

PROGRAM STRUCTURE AND SYLLABUS For PHARM D

PDB R-08 Regulations

(Applicable for batches admitted from 2023-2024)



ADITYA PHARMACY COLLEGE

(An Autonomous Institution)

Approved by PCI, Permanently Affiliated to JNTUK,
Recognized by UGC (sections 2f)ISO 9001 : 2015 Certified Institution,
Accredited by NAAC with “A” Grade
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PHARM.D. REGULATIONS

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

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

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

CHAPTER-I

1. **Short title and commencement.** – (1) These regulations may be called the Pharm.D. Regulations 2008.
(2) They shall come into force from the date of their publication in the official Gazette.
2. **Pharm.D.** shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3. Duration of the course. –

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

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

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

Phase I – consisting of First and Second academic year.

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

4. Minimum qualification for admission to. –

a) Pharm.D. Part-I Course – A pass in any of the following examinations - 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects: Mathematics or Biology.

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

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

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

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

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

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

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

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –

- i) Pharm.D. Programme – 30 students.
- ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

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

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

T A B L E S

First Year :

Course code	Name of Subject	No.of hours of Theory	No.of hours of Practical	No.of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
T1101	Human Anatomy and Physiology	3	-	1
T1102	Pharmaceutics	2	-	1
T1103	Medicinal Biochemistry	3	-	1
T1104	Pharmaceutical Organic Chemistry	3	-	1
T1105	Pharmaceutical Inorganic Chemistry	2	-	1
T1106	Remedial Mathematics/ Biology	3	-	1
T1108	Human Anatomy and Physiology Practical	-	3	-
T110A	Pharmaceutics Practical	-	3	-

T110B	Medicinal Biochemistry Practical	-	3	-
T1105C	Pharmaceutical Organic Chemistry Practical	-	3	-
T1105	Pharmaceutical Inorganic Chemistry Practical	-	3	-
T110D	Remedial Mathematics/ Biology Practical	-	3*	-
Total hours		16	18	6 = (40)

* For Biology

Second Year:

Course code	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
T2101	Pathophysiology	3	-	1
T2102	Pharmaceutical Microbiology	3	-	1
T2103	Pharmacognosy & Phytopharmaceuticals	3	-	1
T2104	Pharmacology-I	3	-	1
T2105	Community Pharmacy	2	-	1
T2106	Pharmacotherapeutics-I	3	-	1
T2107	Pharmaceutical Microbiology Practical	-	3	-
T2108	Pharmacognosy & Phytopharmaceuticals Practical	-	3	-
T2109	Pharmacotherapeutics-I Practical	-	3	-
Total Hours		17	9	6 = 32

Third Year:

Course code	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
T3101	Pharmacology-II	3	-	1
T3102	Pharmaceutical Analysis	3	-	1
T3103	Pharmacotherapeutics-II	3	-	1
T3104	Pharmaceutical Jurisprudence	2	-	-
T3105	Medicinal Chemistry	3	-	1
T3106	Pharmaceutical Formulations	2	-	1
T3107	Pharmacology-II Practical	-	3	-
T3108	Pharmaceutical Analysis Practical	-	3	-
T3109	Pharmacotherapeutics-II Practical	-	3	-
T3110	Medicinal Chemistry Practical	-	3	-
T3111	Pharmaceutical Formulations Practical	-	3	-
Total hours		16	15	5 = 36

Fourth Year:

Cours e code	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
T4101	Pharmacotherapeutics-III	3	-	1
T4102	Hospital Pharmacy	2	-	1
T4103	Clinical Pharmacy	3	-	1
T4104	Biostatistics & Research Methodology	2	-	1
T4105	Biopharmaceutics & Pharmacokinetics	3	-	1
T4106	Clinical Toxicology	2	-	1

T4107	Pharmacotherapeutics-III Practical	-	3	-
T4108	Hospital Pharmacy practical	-	3	-
T4109	Clinical Pharmacy Practical	-	3	-
T4110	Biopharmaceutics & Pharmacokinetics Practical	-	3	-
Total hours		15	12	6 = 33

Fifth Year:

Course code	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
T5101	Clinical Research	3	-	1
T5102	Pharmaco epidemiology and Pharmaco economics	3	-	1
T5103	Clinical Pharmacokinetics & Pharmaco therapeutic Drug Monitoring	2	-	1
T5104	Clerkship *	-	-	1
T5105	Project work (Six Months)	-	20	-
Total hours		8	20	4 = 32

* Attending ward rounds on daily basis

Sixth Year:

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

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

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

9. Approval of the authority conducting the course of study. –

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

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

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed: Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non- teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination. –

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

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

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

T A B L E S

First Year examination :

S.No.	Name of Subject	Maximum marks		
		Examina Tion	Session al	Total
T1101	Human Anatomy and Physiology	70	30	100
T1102	Pharmaceutics	70	30	100
T1103	Medicinal Biochemistry	70	30	100
T1104	Pharmaceutical Organic Chemistry	70	30	100
T1105	Pharmaceutical Inorganic	70	30	100

	Chemistry			
T1106	Remedial Mathematics/ Biology	70	30	100
T1108	Human Anatomy and Physiology Practical	70	30	100
T110A	Pharmaceutics Practical	70	30	100
T110B	Medicinal Biochemistry Practical	70	30	100
T1105C	Pharmaceutical Organic Chemistry Practical	70	30	100
T1105	Pharmaceutical Inorganic Chemistry Practical	70	30	100
T110D	Remedial Mathematics/ Biology Practical	70*	30*	100*
Total Marks		840	360	1200

*for Biology

Second Year examination:

S.No.	Name of Subject	Maximum marks		
		Examination	Sessional	Total
T2101	Pathophysiology	70	30	100
T2102	Pharmaceutical Microbiology	70	30	100
T2103	Pharmacognosy & Phytopharmaceuticals	70	30	100
T2104	Pharmacology-I	70	30	100
T2105	Community Pharmacy	70	30	100
T2106	Pharmacotherapeutics-I	70	30	100
T2107	Pharmaceutical Microbiology Practical	70	30	100
T2108	Pharmacognosy & Phytopharmaceuticals Practical	70	30	100
T2109	Pharmacotherapeutics-I Practical	70	30	100
Total Marks		630	270	900

Third Year examination:

S.No.	Name of Subject	Maximum marks		
		Examina Tion	Session al	Total
T3101	Pharmacology-II	70	30	100
T3102	Pharmaceutical Analysis	70	30	100
T3103	Pharmacotherapeutics-II	70	30	100
T3104	Pharmaceutical Jurisprudence	70	30	100
T3105	Medicinal Chemistry	70	30	100
T3106	Pharmaceutical Formulations	70	30	100
T3107	Pharmacology-II Practical	70	30	100
T3108	Pharmaceutical Analysis Practical	70	30	100
T3109	Pharmacotherapeutics-II Practical	70	30	100
T3110	Medicinal Chemistry Practical	70	30	100
T3111	Pharmaceutical Formulations Practical	70	30	100
Total Marks		770	330	1100

Fourth Year examination :

S.No.	Name of Subject	Maximum marks		
		Examina Tion	Session al	Total
T4101	Pharmacotherapeutics-III	70	30	100
T4102	Hospital Pharmacy	70	30	100
T4103	Clinical Pharmacy	70	30	100
T4104	Biostatistics & Research Methodology	70	30	100
T4105	Biopharmaceutics & Pharmacokinetics	70	30	100
T4106	Clinical Toxicology	70	30	100
T4107	Pharmacotherapeutics-III Practical	70	30	100
T4108	Hospital Pharmacy practical	70	30	100

T4109	Clinical Pharmacy Practical	70	30	100
T4110	Biopharmaceutics & Pharmacokinetics Practical	70	30	100
Total Marks		700	300	1100

Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory		
		Examination	Sessional	Total
T5101	Clinical Research	70	30	100
T5102	Pharmacoepidemiology and Pharmacoeconomics	70	30	100
T5103	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100
T5104	Clerkship *	70	30	100
T5105	Project work (Six Months)	100**	-	100
Total marks		380	120	500

Attending ward rounds on daily basis. ** 30 marks – viva-voce; 70 marks – Thesis work

Scheme of Practical Examination:

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

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

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

12. Mode of examinations.

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

13. Award of sessional marks and maintenance of records.—

- (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.
- (2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.
- (3) The sessional marks in practicals shall be allotted on the following basis:-
 - (i) Actual performance in the sessional examination (20 marks);
 - (ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10marks)

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

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

16. Internship.—

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

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

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

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

CHAPTER-III

Practical training

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

20. Project work.—

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

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

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

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

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

- (i) students shall work in groups of not less than *two* and not more than *four* under an authorized 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 Department

23. Reporting.—

- (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution
- (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-titles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. Evaluation.— The following methodology shall be adopted for evaluating the projectwork—

- (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.

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

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

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

APPENDIX-A
(See regulation 8)
PHARM.D. SYLLABUS

FIRST YEAR

HUMAN ANATOMY & PHYSIOLOGY -THEORY

COURSE CODE: T1101

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Describe the structure (gross and histology) and functions of various organs of the human body;

COB2: Describe the various homeostatic mechanisms and their imbalances of various systems;

COB3: Identify the various tissues and organs of the different systems of the human body;

COB4: Perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;

COB5: Appreciate coordinated working pattern of different organs of each system; and

COB6: Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

COURSE OUTCOMES:

CO	Statement
CO1[L1]	<u>Describe</u> Scope of anatomy and physiology, basic terminologies used in this subject, Structure of cell – its components and their functions, about Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics, skeletal system.
CO2[L2]	<u>Describe</u> about Haemopoetic System, Lymph, Cardiovascular system.
CO3(L2)	<u>Describe</u> about Respiratory system and Digestive system.
CO4(L2)	<u>Explain</u> Nervous system, Urinary system.
CO5(L5)	<u>Describe</u> about Endocrine system and Reproductive system.
CO6(L2)	<u>Demonstrate</u> Sense organs, Skeletal system and Sports physiology.

Lecture wise programme:

3 Hrs. /Week

- 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) Haemopoiesis 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, and 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 cord: Structure & reflexes – mono-poly-planter
- g) Cranial nerves – names and functions
- h) 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

References:

Text books

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

Reference books

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

HUMAN ANATOMY & PHYSIOLOGY – PRACTICAL

COURSE CODE: T1108

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: describe the structure (gross and histology) and functions of various organs of the human body;

COB2: describe the various homeostatic mechanisms and their imbalances of various systems;

COB3: identify the various tissues and organs of the different systems of the human body;

COB4: perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;

COB5: appreciate coordinated working pattern of different organs of each system; and

COB6: appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

COURSE OUTCOMES :

CO	Statement
CO1[L2]	Demonstration about microscope, tissues and bones.
CO2[L2]	Demonstration on hemocytometry and estimation of WBC, RBC Count.
CO3[L4]	Analyse bleeding time, clotting time, hb content, ESR.B.P and Blood group.
CO4[L2]	Explain about Cardiovascular system, Respiratory system, Digestive system Urinary system, Nervous system, Special senses, Reproductive system.
CO5[L2]	Demonstration on family planning and pregnancy diagnosis.
CO6[L4]	Analyse record simple muscle curve using gastrocnemius sciatic nerve preparation.

Course content:

3Hrs. / Week

List of Experiments:

Expt. No	Title	CO
1.	Study of tissues of human body (a) Epithelial tissue. (b) Muscular tissue	CO1
2.	Study of tissues of human body (a) Connective tissue. (b) Nervous tissue.	CO1
3.	Study of appliances used in hematological experiments	CO2
4.	Determination of W.B.C. count of blood.	CO2
5.	Determination of R.B.C. count of blood	CO2
6.	Determination of differential count of blood	CO2
7.	Determination of (a) Erythrocyte Sedimentation Rate. (b) Hemoglobin content of Blood. (c) Bleeding & Clotting time.	CO3

8.	Determination of (a) Blood Pressure. (b) Blood group.	CO3
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	CO3
10.	Study of different family planning appliances	CO4
11.	To perform pregnancy diagnosis test	CO5
12.	Study of appliances used in experimental physiology	CO5
13.	To record simple muscle curve using gastrocnemius sciatic nerve preparation	CO6
14.	To record simple muscle curve using gastrocnemius sciatic nerve preparation diagnosis test	CO6
15.	To record simple summation curve using gastrocnemius sciatic nerve preparation	CO6
16.	To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.	CO6
17.	To record simple fatigue curve using gastrocnemius sciatic nerve preparation	CO6

Scheme of Practical Examination:

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

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

References:

Text books

1. Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

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

PHARMACEUTICS-THEORY

COURSE CODE: T1102

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: know the formulation aspects of different dosage forms.

COB2: do different pharmaceutical calculations involved in formulation.

COB3: formulate different types of dosage forms

COB4: appreciate the importance of good formulation for effectiveness.

COURSE OUTCOMES:

CO	Statement
CO1(L1)	<u>Describe</u> the history of profession of pharmacy, different dosage forms , professional way of handling the prescription along with they can also understand dose calculation for paediatrics based on different factors
CO2(L2)	<u>Explain</u> about the basics of different pharmacopoeia and national formulary
CO3(L2)	<u>Demonstrate</u> the different measuring systems and Preparation of various conventional dosage forms and their stability studies
CO4(L2)	<u>Discuss</u> the various preparation methods and stability evaluations of biphasic liquid dosage forms
CO5(L5)	<u>Assess</u> the Preparation of semisolid dosage forms for body cavity, evaluations.
CO6(L2)	<u>Explain</u> the basics of pharmaceutical calculations , excipients used indifferent dosage forms
CO7(L2)	<u>Demonstrate</u> various extraction methods by using different equipment's and surgical aids
CO8(L4)	<u>Classify</u> various types of pharmaceutical incompatibilities and their overcoming methods

Lecture wise programme:

2 Hrs. /Week

1. Introduction to dosage forms –

- classification and definitions
- Prescription: definition, parts and handling
- 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.

Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

3. Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
4. **Powders and Granules:** Classification, advantages and disadvantages, Preparation of simple and compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
5. **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
6. **Biphasic dosage forms:** Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
7. **Suppositories and pessaries:** Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
8. **Galenicals:** Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
9. Pharmaceutical calculations.
10. **Surgical aids:** Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
11. **Incompatibilities:** Introduction, classification and methods to overcome the incompatibilities

PHARMACEUTICS - PRACTICAL

COURSE CODE: T1109

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: know the formulation aspects of different dosage forms.

COB2: do different pharmaceutical calculation involved in formulation.

COB3: formulate different types of dosage forms.

COB4: appreciate the importance of good formulation for effectiveness.

COURSE OUTCOMES :

CO	Statement
CO1[L6]	Formulate monophasic liquid dosage forms for internal use
CO2[L6]	Design the preparation of monophasic liquid dosage forms for external use
CO3[L6]	Design the preparation of biphasic dosage forms for both internal & external use
CO4[L2]	Discuss the preparation and dispensing methods for solid dosage forms like various powders and granules
CO5[L6]	Formulate various semisolid dosage forms for body cavity (suppositories)
CO6[L2]	Demonstrate the various types of incompatibilities and overcoming methods

Course content

3 Hrs./Week

List of Experiments:

Expt. No	Title	CO
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	CO1
2.	Elixir a. Piperizine citrate elixir BP b. Cascara elixir BPC c. Paracetamol elixir BPC	CO1
3.	Linctus a. Simple Linctus BPC b. Pediatric simple Linctus BPC	CO1
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	CO1&
	e. Strong solution of ammonium acetate IP	CO2
5.	Liniments a. Liniment of turpentine IP* b. Liniment of camphor IP	CO2
6.	Suspensions* a. Calamine lotion b. Magnesium Hydroxide mixture BP	CO3

7.	Emulsions* a. Cod liver oil emulsion b. Liquid paraffin emulsion	CO3
8.	Powders a. Eutectic powder b. Explosive powder c. Dusting powder d. Insufflations	CO4
9.	Suppositories a. Boric acid suppositories b. Chloral suppositories	CO5
10.	Incompatibilities a. Mixtures with Physical b. Chemical & Therapeutic incompatibilities	CO6

Scheme of Practical Examination:

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

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

References:

Text books

1. Cooper and Gunns Dispensing for pharmacy students.
2. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

1. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
2. Remington's Pharmaceutical Sciences.
3. . Register of General Pharmacy by Cooper and Gunn.
4. General Pharmacy by M.L.Schroff

MEDICINAL BIOCHEMISTRY-THEORY

COURSE CODE : T1103

COURSE OBJECTIVES:

COB1: Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

COB 2: Understand the metabolism of nutrient molecules in physiological and pathological conditions.

COB3: Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins

COURSE OUTCOMES:

CO	Statement
CO1[L2]	Summarize Cell and its biochemical organization.
CO2[L3]	Characterise the catalytic activity of enzymes and importance of iso enzymes in diagnosis of diseases.
CO3[L2]	Explain the metabolic process of bio molecules in health and illness (metabolic disorders).
CO4[L5]	Justify the genetic organization of mammalian genome, protein synthesis, replication, mutation and repair mechanism.
CO5[L2]	I illustrate the biochemical principles of organ function tests of kidney, liver and endocrine gland.
CO6[L5]	Assess the qualitative analysis and determination of bio molecules in the body fluids.

Lecture wise programme:

3 Hrs. /Week

- 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 (Atherosclerosis, fatty liver, hypercholesterolemia).
- 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 & amp; decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphyria, jaundice. Metabolic disorder of Amino acids.
- 7. Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8. Introduction to clinical chemistry:** Cell; composition; malfunction; Roll of the clinical chemistry laboratory.
- 9. The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
 - a) Urine analysis (macroscopic and physical examination, quantitative and 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 distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

References:

Text books (Theory)

1. Harpers review of biochemistry – Martin
2. Text book of biochemistry – D.Satyanarayana
3. Text book of clinical chemistry- Alex kaplan & Laverne L.Szabo

Reference books (Theory)

1. Principles of biochemistry – Lehninger
2. Text book of biochemistry – Ramarao
3. Practical Biochemistry-David T.Plummer.
4. Practical Biochemistry-Pattabhiraman.

MEDICINAL BIO CHEMISTRY-PRACTICAL

COURSE CODE: T110A

COURSE OBJECTIVES:

COB 1: Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

COB2: Understand the metabolism of nutrient molecules in physiological and pathological conditions.

COB3: Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

COB4: know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and etc

COB5: Perform the qualitative analysis and determination of bio molecules in the body fluids

COURSE OUTCOMES:

CO	Statement
CO1[L3]	<u>Determine</u> the Qualitative analysis of normal and abnormal constituents of urine.
CO2[L4]	<u>Categories</u> the urine creatinine by Jaffe's method and calcium by precipitation method.
CO3[L5]	<u>Assess</u> the blood sugar by Folin-Wu tube method.
CO4[L1]	<u>Identification</u> of SGOT and SGPT in serum.
CO5[L4]	<u>Analyze</u> Urea, Proteins and serum bilirubin
CO6[L5]	<u>Predict</u> sodium, calcium and potassium in serum.

Course content:

3Hrs. /Week

List of Experiments:

Expt. No.	Title	CO
1.	Qualitative analysis of normal constituents of urine.	CO1
2.	Qualitative analysis of abnormal constituents of urine.	CO1
3.	Quantitative estimation of urine sugar by Benedict's reagent method.	CO1
4.	Quantitative estimation of urine chlorides by Volhard's method.	CO1
5.	Quantitative estimation of urine creatinine by Jaffe's method.	CO1
6.	Quantitative estimation of urine calcium by precipitation method.	CO1

7.	Quantitative estimation of serum cholesterol by Libermann Burchard's method.	CO1
8.	Preparation of Folin Wu filtrate from blood.	CO2
9.	Quantitative estimation of blood creatinine.	CO1
10.	Quantitative estimation of blood sugar Folin-Wu tube method.	CO1
11.	Estimation of SGOT in serum	CO2
12.	Estimation of SGPT in serum	CO2
13.	Estimation of Urea in Serum	CO2
14.	Estimation of Proteins in Serum	CO2
15.	Determination of serum bilirubin	CO3
16.	Determination of Glucose by means of Glucose oxidase.	CO4
17.	Enzymatic hydrolysis of Glycogen/Starch by Amylases.	CO5
18.	Study of factors affecting Enzyme activity.(pH&Temp.)	CO6
19.	Preparation of standard buffer solutions and its pH measurements (any two)	CO4
20.	Experiment on lipid profile tests	CO5
21.	Determination of sodium,calcium and potassium in serum	CO4

Scheme of Practical Examination:

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

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

References

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani

5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

PHARMACEUTICAL ORGANIC CHEMISTRY-THEORY

COURSE CODE: T1104

COURSE OBJECTIVES: Upon completion of course student shall be able to

COB1: Understand the IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds.

COB2: Understand the Free radical substitution, addition, elimination, and oxidation reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds

COB3: Knowledge on named organic reactions with mechanisms methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

COURSE OUTCOME:

CO	Statement
CO1[L5]	<u>Assess</u> the Physicochemical properties of molecules like Melting point, boiling point, etc...
CO2[L5]	<u>Justify</u> Free radicals chain reactions of alkane and Alicyclic compounds
CO3[L2]	<u>Summarize</u> substitution, addition, elimination, Reactions of molecules.
CO4[L2]	<u>Explain</u> theory of resonance and Named reactions with mechanism
CO5[L3]	<u>Determine</u> Oxidation reduction reaction.
CO6[L2]	<u>Illustrate</u> the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol etc...

Lecture wise programme

3Hrs. / Week

1. Structures and Physical properties:

- Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, and ion pairs.
- Acids and bases, Lowry bronsted and Lewis theories
- Isomerism

2. Nomenclature of organic compounds 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. Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups,

kinetics of second and first order reaction, mechanism and kinetics of SN2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

6. Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen 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, adrule of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanimechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin 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, allylcation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allylcation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilicsubstituion in vinylic substrate, vinyliccation, 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. Electrophilic 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, Glyceryltrinitrate, Urea, Ethylene diaminedihydrate, 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.

PHARMACEUTICAL ORGANIC CHEMISTRY-PRACTICAL

COURSE CODE: T110B

COURSE OBJECTIVES:

COB1: Understand the IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds.

COB2: Understand the Free radical substitution, addition, elimination, and oxidation reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds

COB3: Knowledge on named organic reactions with mechanisms methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

COURSE OUTCOMES:

CO	Statement
CO1[L3]	Determine the sources of impurities and methods to determine the impurities in inorganic formulations.
CO2[L5]	Justify the medicinal and pharmaceutical importance of inorganic compounds, drugs and pharmaceuticals
CO3[L2]	Differentiate physiological ions.
CO4[L4]	Categorize inorganic pharmaceuticals as gastrointestinal agents
CO5[L2]	Explain the importance of inorganics as anti-dotes
CO6[L5]	Support the importance of radiopharmaceuticals in medicines.

Course Content:

3Hrs. / Week

List of Experiments:

Expt. No	Title	CO
1.	Preparation of Acetanilide / aspirin (Acetylation)	CO1
2.	Preparation of Benzanilide / Phenyl benzoate (Benzoylation)	CO1
3.	Preparation of P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)	CO1
4.	Preparation of Dibenzylidene acetone (Condensation)	CO1
5.	Preparation of 1-Phenylazo-2-naphthol (Diazotisation and coupling)	CO1
6.	Preparation of Benzoic acid / salicylic acid (Hydrolysis of ester)	CO2
7.	Preparation of M-dinitro benzene (Nitration)	CO2

8.	Preparation of 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde	C02
9.	Preparation of M-phenylenediamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene	C02
10.	Preparation of Benzophenoneoxime 11. Nitration of salicylic acid	C02
11.	Preparation of Nitration of salicylic acid	C02
12.	Preparation of picric acid	C03
13.	Preparation of O-chlorobenzoic acid from O-chlorotoluene	C04
14.	Preparation of cyclohexanone from cyclohexanol	C05
15.	Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.	C06
16.	Introduction to the use of stereo models: Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration	C06

Scheme of Practical Examination:

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

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

Recommended text books:

1. T.R.Morrison and R. Boyd - Organic chemistry,
2. Bentley and Driver-Text book of Pharmaceutical chemistry
3. I.L.Finer- Organic chemistry, the fundamentals of chemistry
4. Organic chemistry – J.M.Cram and D.J.Cram
5. Organic chemistry- Brown
6. Advanced organic chemistry- Jerry March, Wiley
7. Organic chemistry- Cram and Hammered, Pine Hendrickson

PHARMACEUTICAL INORGANIC CHEMISTRY-THEORY

COURSE CODE: T1105

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals.

COB2: Know the analysis of the inorganic pharmaceuticals their applications.

COB3: Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

COURSE OUTCOMES:

CO	Statement
CO1 [L1]	<u>Describe</u> inorganic pharmaceutical errors and volumetric analysis and perform the acid base titrations
CO2 [L2]	<u>Demonstrate</u> about the different types titrations and how to prepare solutions acid-base titrations, redox titrations, non aqueous titrations, complexometric titrations
CO3 [L4]	<u>Analyze</u> the theory of indicators and gravimetry and know about the different types limit tests
CO4 [L5]	<u>Justify</u> the different types of medicinal gasses and various preparations of acidifiers and antacids
CO5 [L3]	<u>Use</u> of cathartics and importance of electrolyte replenishers
CO6 [L6]	<u>Design</u> the different types of antimicrobials ,pharmaceutical aids and various radio pharmaceuticals and their importance

Lecture wise programme:

3 Hrs/ Week

1. Errors
2. Volumetric analysis
3. Acid-base titrations
4. Redox titrations
5. Non aqueous titrations
6. Precipitation titrations
7. Complexometric titrations
8. Theory of indicators
9. Gravimetry
10. Limit tests
11. Medicinal gases
12. Acidifiers
13. Antacids

14. Cathartics
15. Electrolyte replenishers
16. Essential Trace elements
17. Antimicrobials
18. Pharmaceutical aids
19. Dental Products
20. Miscellaneous compounds
21. Radio Pharmaceuticals

PHARMACEUTICAL INORGANIC CHEMISTRY-PRACTICAL

COURSE CODE: T1105C

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals.

COB2: Know the analysis of the inorganic pharmaceuticals their applications.

