 1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
- 2. Pharmacy and Therapeutics committee Organization, functions, and limitations.
- 3. Development of a hospital formulary for 300 bedded teaching hospital
- 4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
- 5. Different phases of clinical trials with elements to be evaluated.
- 6. Various sources of drug information and systematic approach to provide unbiased drug information.
- 7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

- 1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
- 2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – IV YEAR

Theory: 3 Hrs. /Week

(14T00403) CLINICAL PHARMACY (THEORY)

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) -

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Definitions, development and scope of clinical pharmacy

2. Introduction to daily activities of a clinical pharmacist

- a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
- b. Ward round participation
- c. Adverse drug reaction management
- d. Drug information and poisons information
- e. Medication history
- f. Patient counseling
- g. Drug utilisation evaluation (DUE) and review (DUR)
- h. Quality assurance of clinical pharmacy services

3. Patient data analysis

The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

4. Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results

- a. Haematological, Liver function, Renal function, thyroid function tests
- b. Tests associated with cardiac disorders
- c. Fluid and electrolyte balance
- d. Microbiological culture sensitivity tests
- e. Pulmonary Function Tests

5. Drug & Poison information

- a. Introduction to drug information resources available
- b. Systematic approach in answering DI queries
- c. Critical evaluation of drug information and literature
- d. Preparation of written and verbal reports
- e. Establishing a Drug Information Centre
- f. Poisons information- organization & information resources

6. Pharmacovigilance

- a. Scope, definition and aims of pharmacovigilance
- b. Adverse drug reactions Classification, mechanism, predisposing factors, causality assessment [different scales used]
- c. Reporting, evaluation, monitoring, preventing & management of ADRs
- d. Role of pharmacist in management of ADR.
- 7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
- 8. Pharmaceutical care concepts
- 9. Critical evaluation of biomedical literature
- 10. Medication errors

Text books (Theory)

- a. Practice Standards and Definitions The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

Pharm. D – IV YEAR

Practical: 3 Hrs./Week

(14T00409) CLINICAL PHARMACY (PRACTICAL)

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 - 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

- 1. Minimum & Maximum number of pages.
- 2. Reference(s) shall be included at the end.
- 3. Assignment can be a combined presentation at the end of the academic year.
- 4. It shall be computer draft copy.
- 5. Name and signature of the student.
- 6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
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Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

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Pharm. D – IV YEAR

Theory: 2 Hrs. /Week

(14T00404) BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

1. Detailed syllabus and lecture wise schedule

1 Research Methodology

- a) Types of clinical study designs:
 - Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 **Biostatistics**

- 2.1 a) Introduction
 - b) Types of data distribution
 - c) Measures describing the central tendency distributions- average, median, mode
 - d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

<u>Computer System in Hospital Pharmacy</u>: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

<u>Computer In Community Pharmacy</u> Computerizing the Prescription Dispensing process Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system

<u>Drug Information Retrieval & Storage</u>: Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

Pharm. D – IV YEAR

Theory: 3 Hrs. /Week

(14T00405) BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

1. Biopharmaceutics

- 1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

- 2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
- One compartment open model.
 a. Intravenous Injection (Bolus)
 b. Intravenous infusion.
- 4. Multicompartment models.a. Two compartment open model.b. IV bolus, IV infusion and oral administration
- 5. Multiple Dosage Regimens.
 - a. Repititive Intravenous injections One Compartment Open Model
 - b. Repititive Extravascular dosing One Compartment Open model
 - c. Multiple Dose Regimen Two Compartment Open Model
 - 6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis-menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.

- a. Statistical Moment Theory.
- b. MRT for various compartment models.
- c. Physiological Pharmacokinetic model.
- 8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability

Pharm. D – IV YEAR

Practical: 3 Hrs./Week

(14T00410) BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

- 1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
- 2. Comparison of dissolution studies of two different marketed products of same drug.
- 3. Influence of polymorphism on solubility and dissolution.
- 4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
- 5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
- 6. Bioavailability studies of some commonly used drugs on animal/human model.
- 7. Calculation of Ka, Ke, t₁/2, Cmax, AUC, AUMC, MRT etc. from blood profile data.
- 8. Calculation of bioavailability from urinary excretion data for two drugs.
- 9. Calculation of AUC and bioequivalence from the given data for two drugs.
- 10. In vitro absorption studies.
- 11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
- 12. Absorption studies in animal inverted intestine using various drugs.
- 13. Effect on contact time on the plasma protein binding of drugs.
- 14. Studying metabolic pathways for different drugs based on elimination kinetics data.
- 15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
- 16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
- c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

Scheme of Practical Examination:

	Sessional	Annual	
Synopsis	05	15	
Major Experiment	10	25	
Minor Experiment	03	15	
Viva	02	15	
Max Marks	20	70	
Duration	03hrs	04hrs	

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – IV YEAR

Theory: 2 Hrs. /Week

(14T00406) CLINICAL TOXICOLOGY (THEORY)

