Krishna Vishwa Vidyapeeth, (Deemed To Be University), Karad.

Krishna Institute of Pharmacy, Karad.

Programme Name: Doctor of Pharmacy - Post Bacculaurate
(Pharm. D PB)
Programme code: 6302

Course Regulation 2008

PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and
Family Welfare
(Pharmacy Council of India)

VISION

To be recognized as a premier academic institution imparting excellent pharmaceutical education and research

MISSION

To offer quality pharmaceutical education, to create healthcare professionals with requisite skills, knowledge, research aptitude, values and ethics ensuring rewarding careers.

- **M1.** Quality Pharmaceutical Education: To offer outcome based pharmaceutical education to produce qualified and competent pharmacists of International standards
- **M2.** Competent Pharmacist: To create competent pharmacist with requisite skills, knowledge, innovative thinking, Research aptitude and having professional excellence
- **M3.** Rewarding Career: To impart strong ethical values and good Professional behavior, so as to undertake rewarding career in a pharmacy profession, tailor-made to meet stringent requirements of pharmaceutical industry

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

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

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

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

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.

   (2) They shall come into force from the date of their publication in the official Gazette.

2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3. Duration of the course. –

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

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

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

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

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

4. Minimum qualification for admission to. –

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

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

Mathematics or Biology.

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

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

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

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

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

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

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

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
   i) Pharm.D. Programme – 30 students.
   ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

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

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

T A B L E S

First Year:

Course code	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
6302-11T 6302-18P	Pharmacotherapeutics-III	3	3	1
6302-12T 6302-19P	Hospital Pharmacy	2	3	1
6302-13T 6302-20P	Clinical Pharmacy	3	3	1
6302-14T	Biostatistics & Research Methodology	2	-	1
6302-15T 6302-21P	Biopharmaceutics & Pharmacokinetics	3	3	1
6302-16T	Clinical Toxicology	2	-	1
	Total hours	**15**	**12**	**6 = 33**

Second Year:

Course code	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
6302-23T	Clinical Research	3	-	1
6302-24T	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
6302-25T	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	–	1
	Clerkship *	-	-	1
6302-26P	Project work (Six Months)	–	20	–
	Total hours	**8**	**20**	**4 = 32**

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

Third Year:

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

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

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

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

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

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

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

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

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

T A B L E S

First Year examination :

Course code	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
6302-11T 6302-18P	Pharmacotherapeutics-III	70	30	100	70	30	100
6302-12T 6302-19P	Hospital Pharmacy	70	30	100	70	30	100
6302-13T 6302-20P	Clinical Pharmacy	70	30	100	70	30	100
6302-14T	Biostatistics & Research Methodology	70	30	100	-	-	-
6302-15T 6302-21P	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
6302-16T	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Second Year examination :

Course code	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	**Sessional**	**Total**	**Examination**	**Sessional**	**Total**
6302-23T	Clinical Research	70	30	100	-	-	-
6302-24T	Pharmacoepidemiology andPharmacoeconomics	70	30	100	-	-	-
6302-25T	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
	Clerkship *	-	-	-	70	30	100
6302-26P	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAPTER-III
Practical training

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

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

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

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

22. Methodology.— To complete the project work following methodology shall be adopted, namely:—
    (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;
    (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
    (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
    (iv) project work shall be approved by the institutional ethics committee;
    (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
    (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

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

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

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

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

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

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

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

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

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

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

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

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

First Year

6302 -11T 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. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

6302 -18P 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).

6302 -12T 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

   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

6302 -19PHOSPITAL 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**

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

6302 -13T 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

6302 -20P 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.

6302 -14T 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

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.

Data graphics

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

Basics of testing hypothesis

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

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

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

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

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

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

6302 -15T BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

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

2. Pharmacokinetics

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

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

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

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

6302 -21P BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

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

References:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 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.

6302 -16T 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

Second year

6302 -23T CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. **Drug development process:**

   Introduction

   Various Approaches to drug discovery

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

2. **Clinical development of drug:**

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

References :

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

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

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

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

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

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

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

6302 -24T 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

6302 -25T 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