COB3: Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

COURSE OUTCOMES:

CO	Statement
CO1 [L2]	<u>Demonstrate</u> the Limit test for various Inorganic compounds
CO2 [L3]	<u>Determine</u> the purity of the inorganic compounds
CO3 [L4]	<u>Characterize</u> inorganic compounds
CO4 [L1]	<u>Identify</u> the Inorganic pharmaceuticals
CO5 [L5]	<u>Justify</u> the purity of Inorganic compounds
CO6 [L6]	<u>Prepare</u> Inorganic compounds

Course content:

3Hrs. / Week

List of Experiments:

Expt. No	Title	CO
1.	Limit test for chlorides	CO1
2.	Limit test for sulphate	CO1
3.	Limit test for iron	CO1
4.	Limit test for heavy metals	CO1
5.	Limit test for arsenic	CO1
6.	Modified limit tests for chlorides and sulphates	CO1

7.	Ammonium chloride- Acid-base titration	C02
8.	Ferrous sulphate- Cerimetry	C02
9.	Copper sulphate- Iodometry	C02
10.	Calcium gluconate- Complexometry	C02
11.	Hydrogen peroxide – Permanganometry	C02
12.	Sodium benzoate – Nonaqueous titration	C02
13.	Sodium chloride – Modified volhard's method	C02
14.	Assay of KI – KIO ₃ titration	C02
15.	Assay Gravimetric estimation of barium as barium sulphate	C02
16.	Assay Sodium antimony gluconate or antimony potassium tartarate	C02
17.	Estimation of Sodium hydroxide and sodium carbonate	C03
18.	Estimation of Boric acid and Borax	C03
19.	Estimation Oxalic acid and sodium oxalate	C03
20.	Sodium bicarbonate b. Barium sulphate c. Ferrous sulphate d. Potassium chloride	C04
21.	Identification of Barium sulphate	C04
22.	Identification of Ferrous sulphate	C04
23.	Identification of Potassium chloride	C04
24.	Swelling power in Bentonite	C05
25.	Acid neutralising capacity in aluminium hydroxide gel	C05
26.	Ammonium salts in potash alum	C05
27.	Adsorption power heavy Kaolin	C05
28.	Presence of Iodates in KI	C05
29.	Preparation of Boric acids	C06
30.	Preparation of Potash alum	C06
31.	Preparation of Calcium lactate	C06

32.	Preparation of Magnesium sulphate	CO6
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Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment 1&2	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

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

References:

Text books

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

Reference books

1. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
2. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi c. Analytical chemistry principles by John H. Kennedy
3. I.P.1985 and 1996, Govt. of India, Ministry of health

REMEDIAL MATHEMATICS

COURSE CODE: T1106

COURSE OBJECTIVES: Upon completion of the course, the student shall be able to

COB1: Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications

COB2: Solve the problems of different types by applying theory

COB3: Appreciate the important applications of mathematics in pharmacy

COURSE OUTCOMES:

CO1 (L3)	Apply mathematical concepts and principles to perform computations for Pharmaceutical Sciences.
CO2 (L6)	Create, use and analyze mathematical representations and mathematical relationships.
CO3 (L6)	Communicate mathematical knowledge and understanding to help in the field of Clinical Pharmacy.
CO4 (L1)	Perform abstract mathematical reasoning.
CO5(L3)	Apply the techniques like integral calculus and differentiation to analyze complex problem in pharmacokinetics and in the field of clinical pharmacy
CO6(L6)	Analyze the dependent process such as controlled drug delivery and reaction kinetics by laplace transformation techniques

Lecture wise programme :

3Hrs/ Week

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.

References:**Text books**

1. Differential calculus By Shantinakaran
2. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference books

1. Integral calculus By Shanthinaraya
2. Engineering mathematics By B.S.Grewal
3. Trigonometry Part-I By S.L.Loney

REMEDIAL BIOLOGY-THEORY

COURSE CODE: T1106

COURSE OBJECTIVES: Upon completion of the course, the student shall be able to

COB1: Know the classification and salient features of five kingdoms of life.

COB2: Understand the basic components of anatomy & physiology of plant.

COB3: Know understand the basic components of anatomy & physiology animal with special reference to human.

COURSE OUTCOMES:

CO	Statement
CO1[L2]	<u>Demonstrate</u> about Cell biology (Basic Nature of Plant cell and Animal cell)
CO2[L4]	Classification System of Plants.
CO3[L3]	<u>Determine</u> Morphology of plants and its modifications
CO4 [L5]	<u>Assess</u> the Inflorescence and Pollination of flowers. Morphology of fruits.
CO5[L2]	<u>Explain</u> plant Physiology and Taxonomies , study of microbials and animal cell and tissues
CO6[L1]	<u>Describe</u> about Anatomy and Physiology of animals, organization of mammals and Study of poisonous animals

Lecture wise programme

3 Hrs. / Week

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

REMEDIAL BIOLOGY-PRACTICAL

COURSE CODE: T110D

COURSE OBJECTIVES: Upon completion of the course, the student shall be able to

COB1: Know the classification and salient features of five kingdoms of life.

COB2: Understand the basic components of anatomy & physiology of plant.

COB3: Know understand the basic components of anatomy & physiology animal with special reference to human.

COURSE OUTCOMES:

CO	Statement
CO1[L2]	Demonstrate about Cell biology (Basic Nature of Plant cell and Animal cell)
CO2[L4]	Classification System of Plants .
CO3[L3]	Determine Morphology of plants and its modifications
CO4 [L5]	Assess the Inflorescence and Pollination of flowers. Morphology of fruits.
CO5[L2]	Explain plant Physiology and Taxonomies, study of microbials and animal cell and tissues
CO6[L1]	Describe about Anatomy and Physiology of animals, organization of mammals and Study of poisonous animals

Course content:

3 Hrs./Week

List of experiments:

EXP NO:	TITLE	CO
1.	Introduction of biology experiments.	CO1
2.	Study of cell wall constituents and cell inclusions.	CO2
3.	Study of Stem modifications.	CO2
4.	Study of Root modifications	CO3
5.	Study of Leaf modifications	CO4
6.	Identification of Fruits and seeds	CO5
7.	Preparation of Permanent slides	CO6
8.	T.S. of Senna, Cassia, Ephedra, Podophyllum	CO6
9.	Simple plant physiological experiments	CO7
10.	Identification of animals	C07
11.	Detailed study of Frog	CO8
12.	Computer based tutorials	C08

Scheme of Practical Examination:

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

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

References:**Text books**

1. Text book of Biology by S.B.Gokhale
2. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

1. A Text book of Biology by B.V.Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. Outlines of Zoology by M.Ekambaranathaayyer and T.N.Ananthakrishnan.
5. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate

SECOND YEAR

PATHOPHYSIOLOGY- THEORY

COURSE CODE – T2101

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Describe the etiology and pathogenesis of the selected disease states.

COB2: Name the signs and symptoms of the diseases

COB3: Mention the complications of the diseases.

COURSE OUTCOMES:

CO	Statement
CO1[L1]	<u>Define</u> abnormal physiologic processes associated with common disease processes
CO2[L2]	<u>Explain</u> the most common etiologies and predisposing factors associated with human disease.
CO3[L4]	<u>Compare</u> the mechanisms that cause alterations in hormone secretion
CO4[L2]	<u>Explain</u> the classification of tumors and stages of cancer spread. Explain the difference between benign and malignant neoplasms
CO5[L2]	<u>Describe</u> the structure and function of cells and tissues, Cellular adaptations that result from environmental stresses
CO6[L2]	<u>Explain</u> the pathophysiology of common infectious diseases including sexually transmitted diseases

Lecture wise programme

3Hrs. /Week

UNIT – I: Basic principles of cell injury and Adaptation a) Causes, Pathogenesis and morphology of cell injury b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen storage diseases.

UNIT – II: Inflammation a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, and Types of chronic inflammation b) Repairs of wounds in the skin, and factors influencing healing of wounds.

UNIT-III : Diseases of Immunity a) Introduction to T and B cells b) MHC proteins or transplantation antigens c) Immune tolerance – 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, and Mechanism of rejection of allograft. - Acquired immune deficiency syndrome (AIDS) 35 – Amyloidosis.

UNIT-IV : 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.

UNIT –V: Types of shock, mechanisms, stages and management

UNIT-VI: Biological effects of radiation

UNIT-VII : Environmental and nutritional diseases i) Air pollution and smoking- SO₂,NO, NO₂, and CO ii) Protein calorie malnutrition, vitamins, obesity, and pathogenesis of starvation

UNIT-VIII : Pathophysiology of common diseases a. Parkinsonism b. Schizophrenia c. Depression and mania d. Hypertension, e. Stroke (ischaemic and hemorrhage) f. Angina, CCF, Atherosclerosis, and 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

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

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

References:

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

PHARMACEUTICAL MICROBIOLOGY-THEORY

COURSE CODE: T2102

COURSE OBJECTIVES: On completion of this course, the student will be able to:

COB1: Know the anatomy, identification, growth factors, and sterilization of microorganisms.

COB2: Know the mode of transmission of disease-causing microorganisms, symptoms of disease, and treatment aspects.

COB3: Know the estimation of RNA and DNA and there by identify the source.

COB4: Identify the diseases by performing the diagnostic tests.

COB5: Appreciate the behaviour of motility and behavioural characteristics of microorganisms.

COURSE OUTCOMES:

CO	Statement
CO1 [L1]	<u>Understand</u> the importance of microorganisms, able to cultivate, identify, and preserve microorganisms & the nutritional requirements for the cultivation of microbes
CO2 [L3]	<u>Apply</u> the knowledge of sterilization and disinfection processes in the hospital and Pharmaceutical industry
CO3 [L3]	<u>Identify</u> the diseases by performing diagnostic tests
CO4 [L1]	<u>Explain</u> the mechanism of immunity and advocate an immunization program
CO5 [L1]	<u>Interpret</u> the mode of transmission of disease-causing microorganisms, symptoms, diagnostic tests, and treatment
CO6 [L1]	<u>Demonstrate</u> Safe Working Practices in Microbiology, and adhere to the Microbiological Requirements for safe work procedures

Lecture wise programme:

3Hrs. /Week

Unit I: (Introduction to the Science of Microbiology)

- Major divisions of microbial world and Relationships among them.

Unit II: (Morphology & Physiology of Microorganisms)

- Different methods of classification of microbes and study of Bacteria, Fungi, viruses, Rickettsia, and Spirochetes.

Unit III: (Growth & Nutrition)

- Nutritional requirements, growth, and cultivation of bacteria and viruses.
- 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.

Unit IV: (Isolation and Identification of Bacteria)

- Different methods used in the isolation and identification of bacteria with an emphasis on different staining techniques and biochemical reactions.
- Counting of bacteria-Total and Viable counting techniques.

Unit V: (Sterilization)

- 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.

Unit VI: (Disinfectants)

- Study of disinfectants, antiseptics, fungicidal, and virucidal agents and factors affecting their activation and mechanism of action.
- Evaluation of Bactericidal, Bacteriostatic, and Virucidal activities, evaluation of preservatives in pharmaceutical preparations.

Unit VII: (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 program, and importance of booster dose.

Unit VIII: (Diagnostic Tests)

- Diagnostic tests: Schick's Test, Elisa test, Western Blot test, Southern Blot, PCR, Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.

Unit IX: (Microbiological Assays)

- Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, a microbiological assay of Penicillin, Streptomycin, and vitamin B2 and B12.
- Standardization of vaccines and sera.

Unit X: (Study of Infectious Diseases)

Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhoea and HIV.

References:

Textbooks (Theory)

1. Vanitha Kale and Kishor Bhusari “Applied Microbiology” Himalaya Publishing house, Mumbai.
2. Mary Louis Turgeon “Immunology and Serology in Laboratory Medicines” 2nd edition, 1996 Mosby- Yearbook inc St. Louis Missouri
3. Harsh Mohan, “Textbook of Pathology” 3rd edition, 1998, B-3 Ansari road Daryaganj N. Delhi.

Reference books (Theory)

1. Prescott L.M., Jarley G.P Klein D.A “Microbiology” 2nd- edition Mc Graw Hill Company Inc.
2. Rawlins E.A. “Bentley’s Text Book of Pharmaceutics” Bailliere Tindals 24-28 London 1988.
3. Frobisher “Fundamentals of Microbiology” Philadelphia W.B. Saunders.
4. Prescott L.M. Jarley G.P., Klein D.A. “Microbiology.” 2nd edition WMC Brown Publishers, Oxford. 1993.
5. War Roitt, Jonathan Brostoff, David male, “Immunology”3rd edition 1996, Mosby-year book Europe Ltd, London.
6. Pharmacopoeia of India, Govt. of India, 1996.

PHARMACEUTICAL MICROBIOLOGY- PRACTICAL

COURSE CODE: T2107

COURSE OBJECTIVES: On completion of this course, the student will be able to

COB1: Gain Practical Skills in aseptic technique

COB2: Master the Fundamental microbiological techniques

COB3: Develop the Competency in Sterility Testing

COB4: Apply biochemical tests for Microbial Identification

COURSE OUTCOMES

CO	Statement
CO1 [L2]	<u>Study</u> the apparatus used in microbiology & preparation, sterilization of glassware and media
CO2 [L2]	<u>Study</u> different staining techniques, motility characters, enumeration of microorganisms, method of isolation of pure culture, and biochemical testing for the identification of microorganisms
CO3 [L3]	<u>Perform</u> culture sensitivity testing, sterility testing for powder & liquid, and determination of MIC
CO4 [L3]	<u>Perform</u> microbiological assay of antibiotics, vitamins and determination of RWC, Widal, Malaria parasite
CO 5 [L3]	<u>Analyze</u> the microbial contamination in pharmaceutical products through tests like microbial limit testing, preservative efficacy testing, and endotoxin testing .
CO 6 [L3]	<u>Design</u> and implement quality control protocols for aseptic processing and validate sterilization techniques in compliance with regulatory standard.