- 1. General principles involved in the management of poisoning
- 2. Antidotes and the clinical applications.
- 3. Supportive care in clinical Toxicology.
- 4. Gut Decontamination.
- 5. Elimination Enhancement.
- 6. Toxicokinetics.
- 7. Clinical symptoms and management of acute poisoning with the following agents
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
- 8. Clinical symptoms and management of chronic poisoning with the following agents -

Heavy metals: Arsenic, lead, mercury, iron, copper

- 9. Venomous clinical effects of snake bites: Families of venomous snakes. venoms. general management as first aid, early manifestations, complications and snake bite injuries.
- 10. Plants poisoning. Mushrooms, Mycotoxins.
- 11. Food poisonings
- 12. Envenomations Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants

- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR PHARM. D. POST BACCALAUREATE 1ST YEAR

SYLLABUS FOR PHARMACOTHERAPEUTICS I & II (THEORY)

CODE:14T0010

Theory: 3Hrs/week

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Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases.

2.	Respiratory system : Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases	Total = 6 (1+2+2+1)
3.	Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	Total = 8 (3+2+1+1+1)
4.	General prescribing guidelines for a. Paediatric patients b. Geriatric patients c. Pregnancy and breast feeding	Total = 4hrs (1+1+2)
5.	Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial	(3 hrs)
6.	Introduction to rational drug use Definition, Role of pharmacist Essential drug concept Rational drug formulations	Total = 2 hrs (1+1)

7.	Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis	Total = 18 hrs. (2+1+1+2+1+1+1+2 +1+2+1+1+1+1)
8.	Musculoskeletal disorders Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	Total = 6hrs. (2+1+1+!+1)
9.	Renal system Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	`Total = 05hrs. (2+1+1+1)
10.	Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis	Total = 06 hrs. (2+1+2+1)
11.	Dermatology: Psoriasis, Scabies, Eczema, Impetigo	Total = 4hrs.

Text Books

- c. Clinical Pharmacy and Therapeutics Roger and Walker, Churchill Livingstone publication.
- d. Pharmacotherapy: A Pathophysiologic approach Joseph T. Dipiro et al. Appleton & Lange.

References:

- g. Pathologic basis of disease Robins SL, W.B.Saunders publication.
- h. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice Green and Harris, Chapman and Hall publication.
- i. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication.
- j. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- k. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- 1. Relevant review articles from recent medical and pharmaceutical literature.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR <u>PHARMACOTHERAPEUTICS – I & II (PRACTICAL)</u>

CODE:14T00411

Practicals: 3 Hrs./Week

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

- 1. Minimum & Maximum number of pages.
- 2. Reference(s) shall be included at the end.
- 3. Assignment can be a combined presentation at the end of the academic year.
- 4. It shall be computer draft copy.
- 5. Name and signature of the student.
- 6. Time allocated for presentation may be 8+2 Min

Scheme of Practical Examination:

	Sessional	Annual	
Synopsis	05	15	
Major Experiment	10	25	
Minor Experiment	03	15	
Viva	02	15	
Max Marks	20	70	
Duration	03hrs	04hrs	

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D – V YEAR

Theory: 3 Hrs. /Week

(14T00501) CLINICAL RESEARCH (THEORY)

1. Drug development process:

Introduction

Various Approaches to drug discovery

- 1. Pharmacological
- 2. Toxicological
- 3. IND Application
- 4. Drug characterization
- 5. Dosage form

2. Clinical development of drug:

- 1. Introduction to Clinical trials
- 2. Various phases of clinical trial.
- 3. Methods of post marketing surveillance
- 4. Abbreviated New Drug Application submission.
- 5. Good Clinical Practice ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
- 6. Challenges in the implementation of guidelines
- 7. Ethical guidelines in Clinical Research
- 8. Composition, responsibilities, procedures of IRB / IEC
- 9. Overview of regulatory environment in USA, Europe and India.
- 10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
- 11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
- 12. Informed consent Process
- 13. Data management and its components
- 14. Safety monitoring in clinical trials.

References :

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

Pharm. D – V YEAR

Theory: 3 Hrs. /Week

(14T00502) PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

1. Pharmacoepidemiology :

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Phrmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost - minimization, cost- benefit, cost - effectiveness, cost utility

3. Applications of Pharmacoeconomics

Software and case studies

REFERENCES:

- a. Pharmacoepidemiology, Fifth Edition, Editor(s): Brian L. Strom, Stephen E. Kimmel, Sean Hennessy.
- b. Essentials of Pharmacoeconomics (Point (Lippincott Williams & Wilkins)) Karen Rascati
- c. A Textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. G. Parthasarathi, Karin Nyfort-Hansen, Milap C. Nahata

Pharm. D – V YEAR

Theory: 2 Hrs. /Week

(14T00503) CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (THEORY)

1. Introduction to Clinical pharmacokinetics.

2. Design of dosage regimens:

Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. Pharmacokinetics of Drug Interaction:

- a. Pharmacokinetic drug interactions
- b. Inhibition and Induction of Drug metabolism
- c. Inhibition of Biliary Excretion.

