**“KAR BHALA HOGA BHALA”**

# KADI SARVA VISHWAVIDYALAYA, GANDHINAGAR

**(Established vide Gujarat State Government Act 21 of 2007 and approved by UGC (ref F.9-18/2008(cpp-1) March 19, 2009)**

## ACADEMIC REGULATIONS

**EFFECTIVE FROM JUNE 2018**

# PHARM. D
# POST BACCALAUREATE
## (DOCTOR OF PHARMACY)


**K. B. INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH**

GH-6, SECTOR-23, KADI CAMPUS, GANDHINAGAR-382023.

Email: kbiper@kbiper.ac.in, principal@kbiper.ac.in, kbiper95@yahoo.co.in

Phone: 07923249069, 07923245270.

Website: www.kbiper.ac.in, www.ksvuniversity.org.in

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रजिस्ट्री सं. डीएल (एन)-04/0007/2003--05 REGISTERED No. DL(N)—04/0007/2003—05

सत्यमेव जयते

# भारत का राजपत्र
# The Gazette of India

साप्ताहिक/WEEKLY

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।

(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4

[PART III—SECTION 4]

[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]

[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

सदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

''अरब बांगलादेश बैंक लिमिटेड'' शब्दों के स्थान पर ''एबी बैंक लिमिटेड'' शब्द होंगे।

आनन्द सिन्हा

कार्यपालक निदेशक

**[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.

# KADI SARVA VISHWAVIDYALAYA

## PHARM. D (POST BACCALAUREATE)
## ACADEMIC REGULATIONS

### REGULATIONS

These regulations shall be called as "The Regulations for the Pharm. D (Post Baccalaureate) Degree course of the K. B. Institute of Pharmaceutical Education and Research a constituent college of KADI SARVA VISHWAVIDYALAYA". They shall come into force from the Academic Year 2018 – 2019. The regulations and syllabi framed are subject to modifications as per Pharmacy council of India.

### Minimum Qualification for admission to the course

**Pharm.D. (Post Baccalaureate)**

(1) A pass in B.Pharm degree from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:
(2) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.
(3) 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.

### 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).

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 specialty 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 of a preceptor so that he or she may become capable of functioning independently.

### Medium of Instruction and Examinations

Medium of Instruction and Examination shall be English.

### Working days in the academic year

Each academic year shall consist of not less than two hundred working days.

### Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

## Course of study

The course of study for Pharm. D (Post Baccalaureate) shall include the subjects as given in the Tables 1 and 2 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

**Table-1 First Year Pharm. D (Post Baccalaureate)**

| Sr. 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) |
| 4.1 | Pharmacotherapeutics-III | 3 | 3 | 1 |
| 4.2 | Hospital Pharmacy | 2 | 3 | 1 |
| 4.3 | Clinical Pharmacy | 3 | 3 | 1 |
| 4.4 | Biostatistics & Research Methodology | 2 | - | 1 |
| 4.5 | Biopharmaceutics & Pharmacokinetics | 3 | 3 | 1 |
| 4.6 | Clinical Toxicology | 2 | - | 1 |
| 4.7 | Pharmacotherapeutics-I & II | 3 | 3 | 1 |
| | **Total hours** | **18** | **15** | **7 = 40** |

**Table-2 Second Year Pharm. D (Post Baccalaureate)**

| Sr. 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) |
| 5.1 | Clinical Research | 3 | - | 1 |
| 5.2 | Pharmacoepidemiology and | 3 | - | 1 |
| 5.3 | Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring | 2 | - | 1 |
| 5.4 | Clerkship * | - | - | 1 |
| 5.5 | 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 provide the clinical pharmacy services to the allotted wards, under the supervision of a preceptor.

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

## Academic Work:

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective subjects.

**Internal Assessment Marks:**

**Theory:** Three sessional examinations evenly spread during the academic year shall be conducted by the constituent colleges. The average marks of the best two examinations shall be computed out of a maximum of 30 marks and shall constitute the sessional award in theory. Provided further the college 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.

**Practical:** Students are expected to perform the experiment 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 marks. In addition, three practical examinations evenly spread during each academic year shall be conducted. The average marks of the best of 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 for 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 award 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. Marks shall be awarded as per the schemes given in Tables 3 & 4 below:

**University Examinations**

1. Every year there shall be an examination to examine the students.
2. Each examination will 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 3 and 4.