Course content

3 Hrs/week

List of experiments

Exp. No.	Title	CO
1	Study of apparatus used in experimental microbiology	CO1
2	Sterilization of glass wares. Preparation of media and sterilization	CO6
3	Staining techniques – Simple staining; Gram's staining; Negative staining	CO2
4	Study of motility characters	CO2
5	Enumeration of micro-organisms (Total and Viable)	CO5
6	Study of the methods of isolation of pure culture	CO2
7	Biochemical testing for the identification of microorganisms	CO2
8	Cultural sensitivity testing for some micro-organisms	CO5
9	Sterility testing for powders and liquids	CO5
10	Determination of minimum inhibitory concentration	CO3
11	Microbiological assay of antibiotics by cup plate method	CO4
12	Microbiological assay of vitamins by Turbidimetric method	CO4
13	Determination of RWC	CO4
14	Diagnostic tests for some common diseases, Widal, malarial parasite	CO4

Assignments:

1. Visit to some Pathological Laboratories & study the activities and equipment/instruments used and report the same.
2. Visit to milk dairies (Pasteurization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and report the same.

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 Minutes

Scheme of Practical Examination:

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

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

References :

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill Ed.
4. Malcolm Harris, Balliere Tindall, and Cox: Pharmaceutical Microbiology. Rose: Industrial Microbiology. Probisher, Hinsdill, et al: Fundamentals of Microbiology, 9th ed. Japan
5. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
6. Peppler: Microbial Technology.
7. I.P., B.P., U.S.P. - latest editions.
8. Ananthnarayan: Text Book of Microbiology, Orient-Longman, Chennai
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergey manual of systematic bacteriology, Williams and Wilkins- A Waverly Company

PHARMCOGNOSY AND PHYTOPHARMACEUTICALS-THEORY

COURSE CODE: T2103

COURSE OBJECTIVES: Upon completion of the course student shall be able to:

COB1: Understand the basic principles of cultivation, collection and storage of crude drugs

COB2: Know the source, active constituents and uses of crude drugs; and

COB3: Appreciate the applications of primary and secondary metabolites of the plant.

COURSE OUTCOMES:

CO	Statement
CO1[L2]	<u>Explain</u> the basic cultivation, collection and storage of crude drugs.
CO2[L3]	<u>Determine</u> the sources, active constituents and uses of crude drugs.
CO3[L2]	<u>Illustrate</u> Microscopical characteristics of crude drug.
CO4[L5]	<u>Assess</u> the applications of Primary and Secondary metabolites.
CO5[L5]	<u>Classify</u> and characterize carbohydrates, lipids, and proteins in pharmaceuticals .
CO6[L3]	<u>Determine</u> different methods of adulteration of crude drugs

Lecture wise programme:

3 Hrs. /Week

- Introduction.
- Definition, history and scope of Pharmacognosy.
- Classification of crude drugs.
- Cultivation, collection, processing and storage of crude drugs.
- Detailed method of cultivation of crude drugs.
- Study of cell wall constituents and cell inclusions.
- Microscopical and powder Microscopical study of crude drugs.
- Study of natural pesticides.
- Detailed study of various cell constituents.
- Carbohydrates and related products.
- Detailed study carbohydrates containing drugs.(11 drugs)
- Definition, sources, method extraction, chemistry and method of analysis of lipids.
- Detailed study of oils.
- Definition, classification, chemistry and method of analysis of protein.
- Study of plants fibers used in surgical dressings and related products.
- Different methods of adulteration of crude drugs.

PHARMCOGNOSY AND PHYTOPHARMACEUTICALS-PRACTICAL

COURSE CODE: T2108

COURSE OBJECTIVES: Upon completion of the course student shall be able to:

COB1. Understand the basic principles of cultivation, collection and storage of crude drugs

COB2. Know the source, active constituents and uses of crude drugs; and

COB3. Appreciate the applications of primary and secondary metabolites of the plant.

COURSE OUTCOMES:

CO	Statement
CO1[L1]	<u>State</u> cell wall constituents and cell inclusions
CO2[L2]	<u>Demonstrate</u> Macro, Powder and Microscopic study of Datura, Senna, Cassia, Cinnamon, Cinchona, Ephedra, Quassia, Rauwolfia.
CO3[L2]	<u>Demonstrate</u> Macro, Powder and Microscopic study of Clove, Fennel, Coriander, Ginger, Isabgol, Nuxvomica,
CO4[L1]	<u>Identify</u> Iodine value, Saponification value, acid value
CO5[L4]	<u>Perform</u> chemical tests for lipids, Acacia, Agar and Tragacanth, Starches and Gelatin
CO6[L6]	<u>Prepare</u> chemical tests for, Starches and Gelatin

Course content:

3Hrs. / Week

List of Experiments:

Expt No	Name of the Experiment	CO
1	Introduction of pharmacognosy laboratory and experiments	CO1
2	Study of cell wall constituents and cell inclusions	CO1
3	Macro, Powder and Microscopic study of Datura	CO2
4	Macro, Powder and Microscopic study of Senna	CO2
5	Macro, Powder and Microscopic study of cassia	CO2
6	Macro, Powder and Microscopic study of Cinnamon	CO2
7	Macro, Powder and Microscopic study of Cinchona	CO2

8	Macro, Powder and Microscopic study of Ephedra	CO2
9	Macro, Powder and Microscopic study of Quassia	CO2
10	Macro, Powder and Microscopic study of Clove	CO3
11	Macro, Powder and Microscopic study of Fennel	CO3
12	Macro, Powder and Microscopic study of Coriander	CO3
13	Macro, Powder and Microscopic study of Isphagol	CO3
14	Macro, Powder and Microscopic study of Nuxvomica	CO3
15	Macro, Powder and Microscopic study of Rauwolfia	CO2
16	Macro, Powder and Microscopic study of Liquorice	CO3
17	Macro, Powder and Microscopic study of Ginger	CO3
18	Macro, Powder and Microscopic study of Podophyllum	CO3
19	Determination of Iodine value of the given oil or fat	CO4
20	Determination of Saponification value of the given oil or fat and unsaponifiable matter	CO4
21	Determination of Ester value of given oil or fat	CO4
22	Determination of acid value of the given oil or fat	CO4
23	Chemical tests for lipids(castor oil, Sesame oil, Bees wax)	CO5
24	Chemical tests for Acacia	CO5
25	Chemical tests for Agar	CO5
26	Chemical tests for Tragacanth	CO5
27	Chemical tests for Starch, Gelatin	CO6

Scheme of Practical Examination:

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

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

References:

Text books

1. Pharmacognosy by G.E. Trease & W.C.Evans.
2. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

1. Pharmacognosy by Brady &Tyler.E.
2. Pharmacognosy by T.E.Wallis.
3. Pharmacognosy by C.S. Shah & Qadery.
4. Pharmacognosy by M.A. Iyengar.

PHARMACOLOGY- I – THEORY

COURSE CODE:T2104

COURSE OBJECTIVES: Upon completion of the subject student shall be able to (Know, do, appreciate) –

COB1: Understand the pharmacological aspects of drugs falling under the above mentioned chapters;

COB2: Handle and carry out the animal experiments;

COB3: Appreciate the importance of pharmacology subject as a basis of therapeutics; and

COB4: Correlate and apply the knowledge therapeutically.

COURSE OUTCOMES :

CO	Statement
CO1[L2]	<u>Understand</u> the basics concepts of drug toxicity, preclinical evaluation and drug interactions, Receptors
CO2[L4]	<u>Know</u> Classification of Drugs acting on ANS and able to understand the actions of drugs
CO3[L5]	<u>To grasp</u> knowledge on various cardiovascular disorders & able to treat the condition with the drugs
CO4[L2]	<u>Understand</u> & get an overview on various CNS disorders & know the classifications of CNS acting drugs
CO5[L5]	<u>Acquire</u> knowledge on Respiratory problems, causes and their treatment
CO6[L1]	<u>Remember</u> the Pharmacology of Hormones and Hormone antagonists & the release of various autocoids & drug therapy to antagonize actions of autocoids

Lecture wise programme :

3 Hrs. /Week

1. General Pharmacology

- Introduction, definitions and scope of pharmacology
- Routes of administration of drugs
- Pharmacokinetics (absorption, distribution, metabolism and excretion)
- Pharmacodynamics
- 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. Mydriatics and miotic
- 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 hyperlipidemias

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 anesthetics

5. Pharmacology of Drugs acting on Respiratory tract

- a. Bronchodilators
- b. Mucolytics
- c. Expectorants
- d. Antitussives
- e. Nasal Decongestants

6. Pharmacology of Hormones and Hormone antagonists

- a. Thyroid and Anti-thyroid 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 autacoids and their antagonists

- a. Histamines and Anti-histaminics
- b. 5-Hydroxytryptamine and its antagonists
- c. Lipid derived autacoids and platelet activating factor

References:

Text books

1. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
3. 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)

1. 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.
2. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
4. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

COMMUNITY PHARMACY - THEORY

COURSE CODE : T2105

COURSE OBJECTIVES: Upon completion of the course, the student shall be able to know pharmaceutical care services;

COB 1: know the business and professional practice management skills in community pharmacies.

COB2: do patient counselling & provide health screening services to public in community pharmacy.

COB3: respond to minor ailments and provide appropriate medication;

show empathy and sympathy to patients; and appreciate the concept of Rational drug therapy.

COURSE OUTCOMES:

CO	Statement
CO1[L2]	<u>Explain</u> Roles and responsibilities of Community pharmacist in managing and maintenance business of a community pharmacy
CO2[L1]	<u>Describe</u> the parts of prescription, legality & identification of medication related problems like drug interactions
CO 3[L2]	<u>Discuss</u> various methods of inventory management
CO4[L1]	<u>Enumerate</u> Gain knowledge on pharmaceutical care, patient medication adherence, health screening services and OTC medication
CO [L5]	<u>Evaluate</u> the concept of health education as per WHO, study about commonly occurring communicable diseases, causative agents, clinical presentations and prevention of communicable diseases, balanced diet, and treatment & prevention of deficiency disorders, family planning.
CO6 [L3]	<u>Determine</u> symptoms of minor ailments and provide appropriate medication

Lecture wise programme:

2 Hrs. /Week

- 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, and 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, and safety stock**
- 5 **Pharmaceutical care**
Definition and Principles of Pharmaceutical care.

6 Patient counselling

Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels

7 Patient medication 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, Health Education WHO Definition of health, and health promotion, care for children, pregnant & breastfeeding 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, Ophthalmic symptoms, and worms infestations.

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

13 Code of ethics for community pharmacists

Reference books:

1. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
2. Comprehensive Pharmacy Review – Edt. Leon Shargel
Lippincott Williams & Wilkins.

PHARMACOTHERAPEUTICS -I- THEORY

COURSE CODE : T2106

COURSE OBJECTIVES: at completion of this subject , the students will be able to understand

COB1: The pathophysiology of selected disease states and the rationale for drug therapy;

COB2: The therapeutic approach to management of these diseases;

COB3: The controversies in drug therapy;

COB4: The importance of preparation of individualized therapeutic plans based on diagnosis;

COB5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy

COB6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

COURSE OUTCOMES:

CO	Statement
CO1 [L2]	Explain the pathophysiology and management of respiratory and endocrine diseases
CO2 [L1]	Describe the general prescribing guidelines and rational use of drugs of Pediatric patients Geriatric patients, Pregnancy and breast feeding
CO3 [L1]	Describe the general prescribing guidelines and rational use of drugs of Pregnancy and breast feeding
CO4 [L2]	Discuss the pathophysiology and management of Glaucoma, Conjunctivitis- viral & bacterial meningitis
CO5 [L4]	Recognize the role of pharmacist in essential and rational drug use.
CO6 [L1]	Define common etiopathogenesis of Cardio vascular diseases.

Lecture wise programme:

3Hrs. / Week

UNIT I : Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

UNIT II: 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, and Osteoporosis

UNIT III: General prescribing guidelines for a. Paediatric patients b. Geriatric patients c. Pregnancy and breast feeding.

UNIT IV: Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial.

UNIT V: Introduction to rational drug use Definition, Role of pharmacist Essential drug concept and Rational drug formulations.

References:

1. Clinical pharmacy and Therapeutics - Eric T.Herfindal, Williams and Wilkins Publication.

PHARMACOTHERAPEUTICS-I – PRACTICAL

COURSE CODE: T2109

COURSE OBJECTIVES: At completion of this subject it is expected that students will be able to understand

COB1: The pathophysiology of selected disease states and the rationale for drug therapy;

COB2: The therapeutic approach to management of these diseases;

COB3: The controversies in drug therapy;

COB4: The importance of preparation of individualized therapeutic plans based on diagnosis;

COB5: 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)

COURSE OUTCOMES

CO	Statement
CO1[L1]	<u>Identify</u> drug interactions and rationalize the prescription
CO2[L2]	<u>Discuss</u> the therapeutic approach to management of corresponding diseases
CO3[L6]	<u>Design</u> individualized therapeutic plans based on diagnosis
CO4[L4]	<u>Analyse</u> patient counseling
CO5[L1]	<u>Identify</u> therapeutic goals of the treatment.
CO6[L2]	<u>Summarize</u> doses, adverse drug reactions and side effects of the given drugs.

