Regulation

Bachelor of Pharmacy (Practice)

Affiliated to

Assam Science and Technology University

Tetelia Road, Near Assam Engineering College,
Jalukbari, Guwahati, Assam 781013

Girijananda Chowdhury Institute of Pharmaceutical Science
Hatkhowapara, Azara, Guwahati-17, Assam, India

Approved by Pharmacy Council of India (PCI) and
All India Council for Technical Education (AICTE)

PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 18th December, 2014

Bachelor of Pharmacy (Practice) Regulations, 2014

No. 14-117/ 2014- PCI.—In exercise of the powers conferred by Section 10 and 18 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 **Bachelor of Pharmacy (Practice) Regulations, 2014**

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

2. **Bachelor of Pharmacy (Practice)** [B.Pharm. (Practice)] shall consist of a degree certificate of having completed the course of study and passed examination as prescribed in these regulations for the purpose of additional qualification to be entered in the register of pharmacists.

CHAPTER-II

3. Duration of the course. –

The duration of the course shall be of two academic years with each year spread over a period of not less than 180 working days

4. Minimum qualification for admission to the course –

i. A pass in Diploma course in Pharmacy from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act, 1948.
ii. A registered pharmacist.
iii. A minimum of four years of pharmacy practice experience in a community or hospital pharmacy –

   a. A certificate from competent authority stating that the candidate is endorsed as registered pharmacist in the drug license of a pharmacy as proof of practice experience in case of community pharmacist
   b. A certificate from the Principal/Medical Superintendent/competent person of the Hospital/Health Unit stating that the candidate is working as a pharmacist will be accepted as proof of practice experience in case of hospital pharmacist

iv. A 'No Objection Certificate' from the employer in prescribed format (Annexure -A)

Provided that there shall be reservation of seats for the students belonging to the scheduled castes, scheduled tribes and other backward classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration, as the case may be, from time to time.

5. The number of admissions in the programme shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted to 40 students in an academic year

6. Approval of the authority conducting the course of study –

a. No pharmacy institution shall start Bachelor of Pharmacy (Practice) programme or increase the number of admission without obtaining the prior approval of the Pharmacy Council of India.
b. Any pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act shall submit a scheme as prescribed in Appendix-I by the Pharmacy Council of India.
c. The scheme referred to in sub-regulation (b) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed.
d. The institutions approved by the Pharmacy Council of India for running Bachelor of Pharmacy course under section 12 of the Pharmacy Act, 1948 alone shall be eligible for starting Bachelor of Pharmacy (Practice) degree course.

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

7. Course of study. –The course of study shall consist of the subjects as given in the Tables below. The course shall consist of class room teaching and assignment works. The assignment works shall be done at the place of work under the supervision and guidance of teaching staff of the academic institution. The number of contact hours in a week devoted to each subject for class room teaching shall not be less than that noted against it in columns (3) below.

TABLE - I

First Year :

S.No.	Name of Subject	Minimum No. of total contact hours	No. of contact hours /week
(1)	(2)	(3)	(4)
1.1	Pathophysiology and Pharmacotherapeutics I	40	1
1.2	Pathophysiology and Pharmacotherapeutics II	40	1
1.3	Pharmacy Practice I	40	1
1.4	Pharmacy Practice II	40	1
1.5	Applied Pharmaceutics	40	1
1.6	Social Pharmacy I	40	1
1.7	Case presentation,Seminar, Assignments	160	4
	Total	400	10

Second Year :

S.No.	Name of Subject	Minimum No. of total contact hours	No. of contact hours /week
(1)	(2)	(3)	(4)
2.1	Pathophysiology and Pharmacotherapeutics III	40	1
2.2	Pathophysiology and Pharmacotherapeutics IV	40	1
2.3	Pharmacy Practice III	40	1
2.4	Pharmacy Practice IV	40	1
2.5	Social Pharmacy II	40	1
2.6	Pharmaceutical Jurisprudence	40	1
2.7	Case presentation, Seminar, Assignments	160	4
	Total	400	10

8. Syllabus. – The detailed syllabus for each subject of study in the said Tables shall be as specified in the guidelines given in Appendix-III. The guidelines may, with the approval of Central Council of the Pharmacy Council of India, be amended and notified from time to time.

9. Examination. –

1. There shall be an examination at the end of calendar year. The first examination shall be the annual examination and the second examination shall be supplementary examination.
2. The examinations shall be of written nature for theory and for the practicals: The students shall submit the assignments done by them in the form of a report which will be followed by viva-voce carrying maximum marks for each part of a subject as indicated in Tables below :

T A B L E -II

1st Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Assignments (including Viva voce 25%)
		University Examination	**Sessional marks**	**Total**	
1.1	Pathophysiology and Pharmacotherapeutics I	60	40	100	100
1.2	Pathophysiology and Pharmacotherapeutics II	60	40	100	100
1.3	Pharmacy Practice I	60	40	100	100
1.4	Pharmacy Practice II	60	40	100	100
1.5	Applied Pharmaceutics	60	40	100	100
1.6	Social Pharmacy I	60	40	100	100
	Total			600	600

2nd Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Assignments (including Viva Voce-25%)
		University Examination	**Sessional marks**	**Total**	
1.1	Pathophysiology and Pharmacotherapeutics III	60	40	100	100
1.2	Pathophysiology and Pharmacotherapeutics IV	60	40	100	100
1.3	Pharmacy Practice III	60	40	100	100
1.4	Pharmacy Practice IV	60	40	100	100
1.5	Social Pharmacy - II	60	40	100	100
1.6	Pharmaceutical Jurisprudence	60	40	100	100
	Total			600	600

10. Eligibility for appearing at the examination.— A student who produces a certificate from the Head of the Institution in which he has undergone the course in proof of his having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held in theory and has submitted the assignments/ project report duly approved by the supervising teacher shall be eligible for appearing at the examination.

11. Mode of examinations.—

(1) Theory examination shall be of three hours duration.

(2) A student who fails in theory examination of a subject shall be permitted to re-appear in that subject

(3) Assignment work shall consist of evaluation of report by both internal & external examiners with a seminar and viva –voce (Oral) examination.

12. Award of sessional marks and maintenance of records.—

(1) A regular record of theory examinations conducted in an institution imparting the Bachelor of Pharmacy (Practice) Course, shall be maintained for each student in the institution and 40 marks for each subject shall be allotted as internal assessment.

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

13. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in assignment work. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the examination shall be declared to have passed in first class. A student 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 passes in all the subjects in a single attempt.

