# Regulations and Course Curriculum for

(PHARM. D) & (PHARM.D. [POST BACCALAUREATE]) (Amended up to August 2024)



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# DOCTOR OF PHARMACY (PHARM. D) COURSE & DOCTOR OF PHARMACY - (PHARM.D. [POST BACCALAUREATE]) COURSE (Amended up to August 2018)



# **NITTE** (Deemed to be University)

(under Section 3 of UGC Act, 1956)
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# **VISION**

To build a humane society through excellence in education and health care

# MISSION

To develop Nitte (Deemed to be University)
as a centre of excellence imparting quality education, generating competent,
skilled manpower to face the scientific and social challenges, with a high degree
of credibility, integrity, ethical standards and social concern

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#### Curriculum

# I Year Pharm.D.

Human Anatomy and Physiology
Pharmaceutics
Medicinal Biochemistry
Pharmaceutical Organic Chemistry
Pharmaceutical Inorganic Chemistry
Remedial Mathematics/ Biology
Constitution of India

# II Year Pharm.D.

Pathophysiology

Pharmaceutical Microbiology

Pharmacognosy & Phytopharmaceuticals

Pharmacology-I

Community Pharmacy

Pharmacotherapeutics-I

Human Rights, Gender Equity and Environmental Studies

# III Year Pharm.D.

Pharmacology-II
Pharmaceutical Analysis
Pharmacotherapeutics-II
Pharmaceutical Jurisprudence
Medicinal Chemistry
Pharmaceutical Formulations

# IV Year Pharm.D.

Pharmacotherapeutics-III
Hospital Pharmacy
Clinical Pharmacy
Biostatistics & Research Methodology
Biopharmaceutics & Pharmacokinetics
Clinical Toxicology
Pharmacotherapeutics-I & II (for Pharm.D. (Post Baccalaureate)

# V Year Pharm.D.

Clinical Research
Pharmacoepidemiology and Pharmacoeconomics
Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring
Clerkship (Attending ward rounds on daily basis)
Project work (Six Months)

#### Sixth Year Pharm.D.

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

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

# Pharmacy Council of India (PCI) Notifications

- I. Registration procedure of Pharm.D. (Doctor of Pharmacy) passed out students
- II. Pharm.D qualified students can directly register for Ph.D.
- III. Pharm.D an approved qualification for teaching
- IV. Nomenclature of Pharm.D/Pharm.D (Post Baccalaureate) on pass certificates

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

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

New Delhi, 10<sup>th</sup> 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 13<sup>th</sup> 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:-

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

# No. F.9-13/2007-U.3 (A) Government of India Ministry of Human Resource Development (Department of Higher Education) U.3(A) Section

Shastri Bhavan, New Delhi Dated: 4<sup>th</sup> Jun, 2008

#### Notification

- 1. Whereas the Central Government is empowered under Section 3 of the University Grants Commission (UGC) Act, 1956 to declare, on the advice of the UGC, an institution of higher learning as a deemed-to-be-university;
- 2. And whereas, a proposal was received in February, 2007 from Nitte Education Trust, Mangaluru, Karnataka seeking grant of status of deemed-to-be university in the name of Nitte (Deemed to be University) under section 3 of the UGC Act, 1956;
- 3. And whereas, the University Grants Commission has examined the said proposal and vide its communication bearing No. F.26-10/2007(CPP-I/DU), dated the 10<sup>th</sup> March, 2008 has recommended conferment of status of deemed-to-be-university' in the name and style of Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Mangaluru.
- 4. Now, therefore, in exercise of the powers conferred by section 3 of the UGC Act, 1956, the central Government, on the advice of the University Grants Commission (UGC), hereby declare that Nitte (Deemed to be University), Mangaluru, Karnataka, comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru, shall be deemed to be a University for the Purposes of the aforesaid Act.

Sd/ (Sunil Kumar) ernment of India

Joint Secretary to the Government of India

(True Extract of the Notification)

Dated: 24th March, 2009

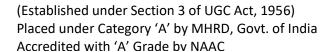
No. F.26-5/2008(CPP-1)

# Office Memorandum

- Whereas the Government of India, Ministry of Human Resource Development, Department of Higher Education vide Notification No. F.9-13/2007-U3(A) dated 4<sup>th</sup> June, 2008 declared Nitte (Deemed to be University), Mangaluru, Karnataka comprising A. B. Shetty Memorial Institute of Dental Sciences, Deralakatte, Mangaluru as Deemed to be University under Section 3 of UGC Act, 1956.
- 2. And whereas now, the University Grants Commission, on the recommendation of an Expert Committee constituted by the Chairman, UGC has agreed for bringing (i) K. S. Hegde Medical Academy, Deralakatte, Mangaluru (ii) Nitte Usha Institute of Nursing Sciences, Deralakatte, Mangaluru (iii) Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, Deralakatte, Mangaluru, (iv) Nitte Institute of Physiotherapy, Deralakatte, Mangaluru under the ambit of Nitte (Deemed to be University), Deralakatte, Mangaluru.

