ANDHRA UNIVERSITY

DOCTOR OF PHARMACY

(2010-2011)

REGULATION AND SYLLABUS

EFFECTIVE FROM 2010-2011 BATCH

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.

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.

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.

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 :

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

* For Biology

Second Year:

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

Third Year:

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

Fourth Year:

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

Fifth Year:

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

***** Attending ward rounds on daily basis.

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 for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomyand Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

PROGRAM EDUCATIONAL OBJECTIVES

Pharm. D. and Pharm. D. (PB)

1. To provide a clinical comprehensive pharmaceutical education leading to Doctor of Pharmacy (Pharm. D.) degree
2. To provide hands on training to impart research aptitude in pharmaceutical sciences challenges of drug discovery and clinical research
3. To inculcate knowledge and skills with clinical research to promote health care
4. To promote leadership capabilities in health care team

PROGRAM OUTCOMES

Pharm. D. and Pharm. D. (PB)

1. Explain knowledge of pharmacy practice and the ability to acquire, manage and use current information for problem solving, patient- specific, population-specific, evidence-based care to promote safe pharmacotherapy outcomes
2. Assess the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of pharmaceuticals
3. Apply critical thinking skills including investigation, analysis, evaluation of information, documentation related to clinical investigations, pharmaceutical care and practices
4. Develop problem-based learning approach in pupil academic and professional life
5. Act efficiently as a leader in the diverse areas of the profession
6. Write, interpret and communicate effectively and scientifically
7. Apply the knowledge and skills gained through education to gain recognition in professional circle and society
8. Collaborate with other health care communities and providing innovative solutions

9. Participate in healthcare initiatives to create awareness about usage of eco-friendly products in society about the effective and safe use of medicines
12. Implementing a cost-effective quality patient care and resource management practices.

PROGRAM SPECIFIC OUTCOMES(PSOs)

Pharm. D. and Pharm. D. (PB)

1. Provide quality based patient-centered care in cooperation with patients, prescribers and members of the inter-professional health care team.
2. Promote healthcare through disease prevention
3. Provide pharmaceutical care including vaccinations and drug therapy monitoring in all practice areas (e.g., inpatient, ambulatory and community practice)
4. Address patient-specific and population-specific needs
5. Apply core knowledge and skills in relation to the evolving biomedical, clinical, epidemiological and social-behavioral sciences in areas supporting high quality pharmacy practice
6. Demonstrate self-calibration skills and a commitment to the lifelong learning needed to provide high quality care.
7. Impart effective interpersonal written and verbal skills, adapt to socioeconomic and cultural factors as well as situational applications.
8. Demonstrate the respect for patient privacy and autonomy, as well as sensitivity and responsiveness to diverse patient populations.
9. Incorporate cost awareness and risk-benefit analysis in patient and population-based care
10. Effectively manage medication use systems and prioritize patient safety and public health.

Pharm.D outcomes

Pharmaceutics / 1.2 and 1.2P (Theory and practical)

Course educational objectives:

1. This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms.
2. It prepares the students for most basics of the applied field of pharmacy.
3. Pharmaceutical calculations, also know about the various pharmacopoeias, various pharmaceutical dosage forms.

Learning objectives:

1. History, pharmaceutical development, Definitions, classification, handling of prescription, posology and calculations.
2. Indian pharmacopoeia, and other such as BP, USP, EU and national formulary. And calculations related to percentages, allegations, proof spirit etc.
3. Formulation and various excipients used in powders, granules, and monophasic and bi-phasic dosage forms.
4. Definition, equipment (Decoction, Maceration and Percolation), applications, evaluation of suppositories, pessaries, and galenicals.
5. Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages. Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

Course outcomes:

1. Know the formulation aspects of different dosage forms.
2. Do different pharmaceutical calculation involved in formulation.
3. Formulate different types of dosage forms.
4. Appreciate the importance of good formulation for effectiveness.

