REGULATIONS 2016

SYLLABUS

for Courses affiliated to the

Kerala University of Health Sciences

Thrissur 680596

DOCTOR OF PHARMACY

(PHARM D-POST BACCALAUREATE)

Course Code283

(2016-17 Academic year onwards)

2016

2. COURSE CONTENT

2.1. Title of course:

Doctor of Pharmacy (Pharm D – Post Baccalaureate)

2.2. Objectives of course

The Doctor of Pharmacy (Pharm D – Post Baccalaureate) education will aim at producing post graduates, having profound knowledge of pharmacy supplemented with knowledge of scientific advances in Modern medicine along with extensive clinical training; who will become efficient and competent health care professional.

The aim of the course is to mould the student to suit the varied requirements of

i. Practice settings in – Hospital Pharmacy and Community Pharmacy.

ii. Clinical Pharmacy services

a. Patient counseling

b. Drug information

c. Therapeutic Drug Monitoring(TDM) and Dose calculation

iii. Academics.

iv. Regulatory affairs.

2.3. Medium of instruction:

The medium of instruction for the course shall be English.

2.4. Course outline

I Year	-	12 months
II Year	-	12 months
III Year (rotatory internship)	-	12 months

The course of study for Pharm.D (Post Baccalaureate) 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

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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	Pharmacotherapeutics- I & II	3	3	1
1.2	Pharmacotherapeutics-III	3	3	1
1.3	Hospital Pharmacy	2	3	1
1.4	Clinical Pharmacy	3	3	1
1.5	Biostatistics & Research Methodology	2	-	1
1.6	Biopharmaceutics & Pharmacokinetics	3	3	1
1.7	Clinical Toxicology	2	-	1
	Total hours	18	15	7=(40)

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	Clinical Research	3	-	1
2.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
2.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
2.4	Clerkship *	-	-	1
2.5	Project work (Six Months)	-	20	-
	Total hours	8	20	4=(32)

*Attending ward rounds on daily basis.

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Third Year:

Internship or residency training including postings in specialty units. The 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.

2.5. Duration

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 (200) 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.

2.6. Syllabus

As mentioned in "Content of each subject in each year" (clause 2.10)

The concept of health care counselling shall be incorporated in all relevant areas.

2.7. Total number of hours

As mentioned in "Content of each subject in each year" (clause 2.10)

2.8. Branches if any, with definition

As mentioned in "Content of each subject in each year" (clause 2.10)

2.9. Teaching, learning methods

Classroom lectures using Blackboard and PowerPoint presentations.

Teaching with Counselling heads, Case presentations, Seminar, Clerkships and projects and any other methods decided by the respective H.O.D's

2.10 Content of each subject in each year

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First Year

1.1 - PHARMACOTHERAPEUTICS I & II (THEORY)

Theory: 3 Hrs. /Week

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

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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.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
2. **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
3. **General prescribing guidelines for**
    a) Paediatric patients
    b) Geriatric patients
    c) Pregnancy and breast feeding
4. **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
5. **Introduction to rational drug use**
   Definition, Role of pharmacist Essential drug concept Rational drug formulations
6. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal

infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis

7. **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
8. **Renal system**
   Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
9. **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
10. **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

1.1 - PHARMACOTHERAPEUTICS - I & II (PRACTICAL)

Practical : 3 Hrs./Week

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

Assignments :

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

Format of the assignment:

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

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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).

1.2 - PHARMACOTHERAPEUTICS – III (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 individualised therapeutic plans based on diagnosis;
e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;

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h. to discuss the controversies in drug therapy;
i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

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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.

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/diseases

Title of the topic

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

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6. Evidence Based Medicine

1.2 - 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.