Sd/ (K. P. Singh) Joint Secretary, University Grants Commission

(True Extract of the Office Memorandum)





# **NOTIFICATION**

Subject: Regulations and Course Curriculum for Pharm.D. and Pharm.D

(Post Baccaulaureate) courses

Reference: Minutes of the Academic Council meeting held on 24th July 2012

In exercise of the Powers conferred under Rule R-08 (g) of the Memorandum of Association, the Academic Council has been pleased to approve the Regulations and Course Curriculum for the Pharm.D. and Pharm.D (Post Baccaulaureate) courses in the Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences.

The Regulations and course curriculum shall come into force from the academic year 2012-13.

By Order,

Registrar

# Nitte (Deemed to be University)

(Under Section (3) of UGC Act, 1956)
(Placed under category 'A' by MHRD, Govt. of India, Accredited with 'A' Grade by NAAC)
Mangalore, Karnataka, India

Regulations and Course Curriculum for Pharm.D. and Pharm.D. (Post Baccalaureate)
(Amended up to August 2024)

# Preamble:

Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences, imparting education and training in pharmaceutical sciences since 1983, started B. Pharm course in 1984. M.Pharm programs were introduced in 1991. From the year 2009-10, the institute became a constituent college of Nitte (Deemed to be University). The Pharm.D program was introduced in the year 2012-13. And in the year 2015-16, Pharm.D (Post Baccalaureate) was started. The regulations for the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes are formulated as under:

# 1. Introduction:

- 1.1. These regulations shall be called Nitte (Deemed to be University) Regulations for Pharm.D. and Pharm.D. (Post Baccalaureate) course and govern the policies and procedures including selection, admission, imparting of instructions, conduct of examinations, evaluation and certification of candidate's performance and all amendments thereto, leading to the award of Pharm.D. and Pharm.D. (Post Baccalaureate) degree. The regulations shall come into effect from the academic year 2012-2013.
- 1.2. This set of regulations shall be binding on all the candidates undergoing the said degree programme.
- 1.3. These regulations may be modified from time to time as mandated by the statutes of the University and the Pharmacy Council of India.
- 1.4. This set of regulations may evolve and get refined or updated or amended or modified or changed through appropriate approvals from the Academic Council or the Board of Management from time to time and shall be binding on all parties concerned including the Candidates, Faculty, Staff, Departments and Institute Authorities.
- 1.5. All disputes arising from this set of regulations shall be addressed to the Board of Management. The decision of the Board of Management is final and binding on all parties concerned. Further, any legal disputes arising out of this set of regulations shall be limited to the jurisdiction of Courts of Mangalore only.

#### 2. Definitions:

Unless the context otherwise requires

- BOM means Board of Management of Nitte (Deemed to be University)
- AC means Academic Council of Nitte deemed to be University
- BOS means Board of Studies (UG and PG) in Pharmaceutical Sciences
- College/Institute means Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences
- He includes both genders He and She; similarly his and / or him, himself includes her, as well in all cases.
- Head of the Institution means the Dean / Principal of the College (Nitte Gulabi Shetty Memorial Institute of Pharmaceutical Sciences)
- Regulations means this set of academic regulations
- Regulatory Authority Authority appointed / constituted by the central / state governments/s to regulate Pharmaceutical Sciences Education.
- Teaching Hospital means Justice K S Hegde Charitable Hospital or any other Hospital owned by, or under the management of Nitte (Deemed to be University)
- University means Nitte (Deemed to be University)
- She means both he and she

# 3. Duration of the Course:

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

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

**Phase II** - consisting of internship or residency training in the sixth year involving posting in specialty units.

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

**Phase I** - consisting of First and Second academic year.

**Phase II** - consisting of Internship or residency training during the third year involving posting in specialty units.

# 4. Medium of Instruction and Examinations:

The medium of Instruction and Examination shall be English.

# 5. Maximum Period for completion of the course:

The maximum period for completion of the Pharm.D course is twelve years and Pharm.D. (Post Baccalaureate) course is six years.