	CO1	CO2	CO3	CO4
LO1		✓		
LO2	✓			
LO3			✓	✓
LO4			✓	✓
LO5				✓

2.1 PATHOPHYSIOLOGY:

COURSE OUTCOMES:

1. This course is structured to acquire thorough knowledge of the relevant aspects of various disease states with reference to its pathological & pharmacological applications.

2. Understanding of basic pathophysiological mechanisms.

3. To learn about the etiopathogenesis of the diseases and able to understand how the biological system responses to the pathogens.

4. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

LEARNING OUTCOMES: At the end of the course students will be able to learn and gain the knowledge on

CHAPTER: 1

LO1: a) Basic principles of Cell injury & Cellular Adaptations - morphological changes occurs in the cell, pathogenesis of cell injury.

b) Abnormalities of the lipids and glycogen infiltration.

CHAPTER: 2

LO2: a) To learn about inflammation – types, pathogenesis, chemical mediators and its role in developing inflammation

b) To study the mechanism of repairing wounds and factors influencing the wound healing.

CHAPTER: 3

LO3: To Learn Immunity, role of immune system a) Introduction to T and B cells b) MHC proteins or transplantation antigens c) Immune tolerance – Hypersensitivity and its types.

LO4: To study autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, allograft, and graft rejection mechanism AIDS, amyloidosis.

CHAPTER: 4

LO5: To learn the general biology, aetiology and pathogenesis of cancer, diagnosis.

CHAPTER: 5 & 6

LO6: a) to learn the aetiology and pathogenesis of shock, management.

b) The biological effects of radiation.

CHAPTER: 7

LO7: a) to learn the pathogenesis of Environmental and nutritional diseases

b) Effects of i) Air pollution and smoking- SO2, NO, NO2, and CO ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

CHAPTER: 8

LO8: To learn the aetiology and pathogenesis of common diseases a. Parkinsonism b. Schizophrenia c. Depression and mania d. Hypertension, e. Stroke (ischaemic and haemorrhage) f. Angina, CCF, Atherosclerosis, Myocardial infarction g. Diabetes Mellitus h. Peptic ulcer and inflammatory bowel diseases i. Cirrhosis and Alcoholic liver diseases j. Acute and chronic renal failure k. Asthma and chronic obstructive airway diseases

CHAPTER: 9

LO9: To learn the etiology and pathogenesis of Infectious diseases such as STD's (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), and Hepatitis- infect

	CO1	CO2	CO3	CO4
LO1		✓		
LO2	✓			
LO3			✓	✓
LO4			✓	✓
LO5				✓
LO6		✓		
LO7				✓
LO8		✓		
LO9				✓

2.6 PHARMACOTHERAPEUTICS-I-THEORY

COURSE EDUCATIONAL OBJECTIVES

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

a) the pathophysiology of selected disease states and the rationale for drug therapy;
b) the therapeutic approach to management of these diseases;
c) the controversies in drug therapy;
d) the importance of preparation of individualised therapeutic plans based on diagnosis;
e) needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
f) describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
g) summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
h) discuss the controversies in drug therapy;
i) discuss the preparation of individualised therapeutic plans based on diagnosis; and

j) Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

LEARNING OUTCOMES LO1

Cardiovascular system:

- Students will be able to comprehend and narrate the epidemiology and pharmacotherapy of the cardiovascular disease like hypertension, congestive heart failure MI, electrophysiology of heart and arrhythmias
- Enumerate the etiological factors of CAD.

LO2

Respiratory system:

- Students will be able to grasp and chronicle the epidemiology, pathophysiology and pharmacotherapy of the asthma, chronic obstructive airway disease ,drug induced pulmonary disease
- Discuss pulmonary function test.
- Explain the etiopathogenesis of COPD

LO3

Endocrine system:

- Students will develop a deep understanding on the etiology, epidemiology, pathophysiology and pharmacotherapy of the thyroid disease, oral contraceptives, hormone replacement therapy and osteoporosis.
- Enumerate the etiopathological factors of Diabetes mellitus.