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**

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

1.3 - 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)
   a. Hospital pharmacy by William .E. Hassan
   b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

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

3. **Lecture wise programme : Topics**

   1 Hospital - its Organisation and functions

   2 Hospital pharmacy-Organisation and management
   a. Organizational structure-Staff, Infrastructure & work load statistics
   b. Management of materials and finance
   c. Roles & responsibilities of hospital pharmacist

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3. The Budget – Preparation and implementation

4 Hospital drug policy

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

5. Hospital pharmacy services

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

6. Manufacture of Pharmaceutical preparations

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

7. Continuing professional development programs

Education and training

8. Radio Pharmaceuticals – Handling and packaging

9. Professional Relations and practices of hospital pharmacist

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1.3 - 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:

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

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

1.4 - 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, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

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

References

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

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**

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

3. **Patient data analysis**

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

4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

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1.4 - 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 counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

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

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1.5 - BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1. Research Methodology

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

2. **Biostatistics**

2.1 Introduction

a) Types of data distribution
b) Measures describing the central tendency distributions- average, median, mode
c) 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.

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

2.4 **Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

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

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1.6 - BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

I. 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

c. Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.

a. Introduction

b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.

a. Statistical Moment Theory.

b. MRT for various compartment models.

c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.

a. Introduction.

b. Bioavailability study protocol.

c. Methods of Assessment of Bioavailability

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1.6 - 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

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f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

1.7 - 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.

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10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

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

References:

a. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis And Treatment Of Poisoning. Second edition. Williams and Willkins publication, London
b. V V Pillay. Handbook of Forensic Medicine And Toxicology. Thirteenth edition 2003 Paras Publication, Hyderabad.

Second Year

2.1 - 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.

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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.

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2.2 - 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 Pharmacoeconomics:

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

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2.3 - CLINICAL PHARMACOKINETICS AND THERAPEUTIC 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 feed back.
   c. Analysis of Population pharmacokinetic Data.
7. **Pharmacogenetics**
   a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
   b. Genetic Polymorphism in Drug Transport and Drug Targets.
   c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

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2.11 No: of hours per subject (lecture-tutorial-seminar-group discussion)

As mentioned in "Course outline" (clause 2.4)

2.12 Practical training

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 first 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 second 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.

2.13 Records

Record to be maintained for all practical subjects

2.14 Dissertation:

There is no dissertation

2.15 Speciality training if any

Not applicable

2.16 Project work to be done if any

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

Objectives of project work.— The main objectives of the project work is to— (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and (ii) develop the students in data collection, analysis and reporting and interpretation skills.

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

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(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.

Qualification of Guide: A postgraduate degree in M.Pharm/PharmD with 5 years experience after P.G is eligible to guide maximum of two groups each group consisting maximum of four students.

Reporting

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

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

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

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

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(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)	b) Presentation of work	(17.5)
c)	c) Communication skills	(17.5)
d)	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.

2.17 Any other requirements [CME, Paper Publishing etc.]

As per the direction of HOD

2.18 Prescribed/recommended textbooks for each subject

As mentioned in "Content of each subject in each year" (clause 2.10)

2.19 Reference books

As mentioned in "Content of each subject in each year" (clause 2.10)

2.20 Journals

All pharmacy and related medical journals

2.21 Logbook

Logbook should be maintained wherever necessary

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3. EXAMINATIONS

3.1 Eligibility to appear for exams

Only such students who produce certificate from the Head of the Institution in which he or she has undergone 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.

3.2 Schedule of Regular/Supplementary exams

There will be one main examinations and one supplementary examination six months apart in each year.

3.3 Scheme of examination showing maximum marks and minimum marks (Minimum marks should be given)

First Year Examination

S. No	Name of Subject	Maximum marks for Theory			Maximum marks for Practical		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Pharmacotherapeutics-I & II	70	30	100	70	30	100
1.2	Pharmacotherapeutics-III	70	30	100	70	30	100
1.3	Hospital Pharmacy	70	30	100	70	30	100
1.4	Clinical Pharmacy	70	30	100	70	30	100
1.5	Biostatistics & Research Methodology	70	30	100	-	-	-
1.6	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
1.7	Clinical Toxicology	70	30	100	-	-	-
Total				700			500

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Second Year Examination

S. No	Name of Subject	Maximum marks for Theory			Maximum marks for Practical		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Clinical Research	70	30	100	-	-	-
2.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
2.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
2.4	Clerkship *	-	-	-	70	30	100
2.5	Project work (Six Months)	-	-	-	100**	-	100
	Total			300			200

*Attending ward rounds on daily basis

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

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 university theory examinations, practical examinations and 50% marks in each of the theory and internal assessment taken together and 50% in practical examinations including internal assessment marks.