# 6. Eligibility for Admissions:

# 6.1 Pharm.D.

Eligibility criteria for admission to Pharm.D. course is

- 1. The student has completed the age of 17 years on or before the 31<sup>st</sup> December of the year of admission
- 2. She has passed the two year PUC examination of the Karnataka PUE Board or an examination considered equivalent by Nitte (Deemed to be University) with not less than 45% marks with Physics and Chemistry as compulsory subjects along with one of the following subjects Mathematics or Biology.

ЭR

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

ΩR

Any other qualification approved by PCI as equivalent to any of the above examinations

# b) Pharm.D. (Post Baccalaureate)

A pass in B.Pharm with 50% mark from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act. The candidate shall be admitted to IV year of the course (lateral entry) which shall be in effect the first year of the Pharm.D (Post Baccalaureate) course.

# 7. Selection of eligible candidates:

Selection to the Pharm.D. and Pharm.D. (Post Baccalaureate) course shall be based on merit obtained in the qualifying examination.

# 8. Withdrawal -Temporary and Permanent:

# 8.1. Temporary Withdrawal:

- 8.1.1. A candidate who has been admitted to the course may be permitted to withdraw temporarily for a period of six months or more up to one year on the grounds of prolonged illness, grave calamity in the family etc., provided:
  - a. He applies <u>stating</u> the reason of withdrawal with supporting documents and endorsement by parent/guardian.
  - b. The College is satisfied that without counting the period of withdrawal candidate is likely to complete his requirement of the degree within maximum time specified.
  - c. There are no outstanding dues or demands with the department, library, hostel, College etc.
- 8.1.2. The tuition fee for the subsequent year may be collected in advance based on the severity of the case before giving approval for any such temporary withdrawal.
- 8.1.3. Scholarship holders are bound by the appropriate rules applicable
- 8.1.4. The decision of the Institute/University regarding withdrawal of a candidate is final and binding.

#### 8.2. Permanent withdrawal:

- 8.2.1. A candidate who withdraws admission before closing date of admission for the academic session is eligible for the refund of the deposit only. The fees once paid will not be refunded on any account.
- 8.2.2. Once the admission for the year is closed, and if a candidate wants to leave the institution, he will be permitted to do so and take the Transfer Certificate from the institute, if required only after remitting all the tuition fees for the remaining years.
- 8.2.3. Those candidates who have received any scholarship/stipend/other forms of assistance from the college shall repay all such amounts in addition to those mentioned in the clause above.
- 8.2.4. The decision of the college/university regarding withdrawal of a candidate is final and binding.

# 9. Conduct and discipline:

- 9.1. Candidates shall conduct themselves within and outside the premises of the Institute in a manner befitting the student of a professional Institution.
- 9.2. As per the order of Honorable Supreme Court of India, ragging in any form is considered as a criminal offence and is banned. Any form of ragging will be severely dealt with.
- 9.3. The following act of omission and/or commission shall constitute gross violation of the code of conduct and are liable to invoke disciplinary measures:
  - 9.3.1. Ragging as defined and described by the Supreme Court/Government
  - 9.3.2. Lack of courtesy and decorum; indecent <u>behaviour</u> anywhere within or outside the campus.
  - 9.3.3. Willful damage or stealthy removal of any property/belongings of the Institute/Hostel or of fellow candidates/citizens.
  - 9.3.4. Possession, consumption or distribution of alcoholic drinks or any kind of hallucinogenic drugs.
  - 9.3.5. Mutilation or unauthorized possession of library books.
  - 9.3.6. Noisy or unseemly <u>behaviour</u>, disturbing studies of fellow candidates.
  - 9.3.7. Hacking in computer systems (such as entering into other person's domain without prior permission, manipulation and/or damage to the computer hardware and software or any other cyber crime etc.)
  - 9.3.8. Plagiarism of any nature.
  - 9.3.9. Any other act of gross indiscipline as decided by the Board of management from time to time.
- 9.4. Commensurate with the gravity of offence, the punishment may be: reprimand, fine, expulsion from the hostel, debarment from an examination, disallowing the use of certain facilities of the College, rustication for a specific period or even outright expulsion from the College, or even handing over the case to appropriate law enforcement authorities or the judiciary, as required by the circumstances.

- 9.5. For any offence committed in (i) a hostel (ii) a department or in a classroom and (iii) elsewhere, the Chief Warden, the Head of the Department and the Head of the Institute, respectively, shall have the authority to reprimand or impose fine.
- 9.6. All cases involving punishment other than reprimand shall be reported to the Vice-chancellor.
- 9.7. Cases of adoption of unfair means and/or any malpractice in an examination shall be reported to the Dean (Academic Affairs) for taking appropriate action.

