



شیوه نوین
رهجویان عصر دانش

PHARM.D (POST BACCALAUREATE) DOCTORATE OF PHARMACY

طول مدت دوره : ۳ سال
مورد تأیید سازمان نظام پزشکی هندوستان
با همکاری مستقیم دانشگاه علوم پزشکی راجیو گاندی
مورد تأیید وزارت بهداشت و درمان در ایران



دو سال آموزش آکادمیک و سال سوم اینترنشیپ، که
پیش نیاز آن لیسانس داروسازی می باشد

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**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA
(RGUHS), BANGALORE – 560 041**

**Pharm D (Post Baccalaureate) Revised Regulations 2008
(Effective from 2012-2013)**

1. Eligibility

1.1 Qualifying Examination

For Pharm D Post (Baccalaureate), a pass in B Pharm degree examination of Rajiv Gandhi University of Health Sciences or B Pharm examination of any other recognized Indian University established by law in India or any other degree courses in Pharmacy recognized as equivalent by RGUHS and Pharmacy Council of India.

1.2 Eligible candidates are directly joining to fourth year Pharm D course as lateral entry.

2. Duration of the course

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.

3. Medium of Instruction

Medium of Instruction and Examination Shall be English.

4. Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately in a recognized institution approved by Pharmacy council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The candidate shall complete prescribed course satisfactorily to be eligible to appear for the respective examination.

5. Course of study

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

First Year Post Baccalaureate

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Pharmacotherapeutics- I & II	3	3	1
1.2	Hospital & Community Pharmacy	3	3	1
1.3	Clinical Pharmacy	3	3	1
1.4	Biostatistics & Research Methodology	2	-	1
1.5	Clinical Toxicology	2	-	1
1.6	Pharmacotherapeutics-III	3	3	1
	Total hours	16	12	6
	Grand total			= 34

Second Year Post Baccalaureate:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
2.1	Clinical Research	3	-	1
2.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
2.3	Clinical Pharmacokinetics & Therapeutic Drug Monitoring	2	-	1
2.4	Clerkship *	-	-	1
2.5	Project work (Six Months)	-	20	-
	Total hours	8	20	4
	Grand total			= 32

**Attending ward rounds on daily basis*

Third Year Post Baccalaureate

Internship or residency training including postings in specialty units. Student should provide the clinical pharmacy services under supervision of a preceptor to the allotted wards.

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

6. Approval of institution conducting the course of study

The regular course for Pharm D (Post Baccalaureate) I, II, and III year shall be conducted by an institution approved by Pharmacy Council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. Institution running Pharm D regular courses only shall be permitted to start Pharm D (Post Baccalaureate) course. The approval and affiliation will be granted only if adequate arrangements for teaching-infrastructure facilities, accommodation, equipments, chemicals, glassware, library, teaching and non-teaching staff are provided as prescribed by Pharmacy Council of India and as required under the norms of Rajiv Gandhi University of Health Science, Karnataka (as prescribed in Appendix B).

7. Academic Work

The teaching staff of respective subjects shall maintain a regular record of attendance in both Theory and Practical.

Internal Assessment Marks

A. Theory: Three sessional examinations evenly spread during the academic year shall be conducted by the affiliated colleges. The average marks of the best two examinations shall be computed out of a maximum 30 marks and shall constitute the sessional marks in theory. Provided further the colleges may conduct one special theory sessional examination towards the end of the academic session for those who might have missed any one of the regular sessional examination on genuine grounds.

B. Practical: Students are expected to perform the number of experiments listed in the respective syllabus. Marks shall be awarded out of a maximum of 10 to each of the practical exercise and an average of those shall be computed out of maximum of 10 each marks. In addition, three practical sessional examinations evenly spread during academic year shall be conducted. The average marks of the best two practical examinations shall be computed out of a maximum of 20 marks. A total of 30 marks shall constitute the sessional award in practical. While awarding the sessional marks of practical experiments, the following considerations should be taken into account.

1. Preparation of the candidate.
2. Manipulative skills.
3. Results of the experiment.
4. Knowledge of the experiment
5. Viva voce pertaining to the experiments only.

The College shall maintain the sessional books of the students and the record of sessional marks of the students.

A regular record of both theory and practical class work and sessional examinations conducted in an institution imparting the course shall be maintained for each student in the institution.

8. Examination for Pharm D (Post Baccalaureate)

- (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 :

Scheme of Examination for Pharm D (Post Baccalaureate) Course

First Year

Sl#	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Pharmacotherapeutics- I & II	70	30	100	70	30	100
1.2	Hospital and Community Pharmacy	70	30	100	70	30	100
1.3	Clinical Pharmacy	70	30	100	70	30	100
1.4	Biostatistics & Research Methodology	70	30	100	-	-	-
1.5	Clinical Toxicology	70	30	100	-	-	-
1.6	Pharmacotherapeutics- III	70	30	100	70	30	100
	Total			600			400 = 1000

Second Year

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practical		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Clinical Research	70	30	100	-	-	-
2.2	Pharmacoepidemiology and Pharmacoconomics	70	30	100	-	-	-
2.3	Clinical Pharmacokinetics & Therapeutic drug monitoring	70	30	100	-	-	-
2.4	Clerkship *	-	-	-	70	30	100
2.5	Project work (6 Months) **	-	-	-	100**		100
	Total			300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)

70 marks – Thesis work

9. Mode of examinations

- (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.
- (2) Practical examination shall also consist of a viva –voce (Oral) examination.
- (3) 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.

