Pharm.D. PB I Year examination :

S.No.	Name of Subject	Maximu	m marks for 7	Theory	Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1	Pharmacotherapeutics-III	70	30	100	70	30	100
2	Hospital Pharmacy& community Pharmacy	70	30	100	70	30	100
3	Clinical Pharmacy	70	30	100	70	30	100
4	Biostatistics & Research Methodology	70	30	100	-	-	-
5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
6	Clinical Toxicology	70	30	100	-	-	-
7	Pharmacotherapeutics-I& II	70	30	100	70	30	100
				700			500

Pharm.D.PB II Year examination :

S.No.	Name of Subject	Maximu	m marks for 7	Гheory	Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks viva-voce (oral)

70 marks Thesis work

- 11. Eligibility for appearing Examination. Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.
- 12. Mode of examinations. (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.
 - (2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.
 - (3) Practical examination shall also consist of a viva voce (Oral) examination.
 - (4) Clerkship examination Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by

pharmaceutical care planning and knowledge of therapeutics shall be assessed.

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

- A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.
- 15. Eligibility for promotion to next year. All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.
- 16. Internship. (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
 - (2) Every student has to undergo one year internship as per Appendix-C to these regulations.
- 17. A Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix D to these regulations.
- 18. Certificate of passing examination. Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

14.

CHAPTER-III

Practical training

- 19. Hospital posting. Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
- 20. Project work. (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
 - (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
- 21. Objectives of project work. The main objectives of the project work is to
 - (i) show the evidence of having made accurate description of published work ofothers and of having recorded the findings in an impartial manner; and
 - (ii) develop the students in data collection, analysis and reporting and interpretationskills.
- 22. Methodology. To complete the project work following methodology shall be adopted, namely:
 - (i) students shall work in groups of not less than *two* and not more than *four* under anauthorised 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.

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;
 - 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).

Text Books

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

Reference Books

- a. Pathologic basis of disease Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice -Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

e.

f. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS - III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

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

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

Title of the topic

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

Assignments:

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

Format of the assignment:

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

Scheme of Practical Examination :

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

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

HOSPITAL PHARMACY & COMMUNITY 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

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 ControlABC, 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

COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

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

Text Books:

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

Reference books:

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

Special requirements:

- 1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
- 2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1.	Synopsis	10
2.	Major Experiment	30
	(Counselling of patients with specific diseases emphasis should be	e given on
	Counselling introduction, content, process and conclusion)	
3.	Minor Experiment(Ability to measure B.P/ CBG / Lung function)	15
1	Prescription Analysis (Analyzing the prescriptions for probable drug int	propertion on

- 4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management) 15
- 5. Viva Voce

10

4. Lecture wise programme :

Topics

- 1 Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist
- 2 Community Pharmacy Management

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

6 Patient counselling

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

7 Patient medication adherence

Definition, Factors affecting medication adherence, role of pharmacistin improving the adherence.

8 Health screening services

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

9 OTC Medication- Definition, OTC medication list & Counselling10

Health Education

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

Commonly occurring Communicable Diseases, causative agents,

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

Syphilis, Gonorrhea and AIDS

Balance diet, and treatment & prevention of deficiency disorders Family planning role of pharmacist

11 Responding to symptoms of minor ailments

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

- 12 Essential Drugs concept and Rational Drug Therapy Role of community pharmacist
- 13 Code of ethics for community pharmacists

HOSPITAL PHARMACY & COMMUNITY 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
- 2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

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

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

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

- 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

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.

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

2.2 Data graphics

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

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)
- d) Linear regression and correlationcorrelation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

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

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

BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

1. Biopharmaceutics

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

2. Pharmacokinetics

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

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

CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

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

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- 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

PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

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

Text Books

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

Reference Books

- a. Pathologic basis of disease Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e.
- 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

PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

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

Assignments :

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

Format of the assignment:

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

Scheme of Practical Examination:

	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).

PHARMACOTHERAPEUTICS – 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 of the Subject Upon completion of the subject student shall be able to -

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

Text books (Theory)

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

Reference books (Theory)

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

3. Detailed syllabus and lecture wise schedule :

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

Title of the topic

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

2 Musculoskeletal disorders

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

3 Renal system

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

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

PHARMACOTHERAPEUTICS – 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.

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

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

Assignments :

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

Format of the assignment :

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

Scheme of Practical Examination :

	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).

P.B II YEAR

CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

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

2. Clinical development of drug:

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

References :

- 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.

PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS(THEORY)

Theory: 3 Hrs. /Week

1. Pharmacoepidemiology :

Definition and scope:

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

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

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

Concept of risk in pharmacoepidemiology

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

Pharmacoepidemiological methods

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

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

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

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

2. Phrmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

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

3. Applications of Pharmacoeconomics

Software and case studies

CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

1. Introduction to Clinical pharmacokinetics.

2. Design of dosage regimens:

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

3. Pharmacokinetics of Drug Interaction:

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

4. Therapeutic Drug monitoring:

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

5. Dosage adjustment in Renal and hepatic Disease.

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

6. Population Pharmacokinetics.

- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with 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

APPENDIX-C (See regulation 16) INTERNSHIP

1) SPECIFIC OBJECTIVES :

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

2) OTHER DETAILS :

- All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

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

1. ASSESSMENT OF INTERNSHIP :

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-
 - (1) Proficiency of knowledge required for each case management SCORE 0-5

(2)	The con	npetency in	skills exp	ected f	or prov	viding	Clinical	l	
	Pharma	cy Services	_		-	_		SCORI	E 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
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Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

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

APPENDIX-D

(See regulation 17) CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

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

(ARCHNA MUDGAL) Registrar-cum-Secretary Pharmacy Council of India New Delhi – 110002