# 10. Graduation Requirements:

A Candidate shall be declared eligible for the award of the degree if he has:

- Fulfilled degree requirements including internship or residency training.
- No dues to the University, Institute, Departments, Hostels, Library, etc.
- No disciplinary action pending against him.

The award of the degree must be recommended by the Board of Management.

# 11. Convocation:

Degrees will be awarded in person for the candidates who have graduated during the preceding academic year. Degrees will be awarded *in absentia* to such candidates who are unable to attend the convocation. Candidates are required to apply for the convocation along with prescribed fee within the specified date, after having satisfactorily completed all degree requirements of the course.

Provisional pass certificate will be issued by the University provided the candidate fulfills requirements mentioned in clause (10) above. The provisional certificate will be issued on submission of an application through the college and will be valid until the convocation.

# 12. Academic Appeals Board (AAB)

There shall be an Academic Appeals Boards constituted by the college and approved by the University

# Constitution:

Head of the institution of a constituent college : Chairman
 A Professor from a constituent college : Member

(Nominated by the Vice-Chancellor)

• Three faculty members : Members

(Nominated by the Head of the institution)

• Controller of Examination : Member Secretary

# Note:

- i The Chairman may co-opt and/or invite more members.
- ii The senior most member in the Board shall act as chairman in the absence of chairperson
- iii The quorum of each meeting shall be a minimum of Four

# Functions of the Board:

- To receive grievance/ complaints in writing from the students regarding anomaly in award of marks due to bias, victimization, erratic evaluation, etc. and redress the complaints.
- To interact with the concerned teacher and the student separately, before taking the decision.
- The decision of the AAB will be based on simple majority.
- The recommendation of the AAB shall be communicated to the University for further appropriate action

# 13. Subjects of Study and Training:

# 13.1 Pharm.D.

Subjects of study and examination scheme for first to sixth year Pharm.D. are given in Tables.

TABLES First Year:

Subject	Name of Subject	No. of	No. of
Code		hours/	hours of
		Week	Tutorial
(1)	(2)	(3)	(4)
12PD11T	Human Anatomy and Physiology	3	1
12PD11P	Human Anatomy and Physiology	3	-
12PD12T	Pharmaceutics	2	1
12PD12P	Pharmaceutics	3	-
12PD13T	Medicinal Biochemistry	3	1
12PD13P	Medicinal Biochemistry	3	-
12PD14T	Pharmaceutical Organic Chemistry	3	1
12PD14P	Pharmaceutical Organic Chemistry	3	-
12PD15T	Pharmaceutical Inorganic Chemistry	2	1
12PD15P	Pharmaceutical Inorganic Chemistry	3	-
12PD16T*	Remedial Mathematics <sup>+</sup> / Biology <sup>++</sup>	3	1
12PD16P*	Remedial Biology <sup>++</sup>	3	-
12PD17T*	Constitution of India	2	-
		33+/36++/30	6
	Total hours - For Maths Deficient: 39		
	For Biology Deficient: 42		
	For No Maths/Bio Deficiency: 35		

<sup>+</sup> For mathematics deficit students ++ For Biology deficit students

<sup>\*</sup> College examination only

# Second Year:

Subject Code	Name of Subject	No. of hours/ Week	No. of hours of Tutorial
(1)	(2)	(3)	(4)
12PD21T	Pathophysiology	3	1
12PD22T	Pharmaceutical Microbiology	3	1
12PD22P	Pharmaceutical Microbiology	3	-
12PD23T	Pharmacognosy & Phytopharmaceuticals	3	1
12PD23P	Pharmacognosy & Phytopharmaceuticals	3	-
12PD24T	Pharmacology-I	3	1
12PD25T	Community Pharmacy	2	1
12PD26T	Pharmacotherapeutics-I	3	1
12PD26P	Pharmacotherapeutics-I	3	-
12PD27T*	Human Rights, Gender Equity and	2	-
	Environmental Studies		
	Total hours	28	6
		Grand Total	34