Course content

List of experiments:

3 Hrs. / Week

Expt. No	TITLE	CO
1.	Analyse the case study of Myocardial infarction.	CO 4
2.	Analyse the case study of Hypertension associated with CAD	CO 4
3.	Analyse the Case study of Diabetes mellitus.	CO 4
4.	Analyse the General Prescribing guidelines for Pregnancy & Breastfeeding women.	CO 4
5.	Analyse the Principle guidelines for Ration drug use	CO 4

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

Format of the assignment:

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

Scheme of Practical Examination:

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

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

References

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice –
3. Green and Harris, Chapman and Hall publication
4. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication

THIRD YEAR

PHARMACOLOGY – II -THEORY

COURSE CODE: T3101

COURSE OBJECTIVES:

COB1: Understand the pharmacological aspects of drugs falling under the above-mentioned chapters

COB2: Carry out the animal experiments confidently

COB3: Appreciate the importance of pharmacology subject as a basis of therapeutics

COB4: Correlate and apply the knowledge therapeutically.

COURSE OUTCOMES:

CO	Statement
CO1[L1]	<u>Demonstrate</u> a thorough understanding of the mechanisms of action, therapeutic uses, and side effects of drugs covered in the course.
CO2 [L2]	<u>Perform</u> and interpret pharmacological experiments on animals with confidence and precision.
CO3 [L3]	<u>Appreciate</u> the role of pharmacology as a foundational science in the development and application of therapeutic interventions.
CO4 [L4]	<u>Correlate</u> pharmacological principles with clinical scenarios to make informed therapeutic decisions.
CO5 [L5]	<u>Analyze</u> and predict potential drug interactions and adverse effects based on pharmacological knowledge.
CO 6 [L6]	<u>Critically</u> evaluate and synthesize current pharmacological research to stay updated with advancements in drug therapy and development.

Lecture wise programme:

3 Hrs./ Week

Unit 1: Pharmacology of Drugs Acting on Blood and Blood Forming Agents

- a. Anticoagulants
- b. Thrombolytics and Antiplatelet Agents
- c. Haemopoietics and Plasma Expanders

Unit 2: Pharmacology of Drugs Acting on Renal System

- a. Diuretics
- b. Anti-diuretics

Unit 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)
- l. Pharmacology of Anthelmintic Drugs
- m. Chemotherapy of Cancer (Neoplasms)

Unit 4: Immunopharmacology

Pharmacology of Immunosuppressants and Stimulants

Unit 5: Principles of Animal Toxicology

- a. Acute Toxicity
- b. Sub-acute Toxicity
- c. Chronic Toxicity

Unit 6: The Dynamic Cell

- a. Cell and Macromolecules: Cellular Classification, Subcellular Organelles, Macromolecules, Large Macromolecular Assemblies
- b. Chromosome Structure: Prokaryotic 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)

Unit 7: The Gene: Genome Structure and Function

- a. Gene Structure: Organization and Elucidation of Genetic Code
- b. Gene Expression: Expression Systems (Prokaryotic 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 Prokaryotes and Eukaryotes. Transcription Factors That Regulate Transcription in Prokaryotes and Eukaryotes. RNA Processing: rRNA, tRNA and mRNA Processing
- d. Protein Synthesis: Mechanisms of Protein Synthesis, Initiation in Eukaryotes, Translation Control and Post-Translation Events
- e. Altered Gene Functions: Mutations, Deletions, Amplifications, LOH,

Translocations, Trinucleotide Repeats and Other Genetic Abnormalities. Oncogenes and Tumor Suppressor Genes

f. Gene Sequencing, Mapping and Cloning of Human Disease Genes

g. Introduction to Gene Therapy and Targeting

h. Recombinant DNA Technology: Principles, Processes (Gene Transfer Technology), and Applications

References:

Text books :

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

Reference books:

1. 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.
2. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
4. 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.

PHARMACOLOGY – II –PRACTICAL

COURSE CODE:T3107

COURSE OBJECTIVES:

COB1: Familiarize students with the handling and care of various laboratory animals used in pharmacological experiments.

COB2: Teach the preparation and use of physiological salt solutions in experimental pharmacology.

COB3: Introduce the laboratory appliances commonly used in pharmacological research.

COB4: Instruct students on the use of anesthetics in laboratory animals.

COB5: Train students to record and interpret dose-response curves using isolated tissue preparations.

COB6: Provide hands-on experience in conducting bioassays using different methods.

COB7: Educate students on the routes of drug administration in animals.

COB8: Enhance students' understanding of experimental techniques and data interpretation for various pharmacological activities.

COURSE OUTCOMES

CO	Statement
CO1 [L1]	Demonstrate the ability to handle and care for laboratory animals such as frogs, mice, rats, guinea pigs, and rabbits.
CO2 [L2]	Prepare and utilize physiological salt solutions effectively in pharmacological experiments.
CO3 [L3]	Identify and use laboratory appliances appropriately in experimental pharmacology.
CO4 [L4]	Apply the principles and procedures for using anesthetics in laboratory animals.
CO5 [L5]	Record and interpret dose-response curves for acetylcholine and histamine using isolated tissue preparations.
CO6 [L6]	Conduct bioassays of acetylcholine and histamine using interpolation and three-point methods.

COURSE CONTENT

3 Hrs./ Week

List of Experiments:

Exp. No.	Title	CO
1.	Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).	CO1
2.	Study of physiological salt solutions used in experimental pharmacology.	CO1
3.	Study of laboratory appliances used in experimental pharmacology.	CO1
4.	Study of use of anesthetics in laboratory animals.	CO2
5.	To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.	CO2
6.	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.	CO3

7.	To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.	CO3
8.	To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.	CO3
9.	Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.	CO4
10.	To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.	CO4
11.	To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.	CO5
12.	To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).	CO5
13.	Study of theory, principle, procedure involved and interpretation of given results for the following experiments:	CO6
a)	Analgesic property of drug using analgesiometer.	CO6
b)	Antiinflammatory effect of drugs using rat-paw edema method.	CO6
c)	Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.	CO6
d)	Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.	CO6
e)	Locomotor activity evaluation of drugs using actophotometer and rotorod.	CO6
f)	Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.	CO6
g)	Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).	CO6

Scheme of Practical Examination:

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

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

References:

Text books (Practical)

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

Reference books (Practical) :

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

PHARMACEUTICAL ANALYSIS – THEORY

COURSE CODE: T3102

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Understand the CGMP aspects in a pharmaceutical industry, Appreciate the importance of documentation, and the scope of quality certifications applicable to pharmaceutical industries, also the responsibilities of QA & QC departments.

COB2: Understand the chromatographic separation and analysis of drugs.

COB3: Understand the principles of volumetric and electro chemical analysis

COB4: Understand the interaction of matter with electromagnetic radiations and its applications in drug.

COURSE OUTCOME:

CO	Statement
CO1 [L2]	<u>Discuss</u> the sources and control of quality variations, validation methods, GLP, ISO 9000, ICH guidelines and their importance in pharmaceutical industry
CO2 [L6]	<u>Develop</u> chromatographic techniques with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.
CO3 [L2]	<u>Summarize</u> on theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications of Electrochemical methods of analysis
CO4 [L1]	<u>Enumerate</u> theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical spectroscopy
CO5 [L2]	<u>Explain</u> theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of polarimetry and X-ray diffraction techniques
CO6 [L1]	<u>Describe</u> theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of Thermal analysis

Lecture wise programme

3 Hrs. /Week

1. Quality Assurance:

- a. Introduction, sources of quality variation, and 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, and 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, R_f value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, and 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, and applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, and 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, and 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's 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, bathochromic 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, and 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, and 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. Introduction to Instrumental Analysis, Robert D.Braun, PharmaMed Press, 2010
2. Instrumental Methods Of Chemical Analysis, 5th Edition, Gurudeep R Chatwal, Sham K Anand, Himalaya Publishing House
3. Spectroscopy, Indian Edition, Donald L. Pavia, Gary M. Lampman, George S. Kriz & James R. Vyvyan, Cengage Learning.
4. Vogel's textbook of quantitative chemical analysis, 6th Edition, Pearson Education, India
5. Quality Assurance and Quality Management in Pharmaceutical Industry, Y. Anjaneyulu & R. Marayya, Robert D.Braun, Pharma Med Press, 2011
6. Instrumental methods of chemical analysis, B.K.Sharma, GOEL Publishing House

PHARMACEUTICAL ANALYSIS - PRACTICAL

Course code: T3108

COURSE OBJECTIVES:

Upon completion of the course the student shall be able to

COB1: Understand the chromatographic separation and analysis of drugs.

COB2: Understand the principles of volumetric and electro chemical analysis

COB3: Understand the interaction of matter with electromagnetic radiations and its applications in drug.

COURSE OUTCOMES:

CO	Statement
CO1 [L1]	Identify the mixture of sample components by Paper chromatography and TLC and interpretation of chromatograms
CO2 [L4]	Analyse the compounds by various spectroscopic instruments like spectrophotometers, fluorimeters, flame photometer
CO3 [L3]	Determine conductometric and potentiometric titrations of mixture of acids and bases
CO4 [L2]	Demonstrate the working and analyzing compounds by HPLC, HPTLC instruments
CO5 [L6]	Develop the working and analyzing compounds by , GC-MS, DSC instruments
CO6 [L5]	Justify IR and NMR Spectra

Course content

3Hrs/Week

List of experiments

Expt. No	Title	CO
1	Separation and identification of Amino Acids by Paper Chromatography.	CO1
2	Separation and identification of Sulpha drugs by TLC technique.	CO1
3	Effect of pH and solvent on the UV spectrum of given compound.	CO2
4	Comparison of the UV spectrum of a compound with that of its derivatives.	CO2
5	Determination of dissociation constant of indicators using UV-Visible spectroscopy.	CO2

6	Conductometric titration of mixture of acids with a strong base.	CO3
7	Potentiometric titration of a acid with a strong base.	CO3
8	Estimation of drugs by Fluorimetric technique.	CO2
9	Study of quenching effect in fluorimetry.	CO2
10	Colourimetric estimation of Supha drugs using BMR reagent.	CO2
11	Simultaneous estimation of two drugs present in given formulation.	CO2
12	Assay of Salicylic Acid by colourimetry.	CO2
13	Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.	CO2
14	Determination of Na/K by Flame Photometry.	CO2
15	Determination of pKa using pH meter.	CO3
16	Determination of specific rotation.	CO5
17	Comparison of the IR spectrum of a compound with that of its derivatives.	CO6
18	Demonstration of HPLC.	CO4
19	Demonstration of HPTLC.	CO4
20	Demonstration of GC-MS.	CO5
21	Demonstration of DSC.	CO5
22	Interpretation of NMR spectra of any one compound.	CO6

Scheme of Practical Examination:

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

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

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.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.

PHARMACOTHERAPEUTICS – II – THEORY

COURSE CODE – T3103

COURSE OBJECTIVES : Upon completion of the course the student shall be able to

COB1 : Know the pathophysiology of selected disease states and the rationale for drug therapy

COB2 : Know the therapeutic approach to management of these diseases

COB3 : Know the controversies in drug therapy

COB4 : Know the importance of preparation of individualised therapeutic plans based on diagnosis

COB5 : 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).

COURSE OUTCOMES:

CO	Statement
CO1 [L1]	<u>Define</u> the pathophysiology of selected disease states and the rationale of drug therapy
CO2 [L2]	<u>Explain</u> the therapeutic approach to management of the diseases.
CO3 [L2]	<u>Explain</u> the controversies in drug therapy
CO4 [L2]	<u>Explain</u> the importance of preparation of individualized therapeutic plans based on diagnosis.
CO5 [L1]	<u>Identify</u> 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).
CO 6 [L3]	<u>Illustrate</u> the evidence-based medicine and able to apply it to provide patient care to diversified patients

Lecture wise programme

3Hrs. / Week

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases

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UNIT – I : 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, Gonorrhoea and Syphilis

UNIT- II: Musculoskeletal disorders Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.

UNIT –III: Renal system Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, and Drug induced renal disorders

UNIT – IV: Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy -nausea and emesis

UNIT- V: Dermatology: Psoriasis, Scabies, Eczema, and Impetigo

References:

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

PHARMACOTHERAPEUTICS – II - PRACTICAL

COURSE CODE – T3109

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: To evaluate the case sheet of patients in a hospital.

COB2: To Understand the progress and changes made in drug therapy

COB3: To Know the controversies in drug therapy

COB4: To present the cases in a professional manner

COURSE OUTCOMES:

CO	Statement
CO 1 [L4]	<u>Determine</u> the drug interactions in the prescription
CO 2 [L4]	<u>Compare</u> and do patient monitoring to identify any unwanted effects
CO 3 [L3]	<u>Demonstrate</u> the therapeutic approach based on the diagnosis
CO 4 [L3]	<u>Demonstrate</u> therapeutic plans based on the individual patients
CO 5 [L2]	<u>Identify</u> patient counseling to provide the information about the disease and therapy
CO 6 [L2]	<u>Explain</u> the significance of laboratory investigations in diagnosing a disease

Course content:

3Hrs./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.

List of Experiments:

Expt.No	Title	CO
1	Define the guidelines on rational use of antibiotics	CO 1, CO6
2	Analyse the case study on Urinary Tract Infections	CO 4
3	Case study on asthma	CO 2
4	Understand the basic principles of cancer therapy	CO 2
5	Case study on Acute renal failure	CO 5
6	Analyse the case study on Chronic renal Failure	CO 3

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

Format of the assignment:

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

Scheme of Practical Examination:

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

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

References:

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

PHARMACEUTICAL JURISPRUDENCE-THEORY

COURSE CODE: T3104

COURSE OBJECTIVES: Upon completion of the subject student shall be able to (Know, do, and appreciate) –

COB1: practice the Professional ethics; understand the various concepts of the pharmaceutical legislation in India.