3.4 Papers in each year

As mentioned in "Content of each subject in each year" (clause 2.10)

3.5 Details of theory exams

Number of papers: As mentioned in "Content of each subject in each year" (clause 2.10)

Duration, Type of questions & number of questions and marks: As mentioned in model question paper as given in curriculum

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1) Theory examination shall be of three hours and practical examination shall be of four hours duration.
2) Theory examination is for 70 marks consisting of three essay questions each carrying 10 marks (3x10 = 30) and eight short notes each carrying 5 marks (8x5= 40)
3) The practical examination shall be evaluated jointly by an internal and an external examiner appointed by the University.
4) Practical examination shall also consist of a viva –voce (Oral) examination. 70 marks for practical examination in each subject are inclusive of 10 marks Viva-voce
5) A Student who fails in theory or practical examination of a subject shall re- appear both in theory and practical of the same subject.
6) 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.

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3.6 Model question paper for each subject with question paper pattern

QP Code: **Reg. No.:.....**

First Year Pharm. D Post Baccalaureate Degree Examinations

(Model Question Paper)

Pharmacotherapeutics I & II

Time: 3 hrs

Max.Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays: (3x10=30)

1. Explain the aetiology, pathophysiologyclinical significance, non pharmacological approach for control and stepwise treatment for asthma.
2. Define angina pectoris and myocardial infarction, briefly outline different types of angina and give the etiopathogenesis of myocardial Infarction. Explain therapeutic management of MI.
3. Explain the aetiology, pathophysiology and therapeutic management of diabetes Mellitus.' Add a note on insulin.

Short notes **(8x5=40)**

4. Describe the prescribing guidelines for paediatric patients.
5. Management of chemotherapy induced nausea and vomiting.
6. Briefly explain about psoriasis.
7. Therapeutic management of glaucoma.
8. Define essential drug list and explain the role of pharmacist in rational drug use.
9. Outline the aetiology of acute renal failure and therapeutic management of chronic renal failure.
10. Therapeutic management of hypertension with special reference to drug of choice.
11. Pathophysiology and pharmacotherapy of tuberculosis with focus on multidrug resistant tuberculosis

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QP Code: **Reg. No.:.....**

First Year Pharm. D Post Baccalaureate Degree Examinations

(Model Question Paper)

Pharmacotherapeutics III

Time: 3 hrs

Max. Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays: (3x10=30)

1. Explain in detail the pathophysiology and pharmacotherapy of peptic ulcer. Discuss the differences between gastric ulcer and duodenal ulcer.
2. Classify different types of anaemias. Explain the pathophysiology and treatment of anaemias.
3. Define stroke. Add a note on etiopathogenesis and its therapeutic management.

Short notes **(8x5=40)**

4. Schizophrenia and its therapeutic management.
5. Discuss the pathophysiology and therapeutic management of inflammatory bowel disease.
6. Chart out and explain the algorithm for epilepsy and therapeutic management of epilepsy
7. Discuss the pathophysiology and therapeutic management of anxiety disorders.
8. Write notes on headache. Explain the pathophysiology and treatment of headache.
9. Discuss the pathophysiology, applied therapeutics and drug of choice in the management of Venous thromboembolism.
10. Pathophysiogy and therapeutic management of epilepsy
11. Explain pain pathways. Discuss the management of various types of pain.