14. Eligibility for promotion to next Class.—

1. All students who have appeared for all the subjects and passed the examination are eligible for promotion to the next year.
2. The student failing in subjects of 1st year B.Pharm. (Practice) examination shall be permitted to proceed to the 2nd year of B.Pharm. (Practice). However, such students shall have to pass all the subjects of the 1st and 2nd year of B.Pharm. (Practice) course and shall complete the course within 4 academic years from the session in which he was admitted in the course, for the consideration of B.Pharm. (Practice) degree.

15. Approval of examinations.— Examinations mentioned in regulations 9 to12 and 14 shall be held by the examining authority approved by the Pharmacy Council of India under sub-section (2) of Section 12 of the Pharmacy Act, 1948.

16. Certificate of passing examination.— every student who has passed the examinations for the Bachelor of Pharmacy (Practice) shall be granted a degree certificate by the examining authority.

CHAPTER-III

17. Assignment work.—

1. To allow the student to understand and develop data collection and reporting skills in the area of community, hospital and clinical pharmacy in particular and principles of pharmacy practice in general, the assignment work shall be carried out under the supervision of a teacher of the Academic Institution on the topic approved by the Head of the Academic Institution. The same shall be announced to students within one month of commencement of the classes in each of the subjects for the session. Assignment shall be presented in a written report and as a seminar before the final examination. External and the internal examiners appointed by the examining authority for the said purpose shall do the assessment of the work done.
2. Assignment work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

18. Objectives of Assignment work.— The main objectives of the work is to—

(i) show the evidence of having made accurate description of work and of having recorded the findings in an impartial manner; and

(ii) develop the students skills in data collection, analysis and reporting and interpretation skills.

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

(i) Not more than ten students shall work under an authorized teacher;

(ii) The topic shall be approved by the Head of the Department or Head of the Institution;

(iii) The work chosen shall be related to the subjects taught in a particular session and due consideration has to be given regarding the suitability for carrying out the work in his workplace.

20. Reporting .— (1) Student working on the assignment shall submit the report after completion of work to the Head of the Department or Head of the Institution. The report should include a certificate issued by the authorized teacher.

(2) Submission of the report shall be done at least one month prior to the commencement of annual examination.

21. Evaluation.— The following methodology shall be adopted for evaluating assignment work—

Evaluation shall be done on the following items:	**Marks**
a) Write up of the assignment	(40)
b) Presentation of work	(15)
c) Seminar	(20)
d) Question and answer skills (viva voce)	(25)
Total	(100 marks)

CHAPTER-IV

22. The fees for the course shall be prescribed by Pharmacy Council of India from time to time for guidance to the State Government/Course Conducting Authorities.

Annexure-A

{See regulation 4(iv)}

Format for 'No Objection Certificate' from the Employer

This to certify that ---------- son/daughter of---------- is working in this Institution/Pharmacy- as-------- since ---------- and the undersigned has no objection if he gets himself admitted in the Bachelor in Pharmacy (Practice) Course for the session----------.
He will be allowed to attend the course and facilities will be provided for carrying out the assignments as part of course in this Institution/Organization.

Signature and seal of the authorized person.

Guidelines for conducting Bachelor of Pharmacy (Practice) course

APPENDIX-I
{See Regulation 6(b) }

SCHEME FOR OBTAINING PRIOR PERMISSION OF PHRMACY COUNCIL OF INDIA FOR CONDUCTING THE BACHELOR OF PHARMACY (PRACTICE) COURSE.

1. Name of the Course Conducting Authority:

2. Complete Postal Address of the Course Conducting Authority:

3. Year of establishment of the Institute:

4. Approval status of the Institute for conducting Bachelor of Pharmacy (B.Pharm) Course:
(Copy of the latest approval to be enclosed)

5. No objection/consent of affiliation from Examining Authority (i.e, University) for starting the course:
(Copy of the letter to be enclosed)

6. Deficiencies as pointed out in the latest Inspection Report:
(Use separate sheet)

7. Proposed date of commencement of the course:

8. Proposed intake capacity:

9. Proposed Time schedule for conducting the course:

10. Details of teaching staff in the specified subject in the following format:

Name of the Department	Sl. No.	Name of the Teachers	Working experience in the Institution	Qualification	Experience	Existing Teaching Load	Any Experience in Hospital/Community/Clinical Research/Practice
1	2	3	4	5	6	7	8
Pharmaceutics							
Pharmacology							
Pharmacy Practice							

11. Declaration of the teachers for teaching the additional Course:
(Declarations from teachers to be enclosed)

12. Whether visiting/part-time teachers to be appointed:
(If yes, furnish the details in the following proforma)

Sl.No.	Name of the Teacher	Qualification	Practice Experience	Present attachment

13. Enclose the acceptance from the visiting teachers as identified:

14. Whether the Institute/Trust is running a Model Community Pharmacy :

15. If not, is there any planning to start the same in near future:

Signature of the Principal with date

APPENDIX-II
{See proviso to regulation 6(d) }

MINIMUM REQUIREMENT FOR OBTAINING
THE APPROVAL OF PHRMACY COUNCIL OF INDIA
FOR CONDUCTING THE BACHELOR OF PHARMACY (PRACTICE) COURSE

PART I - PRINCIPAL

Qualification/ Experience		**Qualification**	**Teaching Experience Required**
		M. Pharm	15 years, out of which 5 years as Prof. / HOD
		Ph.D	10 years, out of which at least 05 years as Asst. Prof

PART II PHYSICAL INFRASTRUCTURE

1. Availability of Land (details)

a. Building : **Own/rented**

b. Total built up area of the college building in Sq.mts : Built up Area
c. Amenities and Circulation Area

2. Class rooms:

Total number of class rooms provided for D. Pharm and B. Pharm/Bachelor of Pharmacy (Practice) course

Class	Required	Available numbers	Required Area * for each Class Room
D. Pharm	02		90 Sq. mts each
B. Pharm	04		90 Sq. mts each (Desirable) 75 Sq. mts each (Essential)
Bachelor of Pharmacy (Practice)	01		40 Sq. mts each

(* To accommodate 60 students)

3. Laboratory requirement for both D. Pharm and B. Pharm and Bachelor of Pharmacy (Practice) course.

Sl. No.	**Infrastructure for**	**Requirement as per Norms**	**Available No. & Area in Sq. mts.**	**Remarks/ Deficiency**
1	Laboratory Area for B. Pharm Course (10 Labs) Laboratory area for D. Pharm Course (03 Labs)	90 Sq .mts x n (n=10) - Including Preparation room - Desirable 75 Sq. mts - Essential		
2	Pharmaceutics Pharmaceutical Chemistry Pharmaceutical Analysis Pharmacology Pharmacognosy	03 Laboratories 03 Laboratories 01 Laboratory 03 Laboratories 02 Laboratories		

	Pharmaceutical Biotechnology (Including Aseptic Room) Total No. Laboratories for B.Pharm and D.Pharm Course	01 Laboratory 13 Laboratories *		
3	Preparation Room for each lab (One room can be shared by two labs, if it is in between two labs)	10 sq mts (Minimum)		
4	Area of the Machine Room	80-100 Sq.mts		
5	Central Instrument Room	80 Sq.mts with A/ C		
6	Store Room – I	1 (Area 100 Sq mts)		
7	Store Room – II (For Inflammable chemicals)	1 (Area 20 Sq mts)		

*For D. Pharm and B. Pharm both.