COB2: know the various parameters in the Drug and Cosmetic Act and rules; know the Drug policy, DPCO, Patent and design act.

COB3: understand the labelling requirements and packaging guidelines for drugs and cosmetics.

COB4: be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

COURSE OUTCOMES:

CO	Statement
CO1 [L1]	Define the Professional ethics and to understand the various concepts of the pharmaceutical legislation in India
CO2 [L2]	Discuss the various parameters in the Drug and Cosmetic Act and rules and to understand the functions various officers comes under D & C act , labelling requirements and packaging guidelines for drugs and cosmetics and pharmacy act
CO3 [L3]	Determine the various parameters, construction , design of bonded and non-bonded laboratory manufacturing, warehousing and storage procedure for alcoholic and non alcoholic in mentioned under medicinal and toilet preparation act
CO4 [L1]	Define about Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations and to know about DPCO , prohibited and exempted classes of advertisements relating drugs and magic remedies described under act
CO5 [L2]	Discuss About Prevention of Cruelty to animals Act-1960. & Patents & design Act-1970.
CO6 [L5]	Assess Brief study of prescription and Non-prescription Products

Lecture wise programme:

2 Hrs. /Week

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, and Y.

Sales, Import, labelling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems Constitution and Functions of DTAB, DCC, and CD. 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, and ER.

5. Medicinal and Toilet Preparation Act –1955.

Objectives, Legal Definitions, Licensing, Bonded and Non-Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations

6. Narcotic Drugs and Psychotropic substances Act-1985 and Rules.

Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, and Schedules to the Act.

7. Study of Salient Features of Drugs and magic remedies Act and its rules.

8. Study of essential Commodities Act Relevant to drugs price control Order

9. Drug Price control Order & National Drug Policy (Current).

10. Prevention of Cruelty to animals Act-1960.

11. Patents & design Act-1970.

12. Brief study of prescription and Non-prescription Products.

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

References:

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

PHARMACEUTICAL MEDICINAL CHEMISTRY - THEORY

COURSE CODE: T3105

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Understand the chemistry of drugs with respect to their pharmacological activity

COB2: Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

COB3: Know the Structural Activity Relationship of different class of drugs

COB4: Study the chemical synthesis of selected drugs

COURSE OUTCOMES:

CO	Statement
CO1 [L2]	<u>Interpret</u> the chemistry of drugs with respect to their pharmacological activity, the drug metabolic pathways, adverse effect and therapeutic value of drugs
CO2 [L2]	<u>Explain</u> the importance of drug design and different techniques of drug design and the principles of metabolism, adverse effects and therapeutic value of drugs
CO3 [L2]	<u>Interpret</u> the Structural Activity Relationship (SAR) of different class of drugs
CO4 [L6]	<u>Synthesize</u> the chemical synthesis of drugs and intermediates, and reaction conditions
CO5 [L6]	<u>Prepare</u> the green chemistry techniques involved in the preparation of synthetic compounds
CO6 [L1]	<u>Describe</u> the compound workout techniques, and purification techniques, the application of TLC techniques for product conformation and purification.

Lecture wise programme

3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (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

- Local anti-infective agents
- Preservatives
- Antifungal agents
- Urinary tract anti-infectives
- Antitubercular agents
- Antiviral agents and Anti-AIDS agents
- Antiprotozoal agents
- Anthelmintics
- Antiscabies and Antipedicular agents

3. Sulphonamides and sulphones

4. Antimalarials

5. Antibiotics

6. Antineoplastic agents

7. Cardiovascular agents

- Antihypertensive agents
- Antianginal agents and vasodilators
- Antiarrhythmic agents
- Antihyperlipidemic agents
- Coagulants and Anticoagulants
- Endocrine

8. Hypo glycemc agents

9. Thyroid and Anti-thyroid agents

10. Diuretics

11. Diagnostic agents

12. Steroidal Hormones and Adrenocorticoids

References:

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toranto.
4. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya,

5. S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
6. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
7. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
8. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
9. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.

PHARMACEUTICAL MEDICINAL CHEMISTRY - PRACTICAL

COURSE CODE: T3110

COURSE OBJECTIVE: Objectives: Upon completion of the course the student shall be able to

COB1: Understand the chemistry of drugs with respect to their pharmacological activity

COB2: Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

COB3: Know the Structural Activity Relationship of different class of drugs

COB4: Study the chemical synthesis of selected drugs

COURSE OUTCOMES:

CO	Statement
CO1[L6]	Perform the assays of important drugs from the course content
CO2[L6]	Preparation of medicinally important compounds or intermediates required for synthesis of drugs
CO3[L6]	Preparation of medicinally important compounds or intermediates required for synthesis of drugs
CO4[L4]	Identification of important drugs
CO5[L3]	Identification of important drugs
CO6[L3]	Determination of dissociation constants and molar refractivity of compounds for QSAR analysis

Course content

3 Hrs. / Week

Expt. No	Title	CO
1	Preparation of benzocaine	CO2
2	Preparation of 7-hydroxy-4-methyl coumarine	CO2
3	Preparation of benzimidazole	CO2
4	Preparation of benztriazole	CO2
5	Preparation of benzilic acid	CO3
6	Preparation of fluorescein	CO3
7	Preparation of 5,5- diphenyl hydantoin	CO3
8	Preparation of 2,3- diphenyl quinoxaline	CO3

9	Identification of sulphonamide	CO4
10	Identification of isoniazid	CO4
11	Identification of metronidazole	CO5
12	Identification of ascorbic acid	CO5
13	Identification of benzocaine	CO5
14	Assay of ascorbic acid	CO1
15	Assay of chloroquine phosphate	CO1
16	Assay of isoniazid	CO1
17	Assay of benzocaine	CO1
18	Assay of metronidazole	CO1
19	Assay of sulphonilamide	CO1
20	Assay of diclofenac sodium	CO1
21	Assay of dapsone	CO1
22	QSAR studies	CO6

Reference Books:

1. Wilson and Gisvold's Textbook of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. William. O. Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M.E., Welly Med. Chemistry M.E. Walffed John Wiley and Sons, Wiley-interscience Publication, New York, Toronto.
4. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya,
5. S.G. Publisher, 6, Dildayal Nagar, Varanasi-10.
6. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi-54.
7. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd., New Delhi-19.
8. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
9. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H.J. Roth and A. Kleemann.
10. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

PHARMACEUTICAL FORMULATIONS - THEORY

COURSE CODE: T3106

COURSE OBJECTIVES:

Upon completion of the course the student shall be able to

COB1: To develop a comprehensive understanding of pharmaceutical dosage forms, including their key concepts and classifications, setting the groundwork for advanced studies in formulation and manufacturing.

COB2: To master the formulation of diverse tablet types, explore tablet excipients and granulation techniques, and gain proficiency in tablet coating. Acquire in-depth knowledge of quality control tests for both coated and uncoated tablets.

COB3: To acquire expertise in the production and filling of hard gelatin capsules, including the selection of raw materials and stringent quality control tests. Explore the intricacies of producing, filling, and evaluating soft gelatin capsules.

COB4: Formulate and evaluate various liquid oral preparations, such as suspensions, emulsions, and solutions. Investigate the stability considerations associated with these formulations.

COB5: To gain insight into parenteral formulations, encompassing large and small volume preparations. Understand the meticulous selection of containers, official tests, and the critical process of sterilization.

COB6: To conceptualize and define controlled and novel drug delivery systems, with examples such as parenteral, transdermal, buccal, rectal, nasal, implants, and ocular systems. Examine the advantages and challenges associated with these advanced delivery methods.

COURSE OUTCOMES:

CO	Statement
CO1[L 1]	<u>Memorize</u> the definition and basic characteristics of dosage forms used in pharmaceutical formulations.
CO2 [L 3]	<u>Demonstrate</u> the application of granulation techniques in tablet manufacturing, considering the properties of the active ingredient and the desired tablet characteristics.
CO3 [L 6]	<u>Design</u> a comprehensive quality control plan for capsule manufacturing, incorporating various tests to ensure product integrity and compliance.
CO4 [L 2]	<u>Explain</u> the essential features of emulsions, suspensions, and solutions as liquid oral dosage forms.
CO5 [L 5]	<u>Critically</u> assess the quality control measures used to ensure the safety and efficacy of parenteral products.
CO6 [L 1] & [L 3]	<u>Memorize</u> the key factors that can affect the absorption of drugs, and the basic anatomy of the skin & <u>Demonstrate</u> the application of concepts in designing drug delivery systems for transdermal, buccal, rectal, nasal, implants, and ocular route.

Lecture wise programme

2 Hrs. /Week

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, and Sterilization.

6. Ophthalmic preparations (Semi – Solids): Introduction and classification, Factors affecting absorption and anatomy of skin, Packaging storage and labeling,

Ointments: Types of Ointment Base, Preparation of ointment, Jellies: Types of jellies
Formulation of jellies Suppositories: Method of preparation, and Types Packaging

7. Definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, and ocular.

PHARMACEUTICAL FORMULATIONS – PRACTICAL

COURSE CODE: T3111

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: To learn and implement the wet granulation technique for the production of ordinary compressed tablets, understanding the process and its impact on tablet characteristics.

COB 2: To master the direct compression method for tablet preparation, emphasizing the efficiency and simplicity of this technique.

COB 3: To formulate soluble and chewable tablets, focusing on creating pharmaceutical dosage forms tailored for specific patient needs and preferences.

COB 4: To understand the formulation and filling process for hard gelatin capsules, emphasizing precision and quality control in pharmaceutical manufacturing.

COB 5: To perform Quality Control (QC) tests on tablets, capsules, and injections to assess their compliance with established standards and ensure product quality.

COB 6: To formulate two liquid oral preparations (Paracetamol Syrup and Aluminum hydroxide gel) and evaluate their potency through assay methods, emphasizing accuracy in formulation.

COURSE OUTCOME:

CO	Statement
CO1 [L 5]	Evaluate and troubleshoot common issues encountered during tablet manufacturing processes.
CO2 [L 2]	Explain the significance of selecting appropriate powders and granules for encapsulation.
CO3 [L 1]	Recall the basic categories of formulation components for parenteral products, including excipients, solubilizers, and stabilizers.
CO [L 5]	Evaluation of parenterals
CO5 [L 6]	Develop two comprehensive formulations for distinct liquid oral preparations, considering solubility, stability, and palatability.
CO6 [L 3]	Demonstrate the ability to select appropriate bases and additives based on the desired properties of the semi-solid product & Explain the basic principles governing the formulation of cosmetic preparations

Course content:

3 Hrs./Week

List of Experiments

Expt. No.	Title of the experiment	CO
1	Manufacture of Tablets a. Ordinary compressed tablet-wet granulation b. Tablets prepared by direct compression. c. Soluble tablet. d. Chewable tablet.	CO1
2	Formulation and filling of hard gelatin capsules	CO1

3	Manufacture of parenterals a. Ascorbic acid injection b. Calcium gluconate injection c. Sodium chloride infusion. d. Dextrose and Sodium chloride injection/ infusion	CO2
4	Evaluation of Pharmaceutical formulations (QC tests) a. Tablets b. Capsules c. Injections	CO3
5	Formulation of two liquid oral preparations and evaluation by assay a. Solution: Paracetamol Syrup b. Antacid suspensions- Aluminum hydroxide gel	CO4
6	Formulation of semisolids and evaluation by assay a. Salicylic acid and benzoic acid ointment b. Gel formulation Diclofenac gel	CO5
7	Cosmetic preparations a. Lipsticks b. Cold cream and vanishing cream c. Clear liquid shampoo d. Tooth paste and tooth powders	CO6
8	Tablet coating (demonstration)	CO1

Scheme of Practical Examination :

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

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

References:

Text books (Theory)

1. Pharmaceutical dosage forms, Vol, I,II and III by lachman
2. Rowlings Text book of Pharmaceutics
3. Tutorial Pharmacy – Cooper & Gun

Reference books (Theory)

1. Remington's Pharmaceutical Sciences
2. USP/BP/IP

FOURTH YEAR

PHARMACOTHERAPEUTICS-III- THEORY

COURSE CODE: T4101

COURSE OBJECTIVES: At completion of this subject, it is expected that students will be able to understand

COB1: The pathophysiology of selected disease states and the rationale for drug therapy;

COB2: The therapeutic approach to management of these diseases;

COB3: The controversies in drug therapy;

COB4: The importance of preparation of individualized therapeutic plans based on diagnosis;

COB5: 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);

COB6: Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

COURSE OUTCOMES:

CO	Statement
CO1[L1]	<u>Identify</u> drug interactions and rationalize the prescription
CO2[L 2]	<u>Discuss</u> the therapeutic approach to management of selected diseases
CO3[L3]	<u>Calculate</u> individualized therapeutic plans based on diagnosis
CO4[L3]	<u>Show</u> patient counseling
CO5[L1]	<u>Arrange</u> planned experiments and prepare laboratory report in a standard format
CO6[L1]	<u>Identify</u> the controversies in drug therapy

Lecture wise programme

3Hrs. / Week

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. Hematological system: Anemia, 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, and headaches.
6. Evidence Based Medicine

PHARMACOTHERAPEUTICS-III-PRACTICAL

COURSE CODE: T4107

Course Objectives:

At completion of this subject it is expected that students will be able to understand

COB1: The pathophysiology of selected disease states and the rationale for drug therapy;

COB2: The therapeutic approach to management of these diseases;

COB3: The controversies in drug therapy;

COB4: The importance of preparation of individualized therapeutic plans based on diagnosis;

COB5: Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy

Course content:

3 Hrs. /Week

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

COURSE OUTCOMES:

CO	Statement
CO1[L1]	Identify drug interactions and rationalize the prescription
CO2[L 2]	Discuss the therapeutic approach to management of selected diseases
CO3[L3]	Calculate individualized therapeutic plans based on diagnosis
CO4[L3]	Show patient counseling
CO5[L1]	Arrange planned experiments and prepare laboratory report in a standard format
CO6[L1]	Identify the controversies in drug therapy

List of Experiments:

Expt. No	Title of the Experiment	CO
1	Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux	CO 1
2	Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease,	CO 5
3	Viral hepatitis including jaundice, and Drug induced liver disorders.	CO 5
4	Hematological system: Anemia, Venous thromboembolism, Drug induced blood disorders.	CO 3
5	Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,	CO 2

6	Psychiatry disorders: Schizophrenia, Affective disorders, Anxiety disorders,	CO 1
7	Sleep disorders, Obsessive Compulsive disorders	CO 1
8	Pain management including Pain pathways, neuralgias, headaches.	CO 2
9	Evidence Based Medicine	CO 4

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

Format of the assignment:

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

Scheme of Practical Examination :

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

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

References

Text Books

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

Reference Books

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

HOSPITAL PHARMACY – THEORY

COURSE CODE: T4102

COURSE OBJECTIVES: Upon completion of the course, the student shall be able to –

COB1: Know various drug distribution methods; know the professional practice management skills in hospital pharmacies.