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QP Code: **Reg. No.:.....**

First Year Pharm. D Post Baccalaureate Degree Examinations

(Model Question Paper)

Hospital Pharmacy

Time: 3 hrs Max.Marks: 70

- Answer all questions
- Draw diagram wherever necessary

Essays:

(3x10=30)

1. What are the various methods of inventory control. Explain in detail about ABC and VED analysis.
2. Explain various drug distribution method in a hospital. Add notes on unit dose dispensing.
3. Define PTC and mention the objective of PTC. Explain the operation and role of PTC.

Short notes (8x5=40)

4. Organization of a hospital pharmacy and roles and responsibilities of hospital pharmacist
5. Define hospital formulary. Explain its contents and advantages and disadvantages.
6. Research and ethics committee in a hospital
7. What are radio pharmaceuticals. Discuss the handling and packaging of radiopharmaceuticals in a hospital.
8. Discuss the hospital pharmacy communications with emphasis on news letters in hospital pharmacy.
9. Explain the role of pharmacist in central sterile supply services
10. What is total parentral nutrition. Explain its components and compounding of TPN.
11. Discuss the professional relations and practices o f hospital pharmacist.

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QP Code: **Reg. No.:.....**

First Year Pharm. D Post Baccalaureate Degree Examinations

(Model Question Paper)

Clinical Pharmacy

Time: 3 hrs

Max.Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays:

(3x10=30)

1. Define drug information centre. Mention the resources and systematic approach in answering a D I query. Enumerate on poison information.
2. Define, classify and mechanism of ADR. Explain on the role of pharmacist in prevention and management of ADR.
3. Define and explain medication error. Add a note on drug therapy monitoring.

Short notes (8x5=40)

4. Development and scope of clinical pharmacy.
5. Ward round participation.
6. Pulmonary function tests.
7. Patient counselling techniques.
8. Pharmaceutical care.
9. Critical evaluation of biomedical literature.
10. Tests associated with cardiac disorders.
11. Drug utilization evaluation.

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QP Code: **Reg. No.:.....**

First Year Pharm. D Post Baccalaureate Degree Examinations

(Model Question Paper)

Biostatistics & Research Methodology

Time: 3 hrs Max.Marks:70

- Answer all questions
- Draw diagram wherever necessary
- Use only ordinary calculator

Essays: (3x10=30)

1. Discuss sample size determination in detail.
2. Explain the uses of computers in drug information retrieval and storage.
3. The fat content In Ice cream made by a firm is examined in two laboratories as given below

   Lab A : 7 8 7 3 8 6 9 4 7 8 Lab B : 9 8 8 4 7 7 9 6 6 6

   Is there a significant difference between the mean fat content obtained by the two laboratories.

Short notes (8x5=40)

4. Calculate the correlation coefficient for the following data

   X : 40 44 58 55 89 98 66 Y : 56 49 53 58 65 76 58
5. Describe the case study method.
6. Three processes A, B and C are tested to see whether their outputs are equivalent. Following observations are obtained.

   A : 10 12 13 13 10 14 15 13 B : 9 11 10 12 13 C : 11 10 15 14 12 13

   Carry out the analysis of variance and state your conclusion.
7. Explain null hypothesis with example
8. Attribute risks.
9. Type I and Type II errors.
10. Graphical presentation
11. Calculate the mean of the following data :

    Class : 0-10 10-20 20-30 30-40 40-50 Frequency: 5 10 40 20 25

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QP Code: **Reg. No.:.....**

First Year Pharm. D Post Baccalaureate Degree Examinations

(Model Question Paper)

Biopharmaceutics & Pharmacokinetics

Time: 3 hrs

Max.Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays: (3x10=30)

1. Derive the pharmacokinetic equation to describe plasma drug concentration when a drug administered via i.v.route, confers on the body two compartment model
2. Discuss the physicochemical factors affecting the drug absorption.
3. Discussthe design and protocol for single dose bioavailability study

Short notes (8x5=40)