10. Criteria for Pass

- a) Candidates who have secured a minimum of 50% marks in the Theory (including sessional) and Practical (including sessional) separately in any subject or subjects shall be declared to have passed in that subject/ and exempted from appearing in that subject/s at subsequent examination.
- b) Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.

11. 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 three subjects shall debar him or her from promotion to the next year classes.

12. Declaration of Class

Class shall be awarded at the end of I, II, III, IV, V and final year of Pharm. D examination and I, II and Final year of Pharm D (Post Baccalaureate) as shown below:

- | | |
|-----------------|---------------------------------|
| 1) Distinction | 75% |
| 2) First class | 60% and above and less than 75% |
| 3) Second Class | 50% and above and less than 60% |

Pass class shall be awarded to such of the candidates who would have passed the examination in more than one attempt. However, this shall not be applicable to candidates who are exempted in Remedial Biology and Remedial Mathematics by the RGUHS Karnataka, Bangalore.

13. 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) A student shall be permitted to start the internship only after having passed in theory and practical of all subjects of all the previous years.
- (3) Every student has to undergo one-year internship as per Appendix-C to these regulations.

14. Award of Degree

a) A candidate who has passed in all the subjects of Pharm D (Post Baccalaureate) and has successfully completed the Internship (as described in appendix C) will be eligible for the award of Pharm D (Post Baccalaureate) Degree.

15. Practical training

1. **Hospital posting** — Every student shall be posted in constituent hospital for a period of not less than seventy five hours to be covered in not less than 200 working days in each of first year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the 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.
2. **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.
3. **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.
4. **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 utilization reviews, Pharmacoepidemiology, pharmacovigilance or pharmacoconomics;
 - (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.
5. **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 RGUHS recognized 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, subtitles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

6. **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.

17. No. of Admissions

Pharm. D. (Post Baccalaureate): 10 students

18. SYLLABUS FOR PHARM. D. Post-Baccalaureate

FIRST YEAR

1.1 PHARMACOTHERAPEUTICS – I & II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. 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. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

- 2 **Respiratory system** : Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
- 3 **Endocrine system** : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 4 **General prescribing guidelines for**
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 5 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 6 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations
- 7 **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 8 **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 9 **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
- 10 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
11. **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

1.1 PHARMACOTHERAPEUTICS – I & II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

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

Assignments :

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

Format of the assignment:

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

Scheme of Practical Examination:

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

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

1.2 HOSPITAL AND COMMUNITY PHARMACY (THEORY)

Theory: 3 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 Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh
- c) Health Education and Community Pharmacy by N.S.Parmar.
- d) WHO consultative group report.
- e) Drug store & Business management by Mohammed Ali & Jyoti.

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.
- d. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

3. Lecture wise programme:

Topics

A. HOSPITAL PHARMACY

1 Hospital - its Organization and functions

2 Hospital pharmacy-Organization and management

- a) Organizational structure-Staff, Infrastructure & work load statistic
- b) Management of materials and finance
- c) Roles & responsibilities of hospital pharmacist

3 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
- 4 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
- 5 Enteral and parenteral nutrition preparations
 - Total Parenteral Nutrition and I.V. admixtures
- 6 Continuing professional development programs
 - Education and training
- 7 Radio Pharmaceuticals – Handling and packaging
- 8 Professional Relations and practices of hospital pharmacist

B. COMMUNITY PHARMACY

- 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 Responding to symptoms of minor ailments
 - Relevant pathophysiology, common drug therapy to,
 - Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia,
 - Ophthalmic symptoms, worm's infestations.
- 4 Code of ethics for community pharmacists
- 5 Good Pharmacy Practice

1.2 HOSPITAL AND COMMUNITY PHARMACY (PRACTICALS)

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Inventory control
4. Prescription Analysis (Analyzing the prescriptions for probable drug interactions and ability to tell the management)

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 300 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).

1.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives:

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 textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi, Karin Nyfort-Hansen and Milap Nahata Orient Langman Pvt.Ltd. ISSN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- 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

1.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

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

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

Assignment:

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

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

Format of the assignment:

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

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1.4 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, semilogarithmic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

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

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process
Use of Computers for Pharmaceutical Care in community pharmacy
Accounting and General ledger system
Drug Information Retrieval & Storage :
Introduction – Advantages of Computerized Literature Retrieval
Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

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1.5 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 Wilkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

1.6 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.

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

1.6 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

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

Assignments:

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

Format of the assignment:

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

Scheme of Practical Examination:

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

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

Second Year

2.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

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

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
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.

2.2 PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. Pharmacoepidemiology:

Definition and scope:

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

Measurement of outcomes in Pharmacoepidemiology

Outcome measure and drug use measures

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

Concept of risk in pharmacoepidemiology

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

Pharmacoepidemiological methods

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

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

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

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

2. Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

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

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics

Software and case studies

2.3 CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

1. **Introduction to Clinical pharmacokinetics.**
2. **Design of dosage regimens:**
Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
3. **Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
4. **Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
5. **Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
6. **Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
7. **Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

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

(i) Hospital Details

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

(ii) Specialty

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

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

INTERNSHIP

1) SPECIFIC OBJECTIVES:

- i) 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 :

- i) 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.
- ii) 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.

3. ASSESSMENT OF INTERNSHIP :

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) 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 competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5
 - (3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5
 - (4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
 - (5) Initiative, participation in discussions, research aptitude. SCORE 0-5

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

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



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