LO4

Ophthalmology:

- Students will have good knowledge encompassing the epidemiology, pathophysiology and pharmacotherapy of the conjunctivitis-viral and bacterial
- Explain the etiopathogenesis and diagnosis of glaucoma

LO4

General prescription guidelines:

➢Students will have good knowledge encompassing the epidemiology, pathophysiology and pharmacotherapy of the conjunctivitis-viral and bacterial

- Explain the general prescribing guidelines for geriatric, paediatric and lactating women

LO5

Introduction to rational drug use:

- Student will appreciate the objectives and the significance of rational drug use in hospitals.

Explain the role of pharmacist in essential drug concept rational drug use

PHARMACOTHERAPEUTICS-I-THEORY

COURSE OUTCOME:

CO1

Student will be generating evaluation abilities per patient cases.

CO2

Student will portray the quality utilization of medicines issues encompassing the therapeutic agent within the treatment of these sicknesses.

CO3

Student will have developed clinical abilities in the therapeutic administration of these conditions.

CO4

Student will continue to develop interpersonal, communication aptitudes.

CO5

Student will provide patient oriented care to an array of patient utilizing the evidence based medic

PHARMACOTHERAPEUTICS-I-THEORY

COURSE OUTCOME:

CO1

Student will be generating evaluation abilities per patient cases.

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Student will portray the quality utilization of medicines issues encompassing the therapeutic agents within the treatment of these sicknesses.

CO3

Student will have developed clinical abilities in the therapeutic administration of these conditions.

CO4

Student will continue to develop interpersonal, communication aptitudes.

CO5

Student will provide patient oriented care to an array of patient utilizing the evidence based medicine

SUBJECT: PHARMACOTHERAPEUTICS-I PRACTICAL

After studying this course, student will be able to:

LO1	Identify drug interactions and rationalize the prescription
LO2	Discuss the therapeutics approach to management of selected drugs and diseases
LO3	Prepare individualized therapeutic plans based on drug and diseases
LO4	Perform patient counselling
LO5	Conduct planned experiments and prepare laboratory report in a standard form.

Mapping of Course Outcomes with Learning Outcomes

	COS					
LOS	S. No	1	2	3	4	5
	1	√		√		
	2			√	√	
	3	√		√		
	4		√	√	√	√

3.3 PHARMACOTHERPAEUTICS-II (THEORY)

COURSE OUTCOMES

At completion of this subject students will be able to-

a. Describe the incidence/prevalence of the disease/condition and recognize the most common causes of the infectious, musculoskeletal, renal, oncological and dermatological diseases/disorders.

b. List common symptoms and name the risk factors and/or major complications.

c. Describe the classification system of the disease and the drug classes.

d. Summarize the medications available for treatment including:

- Brand and generic names of medications included in each class
- Basic mechanism of action (how each class works)
- Main side effects and contraindications
- Non-drug measures useful in treatment

e. Explain the pathophysiology of selected disease states and the rationale for drug therapy.

f. Understand the therapeutic approach to management of these diseases including reference to the latest available evidence.

g. Explain the roles of the pharmacist and various members of the medical team in medication use and controversies in drug therapy.

h. Understand the use of appropriate drug information resources and importance of preparation of individualized therapeutic plans based on diagnosis.

i. 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).

j. Apply standards, guidelines, best practices, and established processes related to safe and effective medication use.

COURSE OUTCOMES

SUBJECT: PHARMACOTHERAPEUTICS-II (PRACTICAL)

On successful completion of the course students will be able to:

1. Apply their knowledge and understanding of the pathophysiology and management (pharmacological and non-pharmacological) of diseases to patient cases.
2. Demonstrate appropriate and effective verbal and non-verbal communication skills with both in-patients, out-patients and health care professionals in dealing with a range of clinical scenarios during their hospital postings.
3. Demonstrate the ability to effectively gather information from patients, health care professionals and other sources of data such as medication charts, medical records in managing a patient case
4. Describe the SOAP format (Subjective, Objective and Assessment & Planning) and identify and define all relevant problems, demonstrate basic fundamental physical assessment techniques
5. Apply pathology and other laboratory data to patient assessment and management in a range of clinical cases.
6. Apply medical imaging and other diagnostic information to patient assessment in a range of clinical case studies.
7. Identify and prioritise therapeutic problems and appropriately select patient specific management regimens, and requirements for monitoring and assessing response to therapy.
8. Apply knowledge and skills of the core principles of pharmacy practice to simulated patient cases including ethics, forensics, confidentiality and quality use of medicines.
9. Identify principles of pharmacokinetics and discuss issues relating to the formulation and manufacture of therapeutic agents in relation to patient cases, assess their healthcare status and needs of a targeted patient population.