1. All the Laboratories should be well lit & ventilated.
2. All Laboratories should be provided with basic amenities and services like exhaust fans and fuming chamber to reduce the pollution wherever necessary.
3. The workbenches should be smooth and easily cleanable preferably made of non-absorbent material.
4. The water taps should be non-leaking and directly installed on sinks. Drainage should be efficient.
5. Balance room should be attached to the concerned laboratories.

4. Administration Area:

Sl.No.	Name of infrastructure	Requirement as per Norms in number	Requirement as per Norms, in area
1	Principal's Chamber	01	30 Sq .mts
2	Office – I – Establishment	01	60 Sq. mts
3	Office – II – Academics		
4	Confidential Room		

5. Staff Facilities:

Sl. No.	Name of infrastructure	Requirement as per Norms in number	Requirement as per Norms in area
1	HODs rooms for B.Pharm Course	Minimum 4	20 Sq mts x 4
2	Faculty Rooms for D.Pharm & B.Pharm course		10 Sq mts × n (n=No. of teachers)
3	Faculty Rooms for Bachelor of Pharmacy (Practice) course		10 Sq mts × n (n=No. of teachers)

6. Museum, Library, Animal House and other Facilities:

Sl No.	Name of infrastructure	Requirement as per Norms in number	Requirement as per Norms in area
1	Animal experimentation learning modules	01	-
2	Library	01	150 Sq. mts

3	Museum	01	50 Sq. mts (May be attached to the Pharmacognosy lab)
4	**Model Pharmacy** **<u>Essential</u>:** **Running Model Community Pharmacy** **<u>Desirable</u>** Drug Model Store	**01**	**80 Sq.mts (including 10 Sq.mt for Drug Information Centre & 10 Sq.mt. for Patient Counselling)**
5	Auditorium / Multi Purpose Hall (Desirable)	01	250 – 300 seating capacity
6	Herbal Garden (Desirable)	01	Adequate number of medicinal plants

7. Student Facilities:

Sl. No.	Name of infrastructure	Requirement as per Norms in number	Requirement as per Norms in area
1	Girl's Common Room (Essential)	01	60 Sqmts
2	Boy's Common Room (Essential)	01	60 Sq.mts
3	Toilet Blocks for Boys	01	24 Sq.mts
4	Toilet Blocks for Girls	01	24 Sq.mts
5	Drinking Water facility – Water cooler (Essential).	01	-
6	Boy's Hostel (Desirable)	01	9 Sq mts/ Room Single occupancy
7	Girl's Hostel (Desirable)	01	9 Sq mts / Room (single occupancy) 20 Sq mts / Room (triple occupancy)
8	Power Backup Provision (Desirable)	01	

8. Computer and other Facilities:

Name	Required
Computer Room for B.Pharm Course	01 system for every 2 students (with internet and Printer facilities) (Area 75 Sq mts)
Computer For Model Pharmacy	As required for teaching and practice purposes and for drug information services
Computer (Latest configuration)	1 system for every 10 students (UG & PG)
Printers	1 printer for every 10 computers
Multi Media Projector	01
Generator (5KVA)	01

9. Library books and periodicals

The minimum norms for the initial stock of books, yearly addition of the books and the number of journals to be subscribed are as given below:

Item	Titles (No)	Minimum Volumes (No)
Number of books	150	1500 adequate coverage of a large number of standard text books and titles in all disciplines of pharmacy
Annual addition of books		150 books per year
Periodicals Hard copies / online		10 National 05 International periodicals
CDS		Adequate Nos
Internet Browsing Facility		Yes/No (Minimum ten Computers)
Reprographic Facilities: Photo Copier Fax Scanner		 01 01 01

10. A. Subject wise Classification:

Sl. No	Subject		
		Titles	Numbers
1	Pharmaceutics		
2	Pharmaceutical Chemistry		
3	Pharmacognosy		
4	Biochemistry and Clinical Pathology		
5	Human Anatomy and Physiology		
6	Health Education and Community Pharmacy		
7	Pharmacy Practice		
8	Pharmacology and Toxicology		
9	Pharmaceutical Jurisprudence		
10	Drug Store and Business Management		
11	Hospital and Clinical Pharmacy		
12	Social Pharmacy		

10. B. Library Staff:

	Staff	Qualification	Required
1	Librarian	M. Lib	1
2	Assistant Librarian	D. Lib	1
3	Library Attenders	10 +2 / PUC	2

PART III ACADEMIC REQUIREMENTS

A. Faculty requirements:

1. Student Staff Ratio:

(Required ratio --- Theory → 40:1 and Assignment → 10:1.

2. Minimum No. of working days for B. PHARM PRACICE: 180

3. Staff Pattern for B. Pharm & B.Phram (Practice) courses department wise:

Professor : Asst. Professor : Lecturer

Department / Division	Name of the post	For strength of 60 students of B.Pharm & 40 students of B.Pharm (Practice)
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	4
Department of Pharmaceutical Chemistry (including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	4
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	5
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacy Practice	Professor	1
	Asst.professor	2
	lecturer	2

4. Teaching Staff required year wise exclusively for B. Pharm (Practice) for intake of 40 Students.

	Staff required for I B. Pharm Practice	Staff required for II B. Pharm Practice
Principal	1	1
Pharmacology	1	1
Pharmaceutics	1	1
Pharmacy Practice	2	2
Part time teaching Staff For pathophysiology and pharmacotherapeutics	As required	As required

At least 2 teachers shall possess M.Pharm (Pharmacy Practice) or Pharm D. Qualification.