**Table-3 First Year Pharm. D (PB) Examination**

| Sr. No. | Name of Subject | Maximum marks for Theory | | | Maximum marks for Practical | | |
|---|---|---|---|---|---|---|---|
| | | University | Sessional | Total | University | Sessional | Total |
| 4.1 | Pharmacotherapeutics-III | 70 | 30 | 100 | 70 | 30 | 100 |
| 4.2 | Hospital Pharmacy | 70 | 30 | 100 | 70 | 30 | 100 |
| 4.3 | Clinical Pharmacy | 70 | 30 | 100 | 70 | 30 | 100 |
| 4.4 | Biostatistics & Research Methodology | 70 | 30 | 100 | - | - | - |
| 4.5 | Biopharmaceutics & Pharmacokinetics | 70 | 30 | 100 | 70 | 30 | 100 |
| 4.6 | Clinical Toxicology | 70 | 30 | 100 | - | - | - |
| 4.7 | Pharmacotherapeutics-I & II | 70 | 30 | 100 | 70 | 30 | 100 |
| | | | | 700 | | | 500 = 1200 |

**Table-4 Second Year Pharm. D (PB) Examination**

| Sr. No. | Name of Subject | Maximum marks for Theory | | | Maximum marks for Practical | | |
|---|---|---|---|---|---|---|---|
| | | University | Sessional | Total | University | Sessional | Total |
| 5.1 | Clinical Research | 70 | 30 | 100 | - | - | - |
| 5.2 | Pharmacoepidemiology and Pharmacoeconomics | 70 | 30 | 100 | - | - | - |
| 5.3 | Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring | 70 | 30 | 100 | - | - | - |
| 5.4 | Clerkship* | - | - | - | 70 | 30 | 100 |
| 5.5 | Project work (Six Months) | - | - | - | 100** | - | 100 |
| | | | | 300 | | | 200 = 500 |

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

***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.

**30 marks: Viva-voce (Oral) + 70 marks: Thesis work = 100 marks Project work

## Criteria for pass

a) Candidates who have secured a minimum of 50% marks in the Theory (including Sessionals) and Practical (including Sessionals) separately in any subject or subjects shall be declared to have passed in that subject/s and exempted from appearing in that subject/s at subsequent examination.

b) **If a student fails in theory or practical** examination of a subject shall **reappear both in theory and practical of the same subject**.

c) Those candidates who fail in one or more subjects shall have to appear only in the subject so failed, in the subsequent examinations.

**Conditions under which candidates are permitted to proceed to next higher class**:

| Class | Condition for promotion and term grant |
|---|---|
| First Year Pharm. D (PB) | Minimum 80% attendance in lectures and practicals |
| Second Year Pharm. D (PB) | **Condition1:** Minimum 80% attendance in lectures and practicals<br>**Condition 2: Fulfillment of any one of the criteria mentioned below**<br>**Criteria no.1. :** Pass in all subjects of First Year Pharm. D (PB)<br>**Criteria no.2. :** Fail in not more than two subjects of Pharm. D (PB) First year.<br>**NOTE:** The student will get one chance of reaching to this criteria by allowing him to attempt in supplementary examination to be taken within 6 months of main examination. During this period the student will be allowed to sit in 2nd year Pharm. D (PB) class but if he fails in more than two subjects he will be considered as detained and will have to rejoin second year only after he reaches at least to above mentioned criteria no.2. |
| Third Year Pharm. D (PB) | **Condition1:** Minimum 80% attendance in lectures and practicals AND<br>**Condition 2: Pass in all subjects of all two years of Pharm. D (PB)**<br>**Since the entire year is Internship, the time from which he fulfills above conditions, the one-year internship will be initiated.** |

**Pharm. D (Post Baccalaureate)**

Candidates of Pharm. D (Post Baccalaureate) admitted as lateral entry to first year Pharm. D Course are permitted to carry not more than any two subjects to second year Pharm. D and appear for second year Pharm. D examination. However, these candidates must pass all the subjects of first & second year Pharm. D to become eligible to third Pharm. D to undergo internship.

**Declaration of Class: Pharm. D (Post Baccalaureate)**

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. (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. The class will be awarded to the student every year based on the above criteria. If he/she passes all the subjects of a particular year in parts he will be awarded only pass class irrespective of what aggregate marks he/she achieves. The class obtained as above in the Second year will be considered for the purpose of final award of class to the student.

**Internship:**

Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and healthcare and acquires skills under the supervision so that he or she may become capable of functioning independently. Every student has to undergo one-year internship as per Pharmacy Council of India regulations.

**Practical training:**

**1. Hospital Posting**: Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in first year of Pharm. D (Post Baccalaureate). Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the second year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

**2. 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 second year of Pharm. D (Post Baccalaureate). 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 are -

I. To 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. To 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 authorized teacher;

(i) Project topic shall be approved by the Head of the Department or Head of the Institution;

(ii) 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/Pharmacoeconomics;

(ii) Project work shall be approved by the institutional ethics committee;

(iii) Student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

(iv) 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 authorized 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 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:

| | |
|---|---|
| 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:

| | |
|---|---|
| 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.

**Award of Ranks:**

- Ranks and Medals shall be awarded on the basis of aggregate of two university examinations of Pharm. D (Post Baccalaureate). However, candidates who fail in one or more subjects during the Pharm. D (Post Baccalaureate) course shall not be eligible for award of ranks.
- Moreover, the candidates should have completed the Pharm. D (Post Baccalaureate) course in minimum prescribed number of years, (two years for Pharm. D (Post Baccalaureate))for the award of Ranks.