4. Discuss briefly the methods for the assessment of bioavailability.
5. Drug elimination
6. Discuss the kinetics of two compartment open model-oral
7. Explain loading dose and its clinical significance
8. Explain MRT and protein binding
9. Discuss any two methods for the estimation Vmax and Km.
10. What are the mechanisms of drug absorption.
11. Explain briefly non-linear pharmacokinetics

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QP Code: **Reg. No.:.....**

First Year Pharm. D Post Baccalaureate Degree Examinations

(Model Question Paper)

Clinical Toxicology

Time: 3 hrs

Max.Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays: (3x10=30)

1. Explain in detail about various types of antidotes and explain its clinical applications.
2. Explain the clinical effects of snake venoms. Add a note on general management of complications related with snake bites.
3. Discuss in detail about the clinical symptoms and management of acute poisoning with paracetamol and salicylates.

Short notes (8x5=40)

4. Radiation poisoning.
5. Organo phosphorous poisoning.
6. Outline the clinical symptoms and management of opiate overdose.
7. Briefly explain the chronic effects and management of arsenic poisoning
8. Discuss the techniques of gut decontamination.
9. Explain the harmful effects and the treatment of dependence of tobacco.
10. Food poisonings.
11. Benzodiazepine poisoning.

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QP Code: **Reg. No.:.....**

Second Year Pharm. D (Post Baccalaureate) Degree Examinations

(Model Question Paper)

Clinical Research

Time: 3 hrs

Max.Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays: (3x10=30)

1. Explain clinical trial protocol as per ICH-GCP guidelines
2. Describe briefly the various phases of clinical trials.
3. Discuss the composition, responsibilities and procedures of IRB/IEC

Short notes (8x5=40)

4. ANDA submission.
5. Explain the safety monitoring in clinical research
6. Explain the role of investigator
7. Explain the design of a patient informed consent with a suitable example
8. Pharmacological approaches to drug discovery
9. Challenges in implementing the ethical guidelines
10. Clinical trial design
11. Methods of post marketing surveillance

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QP Code: **Reg. No.:.....**

Second Year Pharm. D (Post Baccalaureate)

Degree Examinations

(Model Question Paper)

PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Time: 3 hrs

Max.Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays: (3x10=30)

1. Define pharmacoepidemiology. Explainthe history, scope and applicationsof pharmacoepidemiology.
2. Define DUE and explain the steps involved in a DUE. Mention the role of pharmacist in a DUE study.
3. Explain the cost effectiveness analysis and cost utility analysis with its applications in pharmacoeconomic study.

Short notes

(8x5=40)

4. Explain incidence and prevalence in pharmacoepidemiological study.
5. Explain the meta analysis models with examples.
6. Describe the various types of costs in pharmacoeconomic study.
7. Explain the role of pharmacoeconomics in formulary management.
8. Explain the relative risk and attributable risk in pharmacoepidemiological study.
9. Describe spontaneous reporting system.
10. Briefly explain about the pharmacoepidemiological outcome measurements.
11. Explain case control studies with suitable examples.

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QP Code: **Reg. No.:.....**

Second Year Pharm. D (Post Baccalaureate)Degree Examinations

(Model Question Paper)

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

Time: 3 hrs

Max.Marks: 70

•Answer all questions

•Draw diagram wherever necessary

Essays:

(3x10=30)

1. Explain therapeutic drug monitoring. Discuss the indications and protocol for TDM
2. Discuss the dosing of drugs in the elderly &children and in obese patients with suitable examples.
3. Explain the approaches of analysis of population pharmacokinetic data and mention applications.

Short notes (8x5=40)

4. Bayesian theory of adaptive method
5. Dosage adjustment for uremic patients.
6. Effect of genetic polymorphism in drug transport and drug targets.
7. Genetic polymorphism.
8. TDM of drugs used in cardiac and seizure disorders.
9. Extracorporeal removal of drugs.
10. Drug interactions related to inhibition and induction of drug metabolism with one example.
11. Dosage adjustment in renal disease.