5. Number of non-teaching staff available for D. Pharm and B. Pharm course for intake of 60 students:

Sl. No.	Designation	Required Number	Required Qualification	Available		Remarks of the Inspection team
				Number	Qualification	
1	Laboratory Technician	1 for each Dept	D. Pharm			
2	Labortory Assistants/ Attenders	1 for each Lab (minimum)	SSLC			
3	Office Superintendent	1	Degree			
4	Accountant	1	Degree			
5	Store keeper	1	D. Pharm/ Degree			

6	Computer Data Operator	1	BCA / Graduate with Computer Course			
7	First Division Assistant	1	Degree			
8	Second Division Assistant	2	Degree			
9	Peon	2	SSLC			
10	Cleaning personnel	Adequate	---			
11	Gardener	Adequate	---			

B. DOCUMENTATION

Records to be maintained: Essential

Sl. No	Records
1	Admissions Registers
2.	Individual Service Register
3.	Staff Attendance Registers
4.	Sessional Marks Register
5.	Final Marks Register
6.	Student Attendance Registers
7.	Minutes of meetings- Teaching Staff
8.	Fee paid Registers
9.	Acquittance Registers
10.	Accession Register for books and Journals in Library
11.	Log book for chemicals and Equipment costing more than Rupees one lakh
12.	Job Cards for laboratories
13.	Standard Operating Procedures (SOP's) for Equipment
14.	Laboratory Manuals
15.	Stock Register for Equipment
16.	Animal House Records as per CPCSEA
17.	**Record of submission of Assignments by students**
18.	**Record of Case presentation/Seminars conducted**

PART IV – EQUIPMENT AND APPARATUS

The institution shall comply fully by having all equipments as prescribed in SIF for approval of B. Pharm course u/s 12 of the Pharmacy Act.

APPENDIX-III

(See regulation 8)

Course curriculum

1.1. Pathophysiology and Pharmacotherapeutics I

Scope:

Practicing pharmacists will have opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:

Upon completion of the course, the student will be able to

(a) Understand the anatomy and physiology of the respective system

(b) Understand the disease process
(c) Know the signs and symptoms of the disease.
(d) Appreciate the various therapeutic regimens with their advantages and disadvantages.

Course duration:

Learning

40 hours of learning by blended mode of teaching. Blended teaching includes didactic and onsite learning.

Case Presentations

During the course each student should present **5 cases** covering the diseases prescribed in the syllabus.

Assignments
Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Schedules

1. **Introduction to pathophysiology and therapeutics – scope and objectives - 1 hr**

2. **Prescribing guidelines (Drug and dosage selection and dose calculation) for - 4 hrs**
   a) Pediatrics
   b) Geriatrics
   c) Pregnant and breast feeding women
   d) Renally and hepatically challenged patients

3. **Elements of anatomy, etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Cardiovascular System - 15 hrs**
   (a) Hypertension
   (b) Ischemic Heart diseases (Angina and Myocardial Infarction)
   (c) Hyperlipidemia
   (d) Congestive Heart Failure
   (e) Arrhythmias

4. **Elements of anatomy, Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Respiratory System - 12 hrs**

   (a) Asthma
   (b) COPD
   (c) Drug induced pulmonary diseases

5. **Elements of anatomy Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Endocrine System - 8 hrs**

   (a) Diabetes.
   (b) Thyroid diseases

Books/Refernences:
Suggested Assignments:

1.2. Pathophysiology and Pharmacotherapeutics II

Scope:

Practicing pharmacists will have the opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:

Upon completion of the course, the student will be able to

(a) Understand the anatomy and physiology of respective system
(b) Understand the disease process
(c) Know the signs and symptoms of the disease.
(d) Appreciate the various therapeutic regimens with their advantages and disadvantages.

Course duration:

Learning

40 hours of learning by blending method.
Blended mode of education and includes didactic and onsite learning.

Case Presentations

During the course each student should present **5 cases** covering the diseases prescribed in the syllabus.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Schedules

1. Elements of anatomy, Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with -CNS - 18 hr

(a) Anxiety
(b) Depression
(c) Schizophrenia,
(d) Manic depressive disorders
(e) Epilepsy,
(f) Parkinson's disease,
(g) Headaches

2. Elements of anatomy, Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with GI Disorders - 10 hrs

(a) Dyspepsia,
(b) Acid Pepsin Disease,
(c) Inflammatory Bowel Disease.
(d) Liver disorders- Hepatitis, Gall stones, Alcoholic Liver Disease.

3. Elements of anatomy, etiopathogenesis, clinical manifestations and pharmacotherapeutics of diseases associated with hematological System - 8 hrs

(a) Erythropoietic system – Over view, Iron deficiency anemia, Megaloblastic anemia, Sideroblastic anemia, Hemolytic anemia, Venous Thromboembolism, Arterial Thromboembolism, Drug induced blood disorders.

Books and references

Suggested topics for assignment

1.3. Pharmacy Practice I

Scope

Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in community settings through counselling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and provide all hospital pharmacy services including clinical pharmacy services such as drug information and ADR reporting.

Objectives:

Upon completion of the course, the student will be able to

(a) Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
(b) Understand the professional responsibilities of the pharmacists.
(c) Provide the intended services.

Course duration:

Learning

40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Schedules

1. Introduction to Pharmacy Practice – Definition, patient focused approach, scope/areas of practice - **1 hour**

2. Introduction to Clinical Pharmacy - **3Hrs**

a) Definition, Scope, Objectives of Clinical Pharmacy Practice

b) International v/s National scenario

c) Professional responsibilities of Clinical Pharmacists.

3. Clinical Pharmacy daily activities - **6 hrs**

a) Definition, objectives and procedures of

i) Ward round participation

ii) Treatment chart review

iii) Drug information

iv) Patient counseling

v) ADR monitoring and reporting

vi) Therapeutic drug monitoring.

vii) Home Medication Review

b) **Patient Data analysis** - **02 hours**

Patient case history, drug therapy evaluation, identification and resolving of drug related problems.