**Award of degree:**

Candidates who fulfill the requirements mentioned above will be eligible for award of degree during the ensuing convocation.

**Duration for completion of the course of study:**

The duration for the completion of the course shall be fixed as double the actual duration of the course and the students have to pass within the said period, otherwise they have to get fresh Registration.

**Re-evaluation *I* Re-totaling of answer papers:**

There is no provision for revaluation of the answer papers of failed candidates in any examination. However, the failed candidates can apply for re-totaling.

**Re-admission after break of study**

Candidate who seeks re-admission to the course after break of study has to get the approval from the university by paying a condonation fee. No condonation is allowed for the candidate who has more than two years of break up period and he/she have to rejoin the course by paying the required fees

# 4.1 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 individualized 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 individualized therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

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

   **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.

# 4.1 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**

**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.

**Haematological system**: Anaemias, Venous thromboembolism, Drug induced blood disorders.

**Nervous system**: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,

**Psychiatry disorders**: Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders

Pain management including Pain pathways, neuralgias, headaches.

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** | **03 hrs** | **04 hrs** |

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

# 4.2 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)**
   g. Hospital pharmacy by William .E. Hassan
   h. A text book of Hospital Pharmacy by 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 Organization and functions**

   2 Hospital pharmacy-Organization 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**

## 4.2 HOSPITAL PHARMACY (PRACTICAL)

**Practical : 3 Hrs./Week**

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

**List of Assignments:**

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospitals
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 are 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

# 4.3 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 et. al., Orient Orient Langram Pvt. Ltd. ISBN-8125026

**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 utilization 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

## 4.3 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.

## 4.4 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, pie charts, 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, 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.

**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.

# 4.5 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

## 4.5 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, t1/2, 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. i.e., 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. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction $4^{th}$ 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.

# 4.6 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

# 4.7 PHARMACOTHERAPEUTICS I & II (THEORY)

**Theory: 3Hrs/week**

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

| | | |
|---|---|---|
| 1. | **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias | **Total = 13 hrs (3+2+2+2+2+2)** |
| 2. | **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases | **Total = 6 (1+2+2+1)** |
| 3. | **Endocrine system :** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis | **Total = 8 (3+2+1+1+1)** |
| 4. | **General prescribing guidelines for**<br>a. Paediatric patients<br>b. Geriatric patients<br>c. Pregnancy and breast feeding | **Total = 4hrs (1+1+2)** |
| 5. | **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial | **(3 hrs)** |
| 6. | **Introduction to rational drug use** Definition, Role of pharmacist Essential drug concept Rational drug formulations | **Total = 2 hrs (1+1)** |
| 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, Gonarrhoea and Syphillis | **Total = 18 hrs. (2+1+1+2+1+1+1+2 +1+2+1+1+1+1)** |
| 8. | **Musculoskeletal disorders**<br>Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus. | **Total = 6hrs. (2+1+1+!+1)** |
| 9. | **Renal system**<br>Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders | **Total = 05hrs. (2+1+1+1)** |
| 10. | **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis | **Total = 06 hrs. (2+1+2+1)** |
| 11. | **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo | **Total = 4hrs.** |

## 4.7 PHARMACOTHERAPEUTICS – I & II (PRACTICAL)

**Practicals: 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 are 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

# 5.1 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 organization (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 Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized 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.

# 5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

**Theory : 3 Hrs. /Week**

1. **Pharmacoepidemiology : Definition and scope:**
   Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

   **Measurement of outcomes in pharmacoepidemiology**
   Outcome measure and drug use measures
   Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

   **Concept of risk in pharmacoepidemiology**
   Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

   **Pharmacoepidemiological methods**
   Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods
   Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

   **Sources of data for pharmacoepidemiological studies**
   Ad Hoc data sources and automated data systems.

   **Selected special applications of pharmacoepidemiology**
   Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. **Pharmacoeconomics:**

   **Definition, history, needs of pharmacoeconomic evaluations**

   Role in formulary management decisions

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

3. **Applications of Pharmacoeconomics**

   Software and case studies

# 5.3 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

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# APPENDIX-C
## (See regulation 16)
## 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 practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

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

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The 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.

# KADI SARVA VISHWAVIDYALAYA

**YEAR END EXAMINATION (APRIL -2016)**

**PHARM D. (REGULAR & PB)**

**$4^{TH}$ /$1^{ST}$ YEAR**

**(Sub. Code) SUBJECT NAME**

**DATE:** **TIME: 3 HRS** **MARKS: 70**

NOTE: 1) Attempt any four questions from each section.

2) Question 1 and 6 (of 5 marks each) are compulsory.

**SECTION-I** **[35]**

**Q.1**

Q.2

Q.3

Q.4

Q.5

**SECTION-II** **[35]**

**Q.6**

Q.7

Q.8

Q.9

Q.10