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3.7 Internal assessment component

As given in Scheme of examination showing maximum marks and minimum marks (clause 3.3)

3.8 Details of practical/clinical practical exams

As given in content of each subject in each year clause 2.10

3.9 Number of examiners needed (Internal & External) and their qualifications

Examiner – From within this University or other Universities with 5 years Post PG teaching experience.

There shall be two examiners for practical examination-one internal and one external, who will jointly evaluate the performance of the candidate and conduct viva voce examination and award marks.

3.10 Details of viva:

- ***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).

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4. INTERNSHIP

4.1 Eligibility for internship

The student will join the compulsory rotatory internship programme after passing the final professional examination.

Every candidate shall be required, after passing the final Pharm.D(P.B) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D(P.B) as the case may be.

4.2 Details of internship, Duration

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,

(ii) Two months each in three other speciality departments

SPECIFIC OBJECTIVES:

(i) to provide patient care in cooperation with patients, prescribers, and other members of an inter professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

(ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

(iii) to promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk population, and other members of an inter professional team of health care providers.

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(iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.

(v) To develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio economic, political and cultural environment.

(vi) To communicate effectively with patients and the community.

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

4.3 Model of Internship Mark lists

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

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

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

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

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4.4 Extension rules

- Extension of internship: Internship shall be extended by the number of days the students remains absent. These extended days of internship should be completed in the respective external/internal institution.
- Any other leave other than eligible leave less than six months has to be compensated by extension granted by the principal.

4.5 Details of Training given

Third Year:

- Internship or residency training including postings in specialty units. Student should independently provide the clinical pharmacy services to the allotted wards.
- Six months in General Medicine department, and Two months each in three other speciality departments.

5. ANNEXURES

5.1 Check Lists for Monitoring: Log Book, Seminar Assessment etc., to be formulated by the curriculum committee of the concerned Institution

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APPENDIX-A

(See regulation 1.4)

CONDITIONS TO BE FULFILLED BY THE

ACADEMIC TRAINING INSTITUTION

1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
2) Pharm.D (Post Baccalaureate) programmes shall be conducted only in those institutions which -
   a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
   b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

a) Tertiary care hospitals are desirable
b) Medicine[compulsory], and any three specialization of the following
   1. Surgery
   2. Pediatrics
   3. Gynecology and obstetrics
   4. Psychiatry
   5. Skin and VD

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6. Orthopedics

(iii) **Location of the Hospital**

It should be within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

In case the hospital and institution are located in different corporations or municipalities or campuses, the distance between the two shall not be more than 30 kms by road.

(iv) The University shall ascertain that the College is having facilities as per Appendix – A by appointing Technical Expert Committee, constituted for the purpose periodically, for inspection.

3) **TEACHING STAFF REQUIREMENT**

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

ii) Subject wise specialisation of the Teaching Staff :

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or

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		Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice Or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

iii) Teaching Staff :

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

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	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

vi) Workload of Faculty : Professor – 8 hrs. per week Assistant Professor – 12 hrs. per week Lecturers – 16 hrs. per week

v) Training of Pharmacy Practice Faculty :

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training – Minimum 3 months.

c) Training sites – Institutions running pharmacy practice or Programmes for atleast five years.

d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

5) **ACCOMMODATION :**

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

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

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

Total = 8

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In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

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

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

II. Apparatus:

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

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

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B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02
4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

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

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

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

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

II. Apparatus:

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

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

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D. DEPARTMENT OF PHARMACEUTICS :

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01
20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01

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

II. Apparatus:

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

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

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E. **DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :**

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

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

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F. DEPARTMENT OF PHARMACY PRACTICE :

Equipment:

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1
10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE: (1) Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.

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

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G. CENTRAL INSTRUMENTATION ROOM :

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

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APPENDIX-B

(See regulation 3)

CONDITIONS TO BE FULFILLED BY

THE EXAMINING AUTHORITY

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

7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D (Post Baccalaureate) programmes in an approved institution

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