4. Practice Management : - **08 hrs**

a. Professional practice standards - Good Pharmacy Practice – in detail including Good storage practice, good dispensing practices, etc. (national and international scenario) (for both community and hospital pharmacy)
b. Pharmacy Practice Regulations (PCI), Code of Ethics for Pharmacists
c. SOPs, writing SOPs, Documentation, writing various record formats for community and hospital pharmacy, validation of various processes in Hospital & Community Pharmacy.
d. Concept of Accreditation of Pharmacies
e. Validation concepts & instruments for community pharmacy and hospital pharmacy
f. Concept of Audits in community and hospital pharmacy

5. Hospital and Hospital Pharmacy Organisation - **6 Hrs**

a) Definition of Hospital, Hospital Pharmacy, Organizational Structure of Hospital, Hospital Pharmacy, professional roles and responsibilities of hospital pharmacist.

b) Advantages, need and disadvantages/risks of Hospitalization. Nosocomial infections/HAI – worldwide scenario, statistics/prevalence, dangers, precautions to take. Problems related to hospitals, high risk environment.

c) International scenario vs Indian Scenario of Hospital Pharmacy Practice.

d) Hospital Pharmacy Practice - Requirements for functioning of hospital pharmacy, Qualification and experience requirements for pharmacists, work load statistics.

e) Standards of Pharmacies in hospitals

6. Drug Committees - **4 Hrs**

Pharmacy and Therapeutics Committee, Hospital Formulary, Infection Control committee, Institutional Review Board.

7. Community Pharmacy - **8 hrs**

a) Definition, scope and professional responsibilities of community pharmacist.

b) International scenario vs Indian Scenario of Community Pharmacy Practice

c) Pharmacy Assistant/Technician/Salesperson – roles and responsibilities,

d) Community pharmacist's services to other health care professionals, and to nursing homes

8. Community Pharmacy Management - **4 hrs**

Selection of site, legal requirements, procurement, storage, and inventory control, product display, finance management.

Books and references
Suggested assignment topics

1.4. Pharmacy Practice II

Scope

Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in community settings through counseling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and provide all hospital pharmacy services including clinical pharmacy services such as drug information and ADR reporting

Objectives:

Upon completion of the course, the student will be able to

a) Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
b) Understand the professional responsibilities of the pharmacists.
c) Provide the intended services.

Course duration:

Learning

40 hours of learning by blending method.
Blended teaching includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time of Final Examination.

Detailed syllabus and lecture wise teaching schedules

1. **Hospital Pharmacy Stores Management** - **04 hours**

Stores Management, Drug Purchase and Procurement, Inventory Control and GPP. Management of Material and Finance.

2. **Drug Dispensing and Drug Distribution** - **8 hours**

Drug distribution – various methods, individual order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug basket method, Distribution to ICCU/ICU/Emergency wards, Automated drug dispensing systems and devices , Distribution of Narcotic and Psychotropic substances , GPP associated with all these.

3. **Central Sterile Supply Services** - **2 hours**
4. **Prescription and prescription handling** - **5 hours**

a. Definition, Parts of prescriptions, good prescribing practices, legality of prescriptions, identification of drug related problems in prescriptions.
b. Prescription handling, labeling of dispensed medications (Main label, Ancillary label, pictograms), Medication usage instructions.
c. Good dispensing practices
d. Drug Interactions (Drug-Drug, Drug-Food, Drug-Lab investigations) – types, interpretation and detection, prevention, Practice on market prescriptions, Use of drug interaction software's.
e. PPIs – (Patient Package Insert) - Basic concept, Importance and beneficial use of PPIs. Scenario in India and other countries.

5. **Pharmaceutical Care** - **02 hours**

Definition, principles and procedures of pharmaceutical care

6. **Patient Counseling** - **04 hours**

Definition, various stages of patient counseling, barriers in counseling and strategies to overcome barriers in patient counseling. Patient information leaflets- definition, layout and design of PILs.

7. Health Screening Services - 04 hours

Definition, scope, and uses of health screening services, procedures involved in screening blood pressure, capillary blood glucose, body mass index

8. Interpretation of laboratory data - 10 hours

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

books and references

suggested topics for assignments

1.5. Applied Pharmaceutics

Scope

This course is designed to impart a fundamental knowledge on different dosage forms and pharmacokinetic changes in the body. It helps the student to understand the basic concepts regarding, absorption, distribution, metabolism and excretion.

Objectives

Upon completion of the course, the student shall be able to—

a) Understand the formulation principles of various dosage forms
b) Understand the basic principles of stability, storage and administration of various dosage forms
c) Learn above novel drug delivery systems
d) Understand various pharmacokinetic pathways and optimize the drug therapy.
e) Understand Pro Drugs concept.

Course duration:

Learning

40 hours of learning by blended teaching. Blending teaching includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering Pharmaceutical Dosage forms and Pharmacokinetic concepts

Text Books

a. Cooper and Gunns Dispensing for pharmacy students.
b. A text book Professional Pharmacy by N. K. Jain and S. N. Sharma.
c. D.M. Brahmankar and Sunil B Jaiswal. Text Book of Biopharmaceutics and Pharmacokinetics – A treatise. Vallabh Prakashan. Delhi.

Reference Books

a) Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
b) Remington's Pharmaceutical Sciences

Lecture wise program and detailed syllabus

1. Introduction to Pharmaceutical Dosage Forms - **1 hr**
2. Basics of GMP, GLP, QA, QC - **1 hr**

3. Study the following about all dosage forms : - **15 hrs**
    a. Need, advantage, disadvantages
    b. Brief of various ingredients used and need for these, basic properties of inactives. Basic overview of manufacturing without going into details.
    c. Storage, packaging requirements
    d. Possible stability and defects issues
    e. Proper use, special precautions while using, instructions to patients
    f. Bioavailability/biopharmaceutics aspects
4. Introduction to Novel drug delivery systems, instructions to be given to patients – Transdermal, infusion pumps, genetically engineered medicines, etc. - **6 hrs**
5. Introduction to Bio-Pharmaceutics - **1 hr**
6. Absorption of drugs - **3 hrs**
    a) Introduction to absorption, structure and physiology of cell membrane
    b) Factors affecting drug absorption, Absorption of drugs from extra vascular routes.
7. Distribution of Drugs - **2 hrs**
    a) Tissue permeability of drugs, Physiological barriers to drug distribution.
    b) Factors affecting drug distribution.
    c) Volume of drug distribution, Drug protein, drug tissue binding.
8. Biotransformation of drugs - **3 hrs**
    a) Drug metabolizing organs and Enzymes
    b) Phase I reactions, Phase II reactions
    c) Factors affecting biotransformation of the drugs
9. Excretion of drugs - **1 hour**
    Renal excretion of drugs, Factors affecting the renal filtration,
    Non renal routes of drug excretion
10. Prodrugs - **1 hour**
    a) Definition and applications of prodrugs
11. Bioavailability and Bioequivalence - **4 hours**
    a) Definition of bioavailability and bioequivalence
    b) Factors affecting bioavailability.
    c) Importance of BA, BE, BA Classification system, NTI drugs, care to be taken in prescribing and dispensing of such drugs

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination

1.6 Social Pharmacy – I

Scope:

Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in the society. By monitoring the health of the individuals, providing them education about health, precautions, and pharmacists can improve their professional image.