COB2: Provide unbiased drug information to the doctors; know the manufacturing practices of various formulations in hospital set up.

COB3: Appreciate the practice-based research methods; and appreciate the stores management and inventory control.

COURSE OUTCOMES:

CO	Statement
CO1 [L2]	<u>Discuss</u> about Hospital - its organization and functions, Hospital Pharmacy- Organization and management.
CO2 [L2]	<u>Explain</u> the Knowledge about Budget – Preparation and implementation, Hospital drug policy.
CO3 [L1]	<u>Write</u> about Hospital pharmacy services.
CO4 [L6]	<u>Develop</u> to understand Manufacture of Pharmaceutical preparation
CO5 [L5]	<u>Assess</u> the continuing professional development programs.
CO6 [L1]	<u>Define</u> Radio Pharmaceuticals – Handling and packaging, Professional Relations and practices of hospital pharmacist

Lecture wise programme

2 Hrs. /Week

1. **Hospital** - its organization and functions
2. **Hospital pharmacy**- Organization 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
 1. Infection committee
 2. 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, and 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

References:

- 1. WHO consultative group report.
- 2. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- 3. Handbook of pharmacy – health care. Edt. Robin J Harman.
The Pharmaceuticalpress.

HOSPITAL PHARMACY- PRACTICAL

COURSE CODE: T4108

COURSE OBJECTIVES:

COB1: Assessment of drug interactions in the given prescriptions

COB2: Manufacture of parenteral formulations, powders.

COB3: Drug information queries.

COB4: Inventory control

COURSE OUTCOMES:

CO	Statement
CO1 [L1]	<u>Define</u> Drug profile
CO2 [L5]	<u>Assessment</u> of drug interactions in the given prescriptions
CO3 [L2]	<u>Discuss</u> about Manufacture of parenteral formulations.
CO4 [L3]	<u>Choose</u> Manufacture of powders.
CO5 [L1]	<u>List</u> the Drug information queries.
CO6 [L2]	<u>Explain</u> the Inventory control.

Course content

3 Hrs./Week

List of Experiments:

Expt. No	Title	CO
1	Drug profile of given drug (paracetamol)	CO1
2	Drug profile of given drug (Metronidazole)	CO1
3	Drug profile of given drug (Tramadol)	CO1
4	Drug profile of given drug (Ondansetron)	CO1
5	Identification of Drug interactions in the given case study-1	CO2
6	Identification of Drug interactions in the given case study-2	CO2
7	Identification of Drug interactions in the given case study-3	CO2
8	Preparation of normal saline solution	CO3
9	Preparation of Dextrose injection	CO3
10	Preparation of Mannitol injection	CO3
11	Preparation of Sodium chloride injection injection	CO3
12	Preparation of Dusting powder	CO4
13	Preparation of Bulk powder	CO4
14	Drug information Query-1	CO5
15	Drug information Query-2	CO5
16	Drug information Query-3	CO5

17	Inventory control introduction	CO6
18	Inventory control by using ABC analysis	CO6
19	Inventory control by using VED analysis	CO6
20	Inventory control by using EOQ method	CO6

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.

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:

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

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

REFERENCE:

1. Hospital pharmacy by William .E. Hassan
2. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

CLINICAL PHARMACY – THEORY

COURSE CODE: T4103

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

COB1: Describe the etiology and pathogenesis of the selected disease states

COB2: Monitor drug therapy of patient through medication chart review and clinical review

COB3: obtain medication history interview and counsel the patients

COB4: Identify and resolve drug related problems

COB5: Detect, assess and monitor adverse drug reaction

COURSE OUTCOMES

CO	Statement
CO1[L1]	<u>Recall</u> the fundamental principles of clinical pharmacy theory, including the processes involved in monitoring drug therapy, obtaining medication history, and interpreting laboratory
CO 2[L2]	<u>Describe</u> the importance of obtaining comprehensive medication histories and providing patient counselling for effective pharmacotherapy.
CO 3[L3]	<u>Apply</u> knowledge and skills to identify and resolve drug-related problems, ensuring safe
CO 4[L4]	<u>Analyze</u> selected laboratory results within the context of specific disease states to make informed decisions regarding medication regimens.
CO 5[L5]	<u>Evaluate</u> the reliability and relevance of drug information sources to ensure evidence-based practice in clinical pharmacy
CO6[L2]	<u>Explain</u> the types of ADR'S & Drug interactions.

Lecture wise programme

3 Hrs. /Week

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 utilization 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, and 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, and presentation of cases.

8. Pharmaceutical care concepts

9. Critical evaluation of biomedical literature

10. Medication errors

References:

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
2. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
3. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

CLINICAL PHARMACY – PRACTICAL

COURSE CODE: T4109

COURSE OBJECTIVES:

COB1: Assessment of drug interactions & ADR'S in the given prescriptions

COB2: Participating in Ward rounds & Patients counseling regarding with various diseases.

COB3: Monitoring parameters of kidney function tests, liver function tests, cardiac markers.

COB4: Analyse the patient medication history interviews, drug information query, & medication errors in Ward round participation.

COURSE OUTCOMES:

CO	Statement
CO1[L1]	<u>Follow</u> the pharmaceutical activities, integrating the theoretical knowledge & practical skills in clinical pharmacy
CO2[L5]	<u>Assessment</u> of drug information queries in the given prescriptions
CO3[L2]	<u>Discuss</u> about Patients medication counseling skills & understand the patient medication tools in Ward round participation.
CO4[L3]	<u>Choose</u> Knowledge of laboratory investigation to case studies.
CO5[L1]	<u>List</u> the Medication history interviews procedure & process of patient counseling & communication skills.
CO6[L2]	<u>Explain</u> the types of ADR'S & Drug interactions.

Course content:

3 Hrs./Week

List of Experiments

Expt. No	Title	CO
1.	Assessment of drug information queries	CO 2
2.	Discuss about Medication history interviews procedure	CO 1
3.	Discuss about Patients counseling techniques & communication skills	CO 3
4.	Analyse the laboratory investigation parameters regarding with various diseases.	CO 4
5	Drug information query regarding with Rheumatoid Arthritis	CO 4
6	Assessment of Medication history interview of HIV/ AIDS Patient.	CO 5&6

List of Assignments:

1. Laboratory investigations of kidney function tests, liver function tests & cardiac function tests.
2. Medication history interview procedure & counseling techniques, communication skills with patients.
3. Development of Drug & poison information centre.
4. Preparation DUE & Medication history interview charts.
5. Different phases of clinical trials with elements to be evaluated.
6. Providing Various sources of drug information & poison information centre in Dic.

Evaluation of case studies in hospital for Medication errors ,Adrs and find out the suitable management.

References:

- 1.Clinical Pharmacy and Therapeutics, 6th Edition: Edited by Cate Whittlesea, BSc, MSc, PhD, MRPharmS and Karen Hodson, BSc (Pharm), MSc, PhD, MRPharmS , FFRPS
- 2.A Text Book of Clinical Pharmacy Practice: Essential Concepts and Skills. G. Parthasarathi, Karin Nyfort-Hansen, Milap C. Nahata

BIOSTATISTICS AND RESEARCH METHODOLOGY - THEORY

COURSE CODE: T4104

COURSE OBJECTIVES:

COB1: Equip students with the skills to design experiments and formulate research hypotheses for clinical and pharmaceutical studies.

COB2: Enable students to apply appropriate research methodologies and frameworks for conducting effective research studies.

COB3: Provide students with knowledge of various statistical methods to address and solve different research problems.

COB4: Develop students' proficiency in using statistical software packages such as SPSS, Epi Info, and SAS for data analysis and presentation.

COB5: Appraise the importance of computer systems in hospital and community pharmacies, focusing on patient data management, medication orders, and inventory control.

COURSE OUTCOMES:

CO	Statement
CO 1 [L1]	<u>Design</u> the experiment and research hypothesis for a project
CO 2 [L2]	<u>Explain</u> the appropriate framework for research studies
CO 3 [L3]	<u>List</u> the various statistical methods to solve different types of problems
CO 4 [L4]	<u>Demonstrate</u> various statistical software packages
CO 5 [L5]	<u>Appraise</u> the importance of Computer in hospital and Community Pharmacy
CO 6 [L5]	<u>Appraise</u> the statistical technique in solving the pharmaceutical problems

Lecture wise programme

2Hrs. / Week

Unit 1: Research Methodology

- i. Types of clinical study designs:
 - a. Case studies
 - b. Observational studies
 - c. Interventional studies
- ii. Designing the methodology
- iii. 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

- iv. Report writing and presentation of data

Unit 2: Biostatistics

- i. Introduction
- ii. Types of Data Distribution
- iii. Measures Describing the Central Tendency Distributions- Average, Median, and Mode
- iv. Measurement of the Spread of Data- Range, Variation of Mean, Standard Deviation, Variance, Coefficient of Variation, and Standard Error of Mean

Data Graphics

Construction and Labeling of Graphs: Histogram, Pie charts, Scatter plots, Semilogarithmic plots

Basics of Testing Hypothesis

1. Null hypothesis, Level of significance, Power of test, P-value, Statistical estimation of confidence intervals.
2. Level of significance (Parametric data): Students t-test (paired and unpaired), Chi Square test, Analysis of Variance (one-way and two-way)
3. Level of significance (non-parametric data): Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one-way ANOVA)
4. Linear regression and correlation: Introduction, Pearson's and Spearman's correlation and correlation coefficient.
5. Introduction to statistical software: SPSS, Epi Info, SAS.

Statistical Methods in Epidemiology

Incidence and prevalence, relative risk, attributable risk

Unit 3: Computer Applications in Pharmacy

Computer System in Hospital Pharmacy:

- i. Patterns of Computer use in Hospital Pharmacy -Patient record database management
- ii. Medication order entry - Drug labels and list-Intravenous solution and admixture
- iii. Patient medication profiles
- iv. Inventory control
- v. Management report & Statistics.

Computer In Community Pharmacy

1. Computerizing the Prescription Dispensing process
2. Use of Computers for Pharmaceutical Care in community pharmacy
3. Accounting and General ledger system

Drug Information Retrieval & Storage

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

References:

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

BIO PHARMACEUTICS AND PHARMACOKINETICS - THEORY

COURSE CODE: T4105

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB 1: Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.

COB 2: Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

COB 3: To understand the concepts of bioavailability and bioequivalence of drug products and their significance.

COB 4: Understand various pharmacokinetic parameters, their significance & applications.

COURSE OUTCOMES:

CO	Statement
CO1 [L 2]	<u>Demonstrate</u> a foundational understanding the principles of drug absorption, distribution, metabolism and excretion
CO2[L 1]	<u>Describe</u> the mechanisms and evaluate the factors influencing drug absorption, distribution, metabolism and excretion
CO3[L 1]	<u>Enumerate</u> pharmacokinetic models for calculating and interpreting pharmacokinetics parameters
CO4[L 2]	<u>Discuss</u> multiple dosing regimens using pharmacokinetic parameters to optimize therapeutic compliance.
CO5[L 6]	<u>Develop</u> pharmacokinetic parameters of drug demonstrating saturation kinetics
CO6[L 2]	<u>Illustrate</u> protocols for bioavailability testing and evaluate bioequivalence among marketed drug products

Lecture wise programme

3Hrs./ Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics

- Absorption of drugs from gastrointestinal tract.
- Drug Distribution.
- Drug Elimination.

2. Pharmacokinetics

Introduction to Pharmacokinetics.

- Mathematical model
- Drug levels in blood.

- c. Pharmacokinetic model
- d. Compartment models
- e. Pharmacokinetic study.