LEARNING OUTCOMES:

UNIT-1

Infectious diseases:

LO1: Implement the guidelines for the Rational use of antibiotics and Surgical prophylaxis

LO2: explain etiopathogenesis, diagnosis, clinical presentation and management of Tuberculosis

LO3: elucidate the etiopathogenesis, diagnosis, clinical presentation and management of Meningitis

LO4: list the various upper respiratory tract infections

& explain etiopathogenesis, diagnosis, clinical presentation and management of various Upper respiratory tract infections

LO5: list the various Lower respiratory tract infections

& explain etiopathogenisis, diagnosis, clinical presentation and management of various Lower respiratory tract infections.

LO6: explain etiopathogenesis, diagnosis, clinical presentation and management of Gastroenteritis

LO7: explain etiopathogenesis, diagnosis, clinical presentation and management of Endocarditis

LO8: explain etiopathogenesis, diagnosis, clinical presentation and management of Septicaemia

LO9: explain etiopathogenesis, diagnosis, clinical presentation and management of Urinary tract infections

LO10: explain etiopathogenesis, diagnosis, clinical presentation and management of Malaria

LO11: explain etiopathogenesis, diagnosis, clinical presentation and management of HIV & Discuss the various Opportunistic infections in HIV and their management.

LO12: explain etiopathogenesis, diagnosis, clinical presentation and management of various Fungal infections.

LO13: explain etiopathogenisis, diagnosis, clinical presentation and management of various Viral infections

LO14: explain etiopathogenisis, diagnosis, clinical presentation and management of Gonorrhoea

LO15: explain various stages of Syphilis with its management

Pharmaceutical Jurisprudence / 3.4

Course educational objectives:

1. This course exposes the student to several important legislations related to the profession of pharmacy in India.
2. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc.
3 .Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

Learning objectives:

1. Pharmaceutical Legislations – A brief review. Drugs and Cosmetics Act, 1940, and its rules 1945. Objectives, Legal definition, Study of various Schedule's with Sales, Import, labeling and packaging of Drugs and Cosmetics Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB, DCC, CDL. Qualification and duties –Govt. analyst and Drugs Inspector.
2. Pharmacy Act –1948. Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, Medicinal and Toilet Preparation Act – 1955. Licensing, Bonded and Non-Bonded Laboratory, Ware Housing,
3. Narcotic Drugs and Psychotropic substances Act-1985 and Rules, 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, Drug Price control Order & National Drug Policy (Current).
4. Prevention Of Cruelty to animals Act-1960. 11. Patents & design Act-1970, Brief study of prescription and Non-prescription Products.

Course outcomes:

1. Practice the Professional ethics;
2. Understand the various concepts of the pharmaceutical legislation in India.
3. Know the various parameters in the Drug and Cosmetic Act and rules.
4. Know the Drug policy, DPCO, Patent and design act.
5. Understand the labeling requirements and packaging guidelines for drugs and cosmetics.
6. Able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act and,

7. Other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

	CO1	CO2	CO3	CO4	CO5	CO6	CO7
LO1	✓		✓		✓		✓
LO2	✓	✓				✓	✓
LO3	✓			✓			
LO4	✓					✓	

Pharmaceutical Formulations / 3.6 and 3.6P

Course educational objectives:

This subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
This also deals with practical oriented knowledge on dosage forms.
Also know the industrial aspects and working field in that area.

Learning objectives:

1. Pharmaceutical dosage form- concept and classification 2. Tablets: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.