Objectives:

Upon completion of the course, the student will be able to

a) Understand the social responsibility of the pharmacists in the society
b) Understand the health policies
c) Provide health care services to patients.

Course duration:

Learning

40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts

Detailed syllabus and topics

1. **Introduction to Social Pharmacy** –
   a) Definition and Scope - Introduction to Social Pharmacy as a discipline and its various concepts. Sociological Understanding of Health and Illness, Role of Pharmacist in Public Health - **1hr**
   b) WHO Definition of health – various dimensions of health - **1 hr**
   c) Introduction and broad overview of health systems, infrastructure, and functioning in India and other countries – both in Public and private sector. National health programmes in India – brief study of these and the role of pharmacist in each of these. - **5 hrs**

2. **Drugs, Industry & Policies** - **7 hrs**
   a. Drugs and developed countries, developing countries, GATT, patents, Patents Act.
   b. Pharmaceutical Industry and its activities, Classification systems of drugs, Social marketing – brief study of organizations and functioning like Medicines Sans Frontiers
   c. Concept of RUM, WHO Essential Medicines, Irrational medicine use and its associated problems, etc., Evidence based medicine, STGs (Standard Treatment Guidelines)
   d. National Drug Policy, National Health Policy, Pharmacy & Drug Ethics –

3. **Pharmacoeconomics** – Definition, types of pharmacoeconomic models, consumption of drugs, pharmaceutical pricing and reimbursement, Health Insurance - **3 hrs**
4. **Pharmacoepidemiology** – Definition, scope, advantages and disadvantages. - **3 hrs**

5. **Health Promotion and Health education** - **20 hrs**

a) Epidemiology of Communicable Diseases : Causative agents and Clinical presentations and Role of Pharmacist in prevention of communicable diseases :
   (i) Respiratory infections – chickenpox, measles, rubella, mumps, influenza (including Avian-Flu, H1N1), diphtheria, whooping cough, meningococcal meningitis, acute respiratory infections, tuberculosis
   (ii) Intestinal infections – poliomyelitis, viral hepatitis, cholera, acute diarrhoeal diseases, typhoid, food poisoning, amebiasis, worm infestations
   (iii) Arthropod-borne infections - dengue, malaria, filariasis and, chikungunya
   (iv) Zoonoses – rabies, yellow fever, Japanese encephalitis, plague, human salmonellosis, ricketsial diseases, taeniasis, hydatid disease, leishmaniasis
   (v) Surface infections – trachoma, tetanus, leprosy, STDs, HIV/AIDS
   (vi) Emerging and reemerging infectious diseases.

Text books (Theory)

1. *Social Pharmacy – Innovation and development edt. Geoff Harding, Sarah Nettleton and Kevin taylor. The Pharmaceutical Press.*
2. **Text Book of Community Pharmacy Practice. RPSGB Publication**

2nd Year

2.1 Pathophysiology and Pharmacotherapeutics III

Scope:

Practicing pharmacists will have opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:

Upon completion of the course, the student will be able to

(a) Understand the anatomy and physiology of the respective system
(b) Understand the disease process
(c) Know the signs and symptoms of the disease.
(d) Appreciate the various therapeutic regimens with their advantages and disadvantages

Course duration:

Learning

40 hours of learning by blended teaching. Blended teaching includes didactic and onsite learning.

Case Presentations

During the course each student should present **5 cases** covering the diseases prescribed in the syllabus.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and Lecture wise schedules

1. Infectious diseases: - 25 Hours

(a) Guidelines for the rational use of antibiotics and surgical Prophylaxis.

(b) Pathophysiology and Pharmacotherapeutics of Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection-Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis

2 Musculoskeletal disorders - 08 Hrs

(a) Basics of Anatomy and physiology of musculoskeletal system.

(b) Pathophysiology and Pharmacotherapeutics of Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic Lupus Erythematosus

3 Renal system - 07 Hrs

a) Basics of anatomy and physiology of Renal system

b) Pathophysiology and pharmacotherapeutics of Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

Books and references

Suggested topics for assignment.

2.2. Pathophysiology and Pharmacotherapeutics IV :

Scope:

Practicing pharmacists will have opportunity to review the case notes or prescriptions in their practice setting and able to identify and resolve the drug related problems. This will ensure the improved patient care and decreases the unnecessary health care expenditure.

Objectives:

Upon completion of the course, the student will be able to :

a) Understand the anatomy and physiology of the respective system
b) Understand the disease process
c) Know the signs and symptoms of the disease.
d) Appreciate the various therapeutic regimens with their advantages and disadvantages

Course duration:

Learning

40 hours of learning by blended teaching . Blended teaching includes didactic and onsite learning.

Case Presentations

During the course each student should present **5 cases** covering the diseases prescribed in the syllabus.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed Syllabus and Lecture Wise Program

1. Oncology: - **15 Hrs**

Basic principles of Cancer therapy,
General introduction to cancer chemotherapeutic agents,
Chemotherapy of breast cancer, leukemia.
Management of chemotherapy induced nausea and emesis

2. Dermatology: - **7 Hrs**

(a) Pathophysiology and Pharmacotherapeutics of
Psoriasis, Scabies, Eczema, Impetigo

3. Women's Health - **10 Hrs**

(a) Physiology of Menstrual Cycle
(b) Contraception – Physical Methods, Chemical Methods, IUDs, and Permanent methods.
(c) Disorders related to Menstrual Cycle – Polycystic ovary Syndrome, Dysmenorrhea, Premenstrual Syndrome.
(d) Obstetric Drug Therapy – Trimesters of Pregnancy, Common complaints of Pregnancy and their management – nausea, vomiting, reflex esophagitis, Diabetes mellitus, Hypertension and Preeclampsia, FDA Categorisation of drugs in Pregnancy
(e) Menopause – signs and symptoms and Management

4. **Elements of anatomy and Physiology of Vision Etiopathogenesis, diagnostic techniques, clinical manifestations and pharmacotherapeutics of diseases associated with Eye such as**

(a) Glaucoma
(b) Infectious ophthalmic diseases - **3hrs**

Books and references
Suggested topics for assignment

2.3. Pharmacy Practice III

Scope:

Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in community settings through counseling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and providing all hospital pharmacy services including clinical pharmacy services such as drug information and Pharmacovigilance.

Objectives:

Upon completion of the course, the student will be able to

a. Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
b. Understand the professional responsibilities of the pharmacists.
c. Provide the intended services.