3. One compartment open model.

- a. Intravenous Injection (Bolus)
- b. Intravenous infusion.

4. Multicompartment models.

- a. Two compartment open model.
- b. IV bolus, IV infusion and oral administration.

5. Multiple – Dosage Regimens.

- a. Repetitive Intravenous injections – One Compartment Open Model
- b. Repetitive 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. Non compartmental 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.

BIO PHARMACEUTICS AND PHARMACOKINETICS - PRACTICAL

COURSE CODE: T4110

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Develop and implement methods aimed at enhancing the dissolution characteristics of slightly soluble drugs.

COB2: Conduct comparative dissolution studies to evaluate differences between two distinct marketed products containing the same drug.

COB3: Investigate the influence of polymorphism on both solubility and dissolution behavior of drugs.

COURSE OUTCOMES:

CO	Statement
CO1[L 1]	Define and explain the concepts of solubility, dissolution, and polymorphism in the context of pharmaceuticals. Recall and identify various factors influencing drug solubility and dissolution rates.
CO2[L 3]	Apply experimental techniques to determine protein binding in various biological samples.
CO3[L 4]	Interpret and analyze the pharmacokinetic parameters associated with in vivo bioavailability studies.
CO4[L 3]	Demonstrate adherence to ethical standards and regulatory guidelines in the handling and analysis of biological samples
CO5[L 4]	Compare urinary excretion profiles of different drugs or formulations to assess variations in pharmacokinetic behaviour.
CO6[L 5]	Evaluate the significance of different metabolic routes in the overall disposition of drugs

Course content

3Hrs./Week

List of Experiments:

Expt. No	Title	CO
1.	Improvement of dissolution characteristics of slightly soluble drugs by some methods	CO1
2.	Comparison of dissolution studies of two different marketed products of same drug.	CO1
3.	Influence of polymorphism on solubility and dissolution	CO1
4.	Protein binding studies of highly protein bound drugs and poorly protein bound drugs	CO2
5.	Extent of plasma protein binding studies on the same drug (highly and poorly protein bound) at different concentrations	CO2

6.	Bio availability studies of some commonly used drugs on animals/human models	CO2
7.	Calculation of AUC, AUMC, MRT, Cmax from blood profile data	CO3
8.	Calculation of bio availability from urinary excretion data for two drugs	CO3
9.	Calculation of AUC and bio equivalence from the given data for two drugs	CO3
10.	<i>In vitro</i> absorption studies	CO3
11.	bio equivalence studies on the different drugs marketed tetracycline, sulphamethoxazole, trimethoprome, aspirin on animals and human models	CO4
12.	Absorption studies in animal inverted intestine using various drugs	CO4
13.	Effect on contact time on the plasma protein binding of the drugs	CO5
14.	Studying metabolic pathways for different drugs based on elimination	CO5
15.	Calculation of elimination half life for different drugs by using urinary elimination data and blood level data.	CO6
16.	Determination of renal clearance	CO6

References:

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
3. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert F Notari .
6. Biopharmaceutics; By Swarbrick .
7. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi.
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996

CLINICAL TOXICOLOGY- THEORY

COURSE CODE: T4106

COURSE OBJECTIVE: Upon completion of the subject student shall be able to

COB1: Evaluate alternative ways of solving problems related to health.

COB2: Acquire knowledge on symptoms and management of poison.

COB3: Acquire envenomation and substance abuse cases, focusing on clinical symptoms and treatment strategies

COURSE OUTCOMES:

CO	Statement
CO1 [L2]	<u>Explain</u> the general principles involved in the management of poisoning, Antidotes and supportive care.
CO2 [L2]	<u>Explain</u> the Gut Decontamination, Elimination Enhancement techniques & Toxicokinetics.
CO3 [L1]	<u>Describe</u> about clinical symptoms and management of acute and chronic poisoning
CO4 [L1]	<u>Describe & understand</u> various Families of venomous snakes and know symptoms, first aid & treatment
CO5 [L1]	<u>Describe</u> about Plant, Food poisoning and Envenomation's.
CO6 [L2]	<u>Illustrate</u> on the signs and symptoms of substance abuse and treatment of dependence.

Lecture wise programme

2Hrs/Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –

- a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse: Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

1. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Wilkins publication, London
2. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

FIFTH YEAR

CLINICAL RESEARCH-THEORY

COURSE CODE: T5101

COURSE OBJECTIVES: On completion of this course, the student will be able to

COB1: To understand the regulatory and ethical requirements.

COB2: To know the concept of the new drug development process.

COB3: To conduct the clinical trials per regulatory and ethical requirements.

COB4: To know safety monitoring and reporting in clinical trials.

COB5: To coordinate the clinical trials and promote quality drug trial research.

COURSE OUTCOMES :

CO	Statement
CO 1 [L2]	<u>Discuss</u> the Pharmacological and Toxicological considerations in the process of development of new drugs
CO 2 [L2]	<u>Discuss</u> the principles and phases in the clinical trial of the drug.
CO 3 [L2]	<u>Explain</u> the guidelines for ethics and safe monitoring in the clinical trial of a drug.
CO 4 [L6]	<u>Design</u> the documents of clinical trials.
CO 5 [L4]	<u>Distinguish</u> the guidelines of national and international regulatory bodies for clinical trials.
CO 6 [L1]	<u>Recognize</u> differing roles and obligations of the Investigator, Sponsor, and Institutional Review Board.

Lecture wise programme

3 Hrs. / Week

1. Drug development process

Introduction

Various Approaches to Drug Discovery

1. Pharmacological

2. Toxicological

3. IND Application

4. Drug characterization

5. Dosage form

2. Clinical development of drug

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

References:

Text Books:

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel. D. Edward, Andrew. J. Fletcher Anthony W FOS, Peter D Sloaier Publisher: Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna, and Haynes.

Reference books:

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

PHARMACO EPIDEMIOLOGY & PHARMACO ECONOMICS - THEORY

COURSE CODE – T5102

COURSE OBJECTIVES : Upon completion of the course the student shall be able to

COB1 : Analyse about different types of study designs in Pharmaco epidemiological studies.

COB2 : Understand about scope, history, evolution of Pharmaco epidemiology.

COB3 : Compare the differences between Relative risk, Attribute risk.

COB4 : Understand the concepts of Various studies like Meta analysis, Adhoc data sources, Vaccine safety, & Pharmaco economic evaluation.

COURSE OUTCOMES:

CO	Statement
CO 1[L1]	<u>Compare</u> different study designs
CO 2[L2]	<u>Discuss</u> about Origin and evolution of pharmaco epidemiology
CO 3[L1]	<u>Compare</u> differences between Prevalence and incidence rate
CO 4[L2]	<u>Discuss</u> theoretical aspects of various methods
CO 5[L2]	<u>Play</u> the role in formulary management decisions
CO6[L5]	<u>Explain</u> about different types, methods of preparation of Vaccines & Asses the role of drug induced birth defects in Pharmacoepidemiology

Lecture wise programme

3Hrs./ Week

UNIT – I: Pharmacoepidemiology :

Definition and scope: Origin and evaluation of pharmaco epidemiology need for pharmaco epidemiology, aims and applications. Measurement of outcomes in pharmaco epidemiology. 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 pharmaco epidemiology - Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio.

Pharmaco epidemiological 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, and cohort study. 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, and drug induced birth defects.

UNIT-II : 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, and cost utility

UNIT-III: Applications of Pharmacoeconomics

Software and case studies

References

1. Text book of pharmacoepidemiology and pharmacoeco\nomics Brain L STORM; 5 th edition.Wiley publications.

CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC

DRUG MONITORING - THEORY

COURSE CODE - T5103

COURSE OBJECTIVES: Upon completion of the course the student shall be able to

COB1: Understand about the design and use of individualized dosage regimen.

COB2: Understand about the cause and consequences of drug interactions.

COB3: Compare the dosage adjustments in renal and hepatic diseases.

COB4: Demonstrate the TDM of drugs in various diseased states.

COURSE OUTCOMES:

CO	Statement
CO 1 [L2]	<u>Understand the design</u> of dosage regimens
CO 2 [L2]	<u>Understand</u> the pharmacokinetics of drug interaction
CO 3 [L4]	<u>Compare</u> the dosage adjustments in renal and hepatic diseases
CO 4 [L1]	<u>Define</u> therapeutic drug monitoring (TDM) and demonstrate the TDM of drugs used in following disease conditions: cardio vascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
CO 5 [L2]	<u>Explain</u> Bayesian Theory and dosing with feedback
CO 6 [L2]	<u>Explain</u> genetic polymorphism in Drug Metabolism and Drug Transport

Lecture wise programme

2 Hrs./ Week

UNIT – I: Introduction to Clinical pharmacokinetics

UNIT – II: 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

UNIT – III: Pharmacokinetics of Drug Interaction: a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.

UNIT – IV: Therapeutic Drug monitoring: a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, and Interacting drugs). c. Indications for TDM and 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.

UNIT – V: 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.

UNIT – VI: Population Pharmacokinetics. a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feedback. c. Analysis of Population pharmacokinetic Data.

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

APPENDIX-B
(See regulation 9)

**CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING
INSTITUTION**

- 1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
- 2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948; have 300 bedded hospital attached to it.
- 3) Hospital Details: Institution with their own hospital of minimum 300 beds.
 - A) Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
 - B) Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
 - C) Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.
 - D) Speciality: Tertiary care hospitals are desirable. Medicine[compulsory], and any three specialization of the following
 - I. Surgery
 - II. Pediatrics
 - III. Gynecology and obstetrics
 - IV. Psychiatry
 - V. Skin and VD
 - VI. Orthopedics

Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

1) TEACHING STAFF REQUIREMENT

Staff Pattern : All faculty shall be full time. However part time perceptors in hospital shall be allowed.

Subject wise specialisation of the Teaching Staff :

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I,II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

i) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	Three years experience in Teaching or Research at the level of Lecturer or equivalent.

3.	Professor	<p>i) Basic degree in pharmacy (B.Pharm).</p> <p>ii) Registration as a pharmacist under the Pharmacy Act.</p> <p>iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm).</p> <p>iv) Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.</p>	<p>i) Ten years experience in Teaching or Research.</p> <p>ii) Out of which five years must be as Assistant Professor.</p>
4.	Director or Principal or Head of institute	<p>i) Basic degree in pharmacy (B.Pharm).</p> <p>ii) Registration as a pharmacist under the Pharmacy Act.</p> <p>iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)</p> <p>iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.</p>	<p>i) Fifteen years experience in Teaching or Research.</p> <p>ii) Out of which five years must be as Professor or above in Pharmacy.</p> <p>Desirable : Administrative experience in responsible position.</p> <p>The maximum age for holding the post shall be 65 years.</p>

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

Workload of Faculty :

- i) Professor – 8 hrs. per week
- ii) Assistant Professor – 12 hrs. per week
- iii) Lecturers – 16 hrs. per week

i) Training of Pharmacy Practice Faculty :

- a) Teaching staff will be trained as per the module prescribed by the Central Council.
- b) Duration of training – Minimum 3 months.
- c) Training sites – Institutions running pharmacy practice or
Programmes for atleast five years.
- d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

2) NON-TEACHING STAFF :

Sl.No .	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning Personnel	Adequate	---
11	Gardener	Adequate	---

3) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores.

At least two lecture halls alongwith eight laboratories as specified below should be provided for:

1. Pharmaceutics and Pharmacokinetics Lab	- 2
2. Life Science (Pharmacology, Physiology, Pathophysiology)	- 2
3. Phytochemistry or Pharmaceutical Chemistry	- 2
4. Pharmacy Practice	- 2
Total	8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided. Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet. Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

4) EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

a. DEPARTMENT OF PHARMACOLOGY :

i. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and Systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone
11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01

15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

ii. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

b. DEPARTMENT OF PHARMACOGNOSY :

i. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02
4	Hot air oven	02
5	B.O.D. incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01

12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

ii. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

c. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

i. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01
9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

ii. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser singlenecked	20
3	Reflux flask and condenser double/triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nessler's Cylinders	40

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

d. DEPARTMENT OF PHARMACEUTICS :

i. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12, 20, 40, 60, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01
20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10

30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

ii. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

e. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

f. DEPARTMENT OF PHARMACY PRACTICE :

i) Equipment

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate

7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1
10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.

Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.

g. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Fluorimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

(See regulation 16)

INTERNSHIP

SPECIFIC OBJECTIVES :

- 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.
- 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.
- 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.
- To demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.
- 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.
- To communicate effectively with patients and the community.

OTHER DETAILS :

- 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.
- Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.
- 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.

ASSESSMENT OF INTERNSHIP :

1. 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.

2. Satisfactory completion of internship shall be determined on the basis of the following:-

- i) Proficiency of knowledge required for each case management SCORE 0-5
- ii) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5
- iii) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5
- iv) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
- v) Initiative, participation in discussions, research aptitude. SCORE 0-5

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

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

APPENDIX-D
(See regulation 17)

CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

1. The Examining Authority shall be a statutory Indian University constituted by the Central Government/State Government/Union Territory Administration. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.
2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.
3. It shall provide:-
 - a) adequate rooms with necessary furniture for holding written examinations;
 - b) well-equipped laboratories for holding practical examinations;
 - c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examinations; and
 - d) such other facilities as may be necessary for efficient and proper conduct of examinations.
4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.
5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix-B.
6. In pursuance of sub-section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India, not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.
7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes in an approved institution.