3. Capsules; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.

4. Liquid orals: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations

5. Parenterals Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

6. Ophthalmic preparations (Semi-Solids): Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Ointment Bases, Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of

preparation.

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

Course outcomes:

1. Understand the principle involved in formulation of various pharmaceutical dosage forms.
2. Prepare various pharmaceutical formulation.
3. Perform evaluation of pharmaceutical dosage forms.
4. Understand and appreciate the concept of novel drug delivery systems.

	CO1	**CO2**	**CO3**	**CO4**
LO1	✓	✓	✓	
LO2	✓	✓	✓	
LO3	✓	✓	✓	
LO4	✓	✓	✓	
LO5				✓

This subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

This also deals with practical oriented knowledge on dosage forms.

Also know the industrial aspects and working field in that area.

Learning objectives:

1. Pharmaceutical dosage form- concept and classification 2. Tablets: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets.

Tablet coating, Type of coating, quality control tests for coated tablet.

3. Capsules; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.

4. Liquid orals: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations

5. Parenterals Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

6. Ophthalmic preparations (Semi-Solids): Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Ointment Bases, Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation.

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

4.2 Hospital Pharmacy (Theory)

Course Outcomes:

After studying this course, student will be able to:

1. Discuss the roles and responsibilities of hospital pharmacist, hospital drug policies and guidelines for hospital pharmacy
2. Discuss various drug distribution methods in a hospital pharmacy
3. Apply various methods of inventory control Pharm D - Course Specifications
4. Formulate parenteral preparations
5. Contribute to a newsletter for providing continuous education and awareness
6. Explain about handling and packaging of radiopharmaceuticals

4.2 Hospital Pharmacy (Practical):

After studying this course, student will be able to:

1. Analyse prescriptions for drug interaction
2. Formulate and prepare parenteral formulations and powders

3. Perform inventory analysis
4. Answer drug information queries through literature search
5. Conduct planned experiments and prepare laboratory report in a standard format

Learning Outcomes:

At the end of each unit of learning students will be able to...

Unit -1: Hospital – its organisation and functions

LO1: Define Hospital

LO2: Classify hospital

LO3: Enumerate the functions of hospital

LO4: Discuss the various organisations of hospital

Unit-2: Hospital Pharmacy- Organisation and Management

LO5: Define hospital pharmacy

LO6: List out the organisations of hospital pharmacy

LO7: Discuss the working of different staffs in hospital pharmacy & their qualification requirements

LO8: Describe the maintenance of materials & finance in hospital pharmacy

LO9: Explain the roles & responsibilities of hospital pharmacists

Unit-3: The Budget- Preparation and implementation

LO10: Enumerate the different parts of Budget

LO11: Discuss the procedure of preparing budget

LO12: Describe the implementation of budget in hospitals

Unit-4: Hospital drug policy

LO13: Define Pharmacy and Therapeutic committee

LO14: Discuss about the objectives of

LO15: Describe the composition operation & role of PTC

LO16: Describe the hospital committees & roles of it.

LO17: Explain the role of PTC in drug safety

LO18: Enumerate the role of PTC in ADR monitoring

LO19: Discuss about Hospital formulary & parts of hospital formulary

LO20: Explain the procedure to prepare hospital formulary

LO21: List out different committees in the hospitals

LO22: Discuss the responsibilities of Infection committee

LO23: Outline the responsibilities of Research and ethical committee

Unit -5: Hospital Pharmacy services

LO24: Discuss the procedure for procurement & warehousing of drugs and pharmaceuticals in the hospitals

LO25: Define inventory control

LO26: List out various methods of inventory control

LO27: Identify different types of inventories

LO28: Explain ABC analysis

LO29: Discuss VED analysis

LO30: Describe EOQ

LO31: Enumerate the importance of buffer stock

LO32: Describe the importance of safety stock

LO33: Explain different methods of drug distribution systems in hospitals

LO34: Describe the procedure for Distribution of Narcotic and other controlled substances