Course duration:

Learning

40 hours of learning by blending teaching. Blending teaching includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and Lecture wise program

1. **Drugs and Poison Information** - **06 hrs**
   (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
   (g) Drug Information Bulletin

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2. **Pharmacovigilance** - **05 hrs**
   (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.

3. **Medication Errors -** classification, consequences, prevention, and role of Pharmacist.Dispensing errors, and ways to minimize them. - **03 hrs**

4. Medication adherence - Consequences on non-adherence, role of pharmacist methods to improve adherence, compliance aids - **03 hrs**

5. Communication skills – verbal, written, Body language - **03 hrs**

6. OTC medications – definition, need, and role of Pharmacist. OTC medications in India, counseling for OTC products. Self medication and role of pharmacist in promoting safe self-medication.

- **02 hours**

7. Responding to symptoms/minor ailments - **10 hrs**

Relevant pathophysiology, common non-pharmacological and OTC drug therapy, and referral to doctor – in :Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Worm infestations, Pyrexia, Ophthalmic symptoms, URT infections, skin disorders, oral and dental disorders.

8. Hospital supplies – - **7 hrs**

a. Surgical items/supplies – catheters, syringes & needles, I.v. sets, Ryle's tubes, Study of Wound management, stoma and incontinence products, Surgical dressing like cotton, gauze, bandages and adhesive tapes,

b. sutures, ligatures,

c. patient care equipment – nebulizers, thermometers, .

9. Veterinary Pharmacy – introduction and Role of pharmacist in procurement and distribution of veterinary medicines - **4 hrs**

Books and references

Suggested topics for assignments

2.4. Pharmacy Practice IV

Scope:

Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in community settings through counseling, health screening services, and other education programs. In hospital settings, pharmacists can ensure appropriate dispensing, education to patient, and providing all hospital pharmacy services including clinical pharmacy services such as drug information and Pharmacovigilance.

Objectives:

Upon completion of the course, the student will be able to

a) Understand the professional roles of pharmacists in community, hospital and clinical pharmacy areas.
b) Understand the professional responsibilities of the pharmacists.
c) Provide the intended services.

Course duration:

Learning

40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and lecture wise program

1. **Health Accessories -** - **05 Hrs**

Study and handling of various common health accessories handled in hospital and community pharmacy. Student should have working knowledge, uses and cautions in using these. (Wheel Chairs, Canes, Crutches, and other orthopedic aids, Bed Pans, Vaporizers, Syringes and Needles, Hot water Bottles, Clinical Thermometers, Trusses, First Aid Supplies, Family Medicine Cabinet, etc.

2. **Medical gases –** different gases and their use, coding and care of cylinders, delivery of gases to various parts of hospital, domiciliary oxygen services, and role of pharmacist . - **3 hrs**
3. **I.V admixure services and role of Pharmacist** - **3 hrs**
4. **Total Parenteral Nutrition –** Definition, composition and clinical use of TPN **2 hrs**
5. **Clinical Reseach** - **12 hrs**

Introduction to Clinical trials
Various phases of clinical trial.
Methods of post marketing surveillance
Abbreviated New Drug Application submission
Good Clinical Practice – ICH, GCP,
- Central drug standard control organisation (CDSCO) guidelines, Schedule Y
-Composition, responsibilities, procedures of IRB / IEC
Role and responsibilities of clinical trial personnel as per ICH GC
a. Sponsor
b. Investigators
c. Clinical research associate
d. Auditors
e. Contract research coordinators
f. Regulatory authority

Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
Informed consent Process

6. **Introduction to Biostatistics** - **3hrs**
7. **Research in pharmacy practice areas.**
8. **Continuing education for pharmacists** - **1 hr**
9. **Compunding of Pharmaceuticals in the hospital/community pharmacy.** Weights and measures, calculations involving percentage solutions, allegation, proof spirit, Isotonic solutions. Bulk compounding in hospitals, pre-packaging. - **3Hr**
10. **Manufacturing of Pharmaceutical Formulations in hospital – various aspects, current status** - **03 hrs**
11. **Radiopharmaceuticals – Handling and Packaging, clinical usage, and role of pharmacist** - **02 hrs**
12. **Applications of IT and computers in pharmacy practice** - **2 hrs**
13. **Provision of cytotoxic chemotherapy, and various considerations/handling. Handling of cytotoxic waste and disposal.**

Pharmaceutical (Medicines and allied products) waste management in hospitals, community pharmacy, and the community and the role of the pharmacist. - **3Hr**

14. **Medical Devices & I.V. pumps**
15. **Individualised medicines, Gene therapy, Genomics & proteomics, Biochips, biosensors and MEMS micro electro mechanical systems** - **2 Hr**

2.5. Pharmaceutical Jurisprudence

Scope:

A profession becomes successful when it is guided with suitable laws. This course describes about the Pharmacy Act, Drugs and Cosmetics Act, Dangerous drugs act, Medicinal and Toilet preparation act, DPCO and Professional ethics.

Course Objectives:

Upon completion of the course the student shall be able to

1. Understand various concepts of the pharmaceutical legislation in India
2. Know various rules drafted in Drug and Cosmetic Act, Pharmacy Act, NDPS Acts, relevant to pharmacy practice.
3. Know the Consumer Protection Act, PFA Act, DPCO,.
4. Understand the labeling requirements and packaging guidelines for drugs and cosmetics

Course duration:

Learning

40 hours of learning by blended teaching. Blended teaching method includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Detailed syllabus and Lecture wise Program

1. A brief review of Pharmaceutical legislations. - 01 hr

A Study of various pharmaceutical and related legislations with more emphasis on aspects relevant to community & hospital pharmacy practice in India. Study the aspects only from practical angle, with examples, case studies, etc :

2. Drugs and Cosmetics Act-1940 and Rules 1945 - 15 hrs

- Duties & Responsibilities of Drug Inspectors, other officers, and obligations of the pharmacy to them
- Brief about DTAB, DCC, Drug testing laboratories
- Various drug licences for retail pharmacy, requirements to start a pharmacy/medical store, application forms, issue of licence, display of licences, duration of licences, laws related to stocking, handling and sale of drugs and devices
- Various schedules under the Act & Rule – study in brief –those relevant to pharmacy practice
- Labelling requirements of drugs – various aspects
- Spurious, misbranded, adulterated, counterfeit drugs – various aspects related to this, how to recognize, role of the pharmacist
- Import of drugs for personal use
- Various documents to be maintained under the Act & Rules by a pharmacy
- Storage requirements, handling expired goods
- Various punishments under the Act
- Practical study of Prescription and non-prescription drugs, market samples, examine for labeling, etc.

