

PARUL UNIVERSITY

FIRST YEAR PHARM.D. (P.B.) TEACHING SCHEME

Subject code	Subject Name	Teaching Scheme (Hours)			Theory		Practical		Total marks
		Theory	Tutorial	Practical	External	Internal	External	Internal	
08207401	Pharmacotherapeutics-III	3	1	3	70	30	70	30	200
08207402	Hospital Pharmacy	2	1	3	70	30	70	30	200
08207403	Clinical Pharmacy	3	1	3	70	30	70	30	200
08207404	Biostatistics & Research Methodology	2	1	-	70	30	-	-	100
08207405	Biopharmaceutics & Pharmacokinetics	3	1	3	70	30	70	30	200
08207406	Clinical Toxicology	2	1	-	70	30	-	-	100
08207407	Pharmacotherapeutics-I & II	3	1	3	70	30	70	30	200
	Total	18	7	15	700		500		1200

FIRST YEAR PHARM.D. (P.B.) SYLLABUS

Subject Name: PHARMACOTHERAPEUTICS-III

Subject Code: 08207401

Theory (3 Hours/ Week, Total: 90 Hours)

Teaching Scheme (Hours)				Evaluation Scheme (Marks)				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	3	7	70	30	70	30	200

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

Sr. No.	Course Contents	Hours
1	Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.	26
2	Haematological system: Anaemias, Venous thromboembolism, Drug induced blood disorders.	12
3	Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease	14
4	Psychiatry disorders: Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders	25
5	Pain management including Pain pathways, neuralgias, headaches.	9
6	Evidence Based Medicine	4

Course Materials:

Text Books:

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

Reference Books:

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

Practical (3 Hours/ Week, Total: 90 Hours)

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion, attending ward rounds, follow up the progress and changes made in drug therapy in allotted patients, case presentation upon discharge.

Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

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

Assignments:

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

Format of the assignment:

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

Scheme of Practical Examination

	Internal/ Sessional	External
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max. marks	20	70
Duration	3 hours	4 hours

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

Subject Name: HOSPITAL PHARMACY

Subject Code: 08207402

Theory (2 Hours/ Week, Total: 60 Hours)

Teaching Scheme (Hours)				Evaluation Scheme (Marks)				Total marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	1	-	3	70	30	-	-	100

Sr. No.	Course Contents	Hours
1	Hospital - its Organisation and functions	03
2	Hospital pharmacy-Organisation and management a) Organizational structure-Staff, Infrastructure & work load statistics b) Management of materials and finance c) Roles & responsibilities of hospital pharmacist	08
3	The Budget – Preparation and implementation	04
4	Hospital drug policy a) Pharmacy and Therapeutic committee (PTC) b) Hospital formulary c) Hospital committees - Infection committee - Research and ethical committee d) developing therapeutic guidelines e) Hospital pharmacy communication – Newsletter	10
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	13
6	Manufacture of Pharmaceutical preparations a) Sterile formulations – large and small volume Parenteral b) Manufacture of Ointments, Liquids, and creams c) Manufacturing of Tablets, granules, capsules, and powders d) Total Parenteral nutrition	10
7	Continuing professional development programs Education and training	04
8	Radio Pharmaceuticals – Handling and packaging	04
9	Professional Relations and practices of hospital pharmacist	04

Course Materials:

Text books (Theory)

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

Reference books (Theory)

- 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.

Practical (3 Hours/ Week, Total: 90 Hours)

Practical:

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

Assignments:

Topics of the assignment

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.

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

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Synopsis	05	15
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Max. marks	20	70
Duration	3 hours	4 hours

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Subject Name: CLINICAL PHARMACY

Subject Code: 08207403

Theory (3 Hours/ Week, Total: 90 Hours)

Teaching Scheme (Hours)				Evaluation Scheme (Marks)				Total marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	3	7	70	30	70	30	200

Sr. No.	Course Contents	Hours
1	Definitions, development and scope of clinical pharmacy	04
2	Introduction to daily activities of a clinical pharmacist a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) b. Ward round participation c. Adverse drug reaction management d. Drug information and poisons information e. Medication history f. Patient counselling g. Drug utilisation evaluation (DUE) and review (DUR) h. Quality assurance of clinical pharmacy services	20
3	Patient data analysis The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.	07
4	Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results a. Haematological, Liver function, Renal function, thyroid function tests b. Tests associated with cardiac disorders c. Fluid and electrolyte balance d. Microbiological culture sensitivity tests e. Pulmonary Function Tests	12
5	Drug & Poison information a. Introduction to drug information resources available b. Systematic approach in answering DI queries c. Critical evaluation of drug information and literature d. Preparation of written and verbal reports e. Establishing a Drug Information Centre f. Poisons information- organization & information resources	14
6	Pharmacovigilance a. Scope, definition and aims of Pharmacovigilance b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used] c. Reporting, evaluation, monitoring, preventing & management of ADRs d. Role of pharmacist in management of ADR.	12
7	Communication skills, including patient counselling techniques, medication history interview, presentation of cases.	5
8	Pharmaceutical care concepts	5
9	Critical evaluation of biomedical literature	7

10	Medication errors	4
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Course Materials:

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSN8125026

References

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

Practical (3 Hours/ Week, Total: 90 Hours)

Practical:

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

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

Assignment:

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

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

Format of the assignment:

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

Scheme of Practical Examination

	Internal/ Sessional	External
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max. marks	20	70
Duration	3 hours	4 hours

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

Subject Name: BIostatISTICS AND RESEARCH METHODOLOGY**Subject Code: 08207404****Theory (2 Hours/ Week, Total: 60 Hours)**

Teaching Scheme (Hours)				Evaluation Scheme (Marks)				Total marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	1	-	3	70	30	-	-	100

Sr. No.	Course Contents	Hours
1	Research Methodology a) Types of clinical study designs: Case studies, observational studies, interventional studies, b) Designing the methodology c) Sample size determination and Power of a study Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study d) Report writing and presentation of data	12
2	Biostatistics 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.	12
3	Data graphics Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots	4
4	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, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA) d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient. e) Introduction to statistical software: SPSS, Epi Info, SAS.	16
5	Statistical methods in epidemiology Incidence and prevalence, relative risk, attributable risk	2
6	Computer applications in pharmacy <u>Computer System in Hospital Pharmacy:</u> Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.	14

	<u>Computer In Community Pharmacy</u> Computerizing the Prescription Dispensing process Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system <u>Drug Information Retrieval & Storage :</u> Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval	
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Course Materials:

Reference books (Theory)

- 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

Subject Name: BIOPHARMACEUTICS AND PHARMACOKINETICS**Subject Code: 08207405****Theory (3 Hours/ Week, Total: 90 Hours)**

Teaching Scheme (Hours)				Evaluation Scheme (Marks)				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	3	7	70	30	70	30	200

Sr. No.	Course Contents	Hours
1	Biopharmaceutics <u>1. Introduction to Biopharmaceutics</u> a. Absorption of drugs from gastrointestinal tract. b. Drug Distribution. c. Drug Elimination.	9
2	Pharmacokinetics <u>2. Introduction to Pharmacokinetics.</u> a. Mathematical model b. Drug levels in blood. c. Pharmacokinetic model d. Compartment models e. Pharmacokinetic study.	19
3	<u>3. One compartment open model.</u> a. Intravenous Injection (Bolus) b. Intravenous infusion.	8
4	<u>4. Multicompartment models.</u> a. Two compartment open model. b. IV bolus, IV infusion and oral administration	8
5	<u>5. Multiple – Dosage Regimens.</u> a. Repetitive Intravenous injections – One Compartment Open Model b. Repetitive Extravascular dosing – One Compartment Open model c. Multiple Dose Regimen – Two Compartment Open Model	14
6	<u>6. Nonlinear Pharmacokinetics.</u> a. Introduction b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters.	9
7	<u>7. Noncompartmental Pharmacokinetics.</u> a. Statistical Moment Theory. b. MRT for various compartment models. c. Physiological Pharmacokinetic model.	12

8	<u>8. Bioavailability and Bioequivalence.</u> a. Introduction. b. Bioavailability study protocol. c. Methods of Assessment of Bioavailability	11
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Course Materials:

Reference books (Theory)

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercei 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. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

Practical (3 Hours/ Week, Total: 90 Hours)

Sr. No.	Experiments
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 K_a , K_e , $t_{1/2}$, C_{max} , 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.

Scheme of Practical Examination

	Internal/ Sessional	External
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max. marks	20	70
Duration	3 hours	4 hours

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

Subject Name: CLINICAL TOXICOLOGY

Subject Code: 08207406

Theory (2 Hours/ Week, Total: 60 Hours)

Teaching Scheme (Hours)				Evaluation Scheme (Marks)				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	1	-	3	70	30	-	-	100

Sr. No.	Course Contents	Hours
1	General principles involved in the management of poisoning	2
2	Antidotes and the clinical applications.	2
3	Supportive care in clinical Toxicology.	2
4	Gut Decontamination.	3
5	Elimination Enhancement.	3
6	Toxicokinetics.	4
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	14
8	Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper	9
9	Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries	9
10	Plants poisoning. Mushrooms, Mycotoxins	2
11	Food poisonings	2
12	Envenomations – Arthropod bites and stings	2

13	Substance abuse: Signs and symptoms of substance abuse and treatment of dependence a) CNS stimulants :amphetamine b) Opioids c) CNS depressants d) Hallucinogens: LSD e) Cannabis group f) Tobacco	6
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Course Materials:

Reference books

- 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

Subject Name: PHARMACOTHERAPEUTICS-I &II

Subject Code: 08207407

Theory (3 Hours/ Week, Total: 90 Hours)

Teaching Scheme (Hours)				Evaluation Scheme (Marks)				Total Marks
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3	1	3	7	70	30	70	30	200

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

Sr. No.	Course Contents	Hours
1	Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias	14
2	Respiratory system : Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases	6
3	Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	8
4	General prescribing guidelines for a. Paediatric patients b. Geriatric patients c. Pregnancy and breast feeding	6
5	Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial	5
6	Introduction to rational drug use Definition, Role of pharmacist Essential drug concept Rational drug formulations	3
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, Gonorrhoea and Syphilis	20
8	Musculoskeletal disorders Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	8
9	Renal system Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	8
10	Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis	6
11	Dermatology: Psoriasis, Scabies, Eczema, Impetigo	6

Practical (3 Hours/ Week, Total: 90 Hours)

Practicals :

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