LO35: Outline the role of pharmacist in Central sterile supply services

Unit-6: Manufacture of pharmaceutical preparations

LO36: Discuss about the various stages manufacturing large volume parenteral

LO37: Explain various stages manufacturing small volume parenteral

LO38: Describe various stages manufacturing ointments

LO39: Discuss about the various stages manufacturing liquids

LO40: Enumerate various stages manufacturing creams

LO41: Explain the various stages manufacturing tablets

LO42: Discuss the various stages manufacturing granules

LO43: Describe various stages manufacturing capsules

LO44: Discuss the various stages manufacturing powders

LO45: Explain about the total parenteral nutrition

LO46: Describe the preparation of total parenteral nutrition

Unit -7: Continuing professional development programme

LO47: Explain in detail about continuing professional development programs

LO48: Discuss the training given to the health care professionals in development programme

Unit-8: Radiopharmaceuticals

LO49: Discuss about the importance of Radiopharmaceuticals

LO50: Describe frequently used radio pharmaceuticals in the hospital

LO51: Explain the method for handling radiopharmaceuticals in hospital

LO52: Enumerate method for packaging radiopharmaceuticals in hospital

Unit -9: Professional Relations and practices of hospital pharmacist

LO53: Discuss hospital pharmacist's participation in continuing education programme

LO54: Explain the practices of hospital pharmacist in hospital

LO55: Describe the opportunities for a professional relations programme.

Biopharmaceutics & Pharmacokinetics / 4.5 and 4.5P

Course educational objectives:

1.2This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development.

2.Design of dose and dosage regimen, bioavailability and bioequivalence studies and in solving the problems raised therein.

Learning objectives:

1. Absorption, Distribution, and Elimination.

2. Introduction to Pharmacokinetics, Mathematical model, Drug levels in blood. Pharmacokinetic model, Compartment models, Pharmacokinetic study, One compartment open model. Intravenous Injection (Bolus) b. Intravenous infusion.

3. Multicompartment models: Two compartment open model, IV bolus, IV infusion and oral administration, Multiple-Dosage Regimens, Repititive Intravenous injections, One Compartment Open Model, Repititive Extravascular Dosing-One Compartment Open model, Multiple Dose Regimen-Two Compartment Open Model.

4. Nonlinear Pharmacokinetics: Introduction, Factors causing Non-linearity, Michaelis-menton method of estimating parameters.

5. Noncompartmental Pharmacokinetics: Statistical Moment Theory, MRT for various compartment models, Physiological Pharmacokinetic model, Introduction, Bioavailability study protocol, Methods of Assessment of Bioavailability

Course outcomes:

1. Understanding the concept of biopharmaceutics and its applications in formulation development.

2. Studying pharmacokinetic processes and their relevance in efficacy of dosage form.
3. Learning the concepts of bioavailability and bioequivalence studies.
4. Learning various compartmental models and non-compartmental analysis methods.
5. Understanding concept and mechanisms of dissolution and in vitro in vivo correlation.

	CO1	CO2	CO3	CO4	CO5
LO1	✓				
LO2	✓	✓		✓	
LO3	✓			✓	✓
LO4	✓	✓			
LO5	✓			✓	

Doctor of Pharmacy (Pharm D)

(Approved by the Government of India, Ministry of Health vide letter No. V.13013/1/2007-PMS dated 13th March 2008 announced in the Gazette on India dated 10th May 2008.)
(http://www.pci.nic.in).

Duration of Course:

- Six academic years (Five years study and one year Internship) after PUC or D.Pharm
- Three years (Two years study and one year Internship) after B.Pharm

Intake :

Six years Pharm D program - 30 students
Three years (post Baccalaureate) Pharm D program - 10 students

Course Content :

- Theory and practical subjects very similar for B.Pharm course
- Internship or residency for one year in multi speciality teaching hospital
  Includes postings in speciality hospital units
  Six months in general medicine department
  Two months each in three other speciality departments

Certificate of passing Examination:

Pharmacy Council of India is a national apex body controlling the course; Doctor of Pharmacy (Pharm.D) Degree will be issued by Andhra University after passing examinations.