- Laws relating to various traditional systems/ medicines approved in India
- Banning of drugs

3. **Pharmacy Act – 1948** - **03 hrs**
4. **Medicinal and Toilet Preparation Act-1955** - **04 hrs**
5. **Narcotic Drugs and Psychotropic Substances Act – 1985** - **04 hrs**
6. **Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules, 1954** - **02 hrs**
7. **Essential Commodities Act** - **02 hrs**
8. **Drugs Prices Control Order** - **02hrs.**
9. **Prevention of Cruelty to Animals Act, 1960** - **02 hrs**
10. Consumer Protection Act , 1986 - **02 hrs**
11. Prevention of Food Adulteration Act & Rules, laws relating to Dietary Supplements, Food supplements, etc - **02 Hrs**
12. The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Amendment Act, 2003 - **02 Hrs**

Books and references

2.6. Social Pharmacy II

Scope:

Practicing pharmacists have opportunity to provide various patient care services to improve the patient's health in the society. By monitoring the health of the individuals, providing them education about health, precautions, and pharmacists can improve their professional image.

Objectives:

Upon completion of the course, the student will be able to

a. Understand the social responsibility of the pharmacists in the society
b. Provide professional services to the patients.

Course duration:

Learning

40 hours of learning by blending method. Blending method includes didactic and onsite learning.

Assignments

Each student should complete **two assignments** covering therapeutics and pharmacy practice concepts and will be evaluated at the time Final Examination.

Syllabus and lecture wise programme

A. **Preventive care**:

1. Vaccines, and immunizations – and Role of Pharmacist – **2 hours**
2. Role of Pharmacist in Demography & Family Planning - **2 hours**
3. Mother and child health, importance of breastfeeding, ill effects of formula foods and bottle feeding, and role of Pharmacist - **4 hours**
4. Geriatrics and role of Pharmacist - **1 hour**
5. Effect of Environment on Health & Role of Pharmacist – Water pollution, safe supply of water, **1 hour**

6. Occupational diseases/illnesses and Role of Pharmacist - **1 hours**
7. Mental Health and role of Pharmacist - **1 hours**
8. Psychosocial Pharmacy : Drugs of misuse and abuse – psychotropic and narcotics, and other pharmaceuticals and chemicals, tobacco and tobacco products, alcohol. Social & psychosocial impact of these, role of pharmacist in reducing, preventing the menace.

   Tobacco cessation and role of pharmacist - **3 Hr**

9. Palliative/terminal care and role of pharmacist in handling psychosocial issues - **3Hr**
10. Care for disabled and role of pharmacist in handling psychosocial issues - **2 Hr**
11. Early intervention in hereditary diaseses, screening tests - **1 hour**

B. Nutrition and health : - **20 Hr**

1. Basics of nutrition – Macronutrients and Micronutrients, fibre – importance, sources (Plant and animal origin),
2. Calorific and nutritive values of various foods
3. Daily/recommended dietary allowance and functions of each. Balanced diets – for various individual groups. Nutrition deficiency diseases
4. Food as a medicine. Brief study of various concepts of Naturopathy.
5. Nutrition as per Ayurveda – Ayurvedic outlook to diets – as per prakruti, seasons, seasonal availability of foods, etc. Prakruti study in brief.
6. Wrong/improper foods and food habits, causes of various disease conditions, ill effects of wrong foods/fast foods, timed foods, etc – Western foods as well as Indian foods – reasons for wrong effects on body.
7. Basics of genetically modified foods – advantages, disadvantages
8. Effects of environment on foods, artificial ripening, hybridization, use of pesticides, adulteration, etc.
9. Nutrition/dietary recommendation for different disease conditions – e.g. diabetes, blood pressure, Hyperlipidemia, arthritis, renal disease, liver disease, allergies, etc.
10. Artificial sweeteners, zero calorie concept, glycemic index of foods

11. Dietary supplements, neutraceuticals, food supplements – legal standing, indications, rational use, benefits, ADRs, Drug Interactions, pharmacoeconomics.

C. First Aid Services in Community Pharmacy - **10 hours**

RECOMMENDED BOOKS

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone Publication

2. Pharmacotherapy: A Pathophysiologic Approach - Joseph T. Dipiro et al. Appleton & Lange

3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication

4. Applied Therapeutics: The Clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

5. Text Book of Hospital Pharmacy by Quadry and Merchant.

6. Text Book of Clinical Pharmacy Practice. Edt. G. Parthasarathi, Karin Nyfort Hansen and Milap. C.Nahata. Orient Longman Publications.

7. Text Book of Community Pharmacy Practice. RPSGB Publication.

8. Community Pharmacy Handbook- Jonathan Waterfield

9. Community Pharmacy: Symptoms, Diagnosis and Treatement: Paul Rutter

10. Minor Illness in Major Diseases-the Clinical Manifestation in the Community: Paul Stillman

11. Sociology for Pharmacist: Tayler, Nettleton, Harding

12. Pharmacy Practice: Tayler, Harding

13. Social Pharmacy: Tayler, Geoffery

14. Stockley's Drugs Interaction: Karen Baxter

15. Cooper and Gunn : Dispensing for Pharmacy Students.

16. A text book Professional Pharmacy by N. K. Jain and S. N. Sharma.

17. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.

18. Remington's Pharmaceutical Sciences

19. D.M. Brahmankar and Sunil B Jaiswal. Text Book of Biopharmaceutics and Pharmacokinetics – A treatise. Vallabh Prakashan. Delhi.

20. Biopharmaceutics by Swarbrik

21. Bio pharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.

22. Mithal , B M. Textbook of Forensic Pharmacy. Calcutta : National; 1988.

23. Singh, KK, Editor. Beotra's the Laws of Drugs, Medicines & Cosmetics. Allahabad: Law Book House; 1984.

24. Jain, NK. A Textbook of Forensic Pharmacy. Delhi: Vallabh Prakashan ; 1995.

25. Reports of the Pharmaceutical Enquiry Committee

26. I.D.M.A., Mumbai. DPCO 1995

27. Various Reports of Amendments.

28. Deshapande, S.W. The Drugs and Magic Remedies Act, 1954 and Rules 1955. Mumbai: Susmit Publications; 1998.

29. Eastern Book Company.The Narcotic and Psychotropic Substances Act, 1985, Lucknow: Eastern; 1987.

30. Drug Information About Commonly Used Drugs: P.P.Sharma, R.Sing

ARCHNA MUDGAL, Registrar-cum-Secy.

[ADVT. III/4/Exty./101/14]