4. Therapeutic Drug monitoring:

- a. Introduction
- b. Individualization of drug dosage regimen (Variability Genetic, Age and Weight, disease, Interacting drugs).
- c. Indications for TDM. Protocol for TDM.
- d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
- e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. Dosage adjustment in Renal and hepatic Disease.

- a. Renal impairment
- b. Pharmacokinetic considerations
- c. General approach for dosage adjustment in Renal disease.
- d. Measurement of Glomerular Filtration rate and creatinine clearance.
- e. Dosage adjustment for uremic patients.
- f. Extracorporeal removal of drugs.
- g. Effect of Hepatic disease on pharmacokinetics.

6. Population Pharmacokinetics.

- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with feed back.
- c. Analysis of Population pharmacokinetic Data.

7. Pharmacogenetics

- a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- b. Genetic Polymorphism in Drug Transport and Drug Targets.
- c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

REFERENCES:

- a. Biopharmaceutics and Clinical Pharmacokinetics, Milo Gibaldi
- b. A Textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. G. Parthasarathi, Karin Nyfort-Hansen, Milap C. Nahata

APENDIX A

INTERNSHIP

1. SPECIFIC OBJECTIVES :

- i) To provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.
- ii) To manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii) To promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.
- iv) To demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.
- v) To develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.
- vi) To communicate effectively with patients and the community.

2. OTHER DETAILS :

- i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- ii) Internship or residency training not more than 3 month under regulation 7 and 16 with regulation 2) i) of appendix-C of Pharm.D. Regulations 2008 may be allowed in some other Hospital/Super-specialty hospital in India or abroad.
- iii) Where an intern is posted to hospital for training, there shall be a committee consisting of representatives of the college or university, and the hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the institution which was countersigned by preceptor, Head of the Pharmacy practice and Principal of the college. Template of the certificate and model certificated was attached.
- iv) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate)

examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP:

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-

(1) Proficiency of knowledge required for each case	management	SCORE 0-5
(2) The competency in skills expected for providing C Pharmacy Services	linical	SCORE 0-5
(3) Responsibility, punctuality, work up of case, involvin patient care	vement	SCORE 0-5

- (4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
- (5) Initiative, participation in discussions, research aptitude. SCORE 0-5

ſ	Poor	Fair	Below Average	Average	Above Average	Excellent
	0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship. Template for internship evaluation certificate is attached

APPENDIX B

PRACTICAL TRAINING

(PCI NORMS FOR PHARM. D)

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

Project work .--

(1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

Objectives of project work.— The main objectives of the project work is to—

- (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
- (ii) develop the students in data collection, analysis and reporting and interpretation skills.

Methodology.- To complete the project work following methodology shall be adopted, namely:-

- (i) students shall work in groups of not less than two and not more than four under an authorised teacher;
- (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
- (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
- (iv) project work shall be approved by the institutional ethics committee;
- (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
- (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

Reporting.-

(1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution

- (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

Evaluation.— The following methodology shall be adopted for evaluating the project work—

- (i) Project work shall be evaluated by internal and external examiners.
- (ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
- (iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:		Marks
a) Write up of the seminar		(7.5)
b) Presentation of work		(7.5)
c) Communication skills		(7.5)
d) Question and answer skills		(7.5)
	Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items: Marks

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

MODEL TEMPLATES

Course completion and course evaluation

Internship evaluation certificate

S.No	Components	Score obtained (0-5)
1.	Proficiency of knowledge required for each case management	
2.	The competency in skills expected for providing Clinical Pharmacy Services	
3.	Responsibility, punctuality, work up of case, involvement in patient care	
4.	Ability to work in a team (Behavior with other healthcare professionals	
	including medical doctors, nursing staff and colleagues).	
5.	Initiative, participation in discussions, research aptitude.	

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

This is to certify that Mr./Ms. <u>NAME OF THE STUDENT & REGISTRATION NUMBER</u> has successfully completed his/her internship as per the curriculum of Doctor of Pharmacy (Pharm.D) prescribed by Pharmacy Council of India (PCI), New Delhi and Jawaharlal Nehru Technological University Anantapur (JNTUA), Anantapuramu at <u>NAME OF THE HOSPITAL</u> from <u>internship start date</u> to <u>internship end date</u> and it was ______.

Signature of Principal

Internship certificate

This is to certify that Mr./Ms, <u>NAME OF THE STUDENT & REGITRATION NUMBER</u> has successfully completed his/her internship as per the curriculum of Doctor of Pharmacy (Pharm.D) prescribed by Pharmacy Council of India (PCI), New Delhi and Jawaharlal Nehru Technological University Anantapur (JNTUA), Anantapuramu at <u>NAME OF THE HOSPITAL</u> from <u>internship start date</u> to <u>internship end date</u> and it was______.

Signature of Preceptor

Signature of HOD

Signature of Principal

Name and Designation

Name and Designation

Name and Designation