Duration of the course. –

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

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

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

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

Phase I – consisting of First and Second academic year.

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

Minimum qualification for admission to. –

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

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

Mathematics or Biology.

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

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

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

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

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.

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.

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.

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 :

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

* For Biology

Second Year:

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

Third Year:

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

Fourth Year:

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

Fifth Year:

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

***** Attending ward rounds on daily basis.

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 for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomyand Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

Second Year examination :

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

Third Year examination :

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

Fourth Year examination :

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

Fifth Year examination :

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

* Attending ward rounds on daily basis.

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

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

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

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

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

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

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

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

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

        (i) Actual performance in the sessional examination (20 marks);
        (ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks).

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

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

CHAPTER-III
Practical training

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

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

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

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

    (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

    (ii) develop the students in data collection, analysis and reporting and interpretation skills.

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

    (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;

    (ii) project topic shall be approved by the Head of the Department or Head of the Institution;

    (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;

    (iv) project work shall be approved by the institutional ethics committee;

    (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

    (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

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

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.

(3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

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

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

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

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

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

PHARM. D. POST BACCALAUREATE PROGRAM

(Inclusion of Pharmacotherapeutics I & II subject in the fourth year of the program)

T A B L E S

Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.0	Pharmacotherapeutics-I & II	3	3	1
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	**18**	**15**	**7 = 40**

Fifth Year:

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

Sixth Year:

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

(iii) Six months in General Medicine department, and

(iv) Two months each in three other specialty departments

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

2. 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.

(4) 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.

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

a. 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.

b. 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

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.0	Pharmacotherapeutics-I & II	70	30	100	70	30	100
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				700			500 = 1200

Fifth Year examination :

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

* Attending ward rounds on daily basis.

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

4. 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.

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

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

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

   c. 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.

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

   a. 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.

   b. The sessional marks in practicals shall be allotted on the following basis:-

      (i) Actual performance in the sessional examination (20 marks);
      (ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks).

7. Minimum marks for passing examination. A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects 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.

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

9. 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.

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

11. 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

12. 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.

13. 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.

a. Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

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

(iii) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

(iv) develop the students in data collection, analysis and reporting and interpretation skills.

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

a. students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;

b. 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 utilization reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;

(vii) project work shall be approved by the institutional ethics committee;

(viii) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

(ix) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

16. 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 authorized teacher, Head of the Department as well as by the Head of the Institution

(4) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.

(5) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

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

(iii)Project work shall be evaluated by internal and external examiners.

(iv)Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii)Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

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

(v) Final evaluation of project work shall be done on the following items:		**Marks**
a) Write up of the seminar		(17.5)
b) Presentation of work		(17.5)
c) Communication skills		(17.5)
d) Question and answer skills		(17.5)
	Total	(70 marks)

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

SYLLABUS FOR PHARMACOTHERAPEUTICS I & II (THEORY)

Fourth Year

4.0 PHARMACOTHERAPEUTICS – I & II (THEORY)

Theory: 3 Hrs. /Week

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

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualized therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. to discuss the controversies in drug therapy;
   i. to discuss the preparation of individualized therapeutic plans based on diagnosis; and
   j. Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

   Text Books

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

   Reference Books

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

Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

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

a. Pediatric patients b. Geriatric patients. c. Pregnancy and breast feeding

5. **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
6. **Introduction to rational drug use**
   Definition, Role of pharmacist Essential drug concept Rational drug formulations
7. **Infectious disease**: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections Viral infections, Gonorrhea and Syphilis
8. **Musculoskeletal disorders**: Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus
9. **Renal system:** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal
   Disorders.
10. **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
11. **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

PHARMACOTHERAPEUTICS – I & II (PRACTICAL)

Practicals: 3 Hrs./Week

Practicals:

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

Assignments:

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

Format of the assignment:

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

12. Scheme of Practical Examination:

	Sessional	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15

Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

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

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

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

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

Title of the topic

3 **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.

3 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.

3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,

3 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders

3 Pain management including Pain pathways, neuralgias, headaches.

3 Evidence Based Medicine

Assignments:

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

Format of the assignment:

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

Scheme of Practical Examination :

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

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

4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope**: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know various drug distribution methods;
   b. know the professional practice management skills in hospital pharmacies;
   c. provide unbiased drug information to the doctors;
   d. know the manufacturing practices of various formulations in hospital set up;
   e. appreciate the practice based research methods; and
   f. appreciate the stores management and inventory control.

   Text books: (latest editions)
   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

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

3. **Lecture wise programme :**

   Topics

   1 Hospital - its 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

   a. The Budget – Preparation and implementation

   b. Hospital drug policy
   Pharmacy and Therapeutic committee (PTC)
   Hospital formulary
   Hospital committees
   Infection committee
   Research and ethical committee
   Developing therapeutic guidelines
   Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

a) Procurement & warehousing of drugs and Pharmaceuticals
b) Inventory control

Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

c) Drug distribution in the hospital
   i) Individual prescription method
   ii) Floor stock method
   iii) Unit dose drug distribution method
d) Distribution of Narcotic and other controlled substances
e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

a) Sterile formulations – large and small volume parenterals
b) Manufacture of Ointments, Liquids, and creams
c) Manufacturing of Tablets, granules, capsules, and powders
d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging

9 Professional Relations and practices of hospital pharmacist

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

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

List of Assignments:

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

Special requirements:

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

Scheme of Practical Examination:

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

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

4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

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

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

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.

1 Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.

1 Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.

1 A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.

Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.

Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

6 **Detailed syllabus and lecture wise schedule: Title of the topic**

Definitions, development and scope of clinical pharmacy

Introduction to daily activities of a clinical pharmacist

Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
Ward round participation
Adverse drug reaction management
Drug information and poisons information
Medication history
Patient counseling
Drug utilization evaluation (DUE) and review (DUR)
Quality assurance of clinical pharmacy services

1. **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.

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

   Haematological, Liver function, Renal function, thyroid function tests
   Tests associated with cardiac disorders
   Fluid and electrolyte balance
   Microbiological culture sensitivity tests
   Pulmonary Function Tests

3. **Drug & Poison information**

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

4. **Pharmacovigilance**

   Scope, definition and aims of pharmacovigilance

   Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   Reporting, evaluation, monitoring, preventing & management of ADRs
   Role of pharmacist in management of ADR.

5. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
6. Pharmaceutical care concepts
7. Critical evaluation of biomedical literature
8. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

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

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

Assignment:

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

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

Format of the assignment:

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

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

3. Detailed syllabus and lecture wise schedule

Research Methodology

Types of clinical study designs:
Case studies, observational studies, interventional studies,

Designing the methodology

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

Report writing and presentation of data

Biostatistics

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

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

2.3 **Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)

c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

a. **Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

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

Computer In Community Pharmacy Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

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

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.

3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.

4. Multicompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration

5. Multiple – Dosage Regimens.
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model
   Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis-menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.
   a. Introduction.
   b. Bioavailability study protocol.
   c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, $t_1/2$, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

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

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

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

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

10 CNS stimulants :amphetamine
11 Opioids
12 CNS depressants
13 Hallucinogens: LSD
14 Cannabis group
15 Tobacco

References:

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

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. **Drug development process:**
   Introduction
   Various Approaches to drug discovery
   1. Pharmacological
   2. Toxicological
   3. IND Application
   4. Drug characterization
   5. Dosage form

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

References :

a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. Pharmacoepidemiology :

Definition and scope:

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

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

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

Concept of risk in pharmacoepidemiology

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

Pharmacoepidemiological methods

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

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

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

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

2. Phrmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:
Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics

Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

1. **Introduction to Clinical pharmacokinetics.**

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

3. **Pharmacokinetics of Drug Interaction:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

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

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

6. **Population Pharmacokinetics.**
   a. Introduction to Bayesian Theory.
   b. Adaptive method or Dosing with feedback.
   c. Analysis of Population pharmacokinetic Data.

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