<sup>\*</sup> College examination only

# Third Year:

Subject Code	Name of Subject	No. of hours/ Week	No. of hours of Tutorial
(1)	(2)	(3)	(4)
12PD31T	Pharmacology-II	3	1
12PD31P	Pharmacology-II	3	-
12PD32T	Pharmaceutical Analysis	3	1
12PD32P	Pharmaceutical Analysis	3	-
12PD33T	Pharmacotherapeutics-II	3	1
12PD33P	Pharmacotherapeutics-II	3	-
12PD34T	Pharmaceutical Jurisprudence	2	-
12PD35T	Medicinal Chemistry	3	1
12PD35P	Medicinal Chemistry	3	-
12PD36T	Pharmaceutical Formulations	2	1
12PD36P	Pharmaceutical Formulations	3	-
	Total hours	31	5
	Grand Total		36

# Fourth Year:

Subject Code	Name of Subject	No. of hours/ Week	No. of hours of Tutorial
(1)	(2)	(3)	(4)
12PD41T	Pharmacotherapeutics-III	3	1
12PD41P	Pharmacotherapeutics-III	3	-
12PD42T	Hospital Pharmacy	2	1
12PD42P	Hospital Pharmacy	3	-
12PD43T	Clinical Pharmacy	3	1
12PD43P	Clinical Pharmacy	3	-
12PD44T	Biostatistics & Research Methodology	2	1
12PD45T	Biopharmaceutics & Pharmacokinetics	3	1
12PD45P	Biopharmaceutics & Pharmacokinetics	3	-
12PD46T	Clinical Toxicology	2	1
	Total hours	27	6
	Grand Total		33

# Fifth Year:

Subject Code	Name of Subject	No. of hours/ Week	No. of hours of Tutorial
(1)	(2)	(3)	(4)
12PD51T	Clinical Research	3	1
12PD52T	Pharmacoepidemiology and	3	1
	Pharmacoeconomics		
12PD53T	Clinical Pharmacokinetics &	2	1
	Pharmacotherapeutic Drug Monitoring		
12PD54	Clerkship *	-	1
12PD55P	Project work (Six Months)	20	-
	Total hours	28	4
	Grand Total		32

<sup>\*</sup> Attending ward rounds on daily basis.

# Sixth Year:

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

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

# 13.2 Pharm.D. (Post Baccalaureate)

Subjects of study and examination scheme for Pharm.D. (Post Baccalaureate) course are given in Tables.

# First Year:

Subject Code	Name of Subject	No. of hours/ Week	No. of hours of Tutorial
(1)	(2)	(3)	(4)
12PD41T	Pharmacotherapeutics-III	3	1
12PD41P	Pharmacotherapeutics-III	3	-
12PD42T	Hospital Pharmacy	2	1
12PD42P	Hospital Pharmacy	3	-
12PD43T	Clinical Pharmacy	3	1
12PD43P	Clinical Pharmacy	3	-
12PD44T	Biostatistics & Research Methodology	2	1
12PD45T	Biopharmaceutics & Pharmacokinetics	3	1
12PD45P	Biopharmaceutics & Pharmacokinetics	3	-
12PD46T	Clinical Toxicology	2	1
12PD47T	Pharmacotherapeutics I & II	3	1
12PD47P	Pharmacotherapeutics I & II	3	-
	Total hours	33	7
	Grand Total		40

# Second Year:

Subject Code	Name of Subject	No. of hours/ Week	No. of hours of Tutorial
(1)	(2)	(3)	(4)
12PD51T	Clinical Research	3	1
12PD52T	Pharmacoepidemiology and	3	1
	Pharmacoeconomics		
12PD53T	Clinical Pharmacokinetics &	2	1
	Pharmacotherapeutic Drug Monitoring		
12PD54	Clerkship *	-	1
12PD55P	Project work (Six Months)	20	-
	Total hours	28	4
	Grand Total		32

<sup>\*</sup> Attending ward rounds on daily basis.

# Third Year:

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

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

#### 14. Attendance:

15.1 A candidate pursuing Pharm.D. course shall study in the concerned department of the Institution for the entire period as a full-time candidate. No candidate is permitted to work in any outside laboratory / institution / industry / pharmacy, etc., during the period of study. No candidate shall join any other course of study or appear for any other degree examination conducted by this university or any other university in India or abroad during the period of registration.

15.2 Each year shall be taken as a unit for the purpose of calculating attendance.

15.3 A candidate who has put in a minimum of 80% of attendance in the theory and practical assignments separately and who has fulfilled all other requirements of the course shall be permitted to appear for the University examination.

# 15. Examinations

- 1. Every year there shall be an annual examination and a supplementary examination to examine the students.
- 2. 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:

# 15.1. Scheme of Examination

#### **TABLES**

# Pharm.D.

# First Year examination:

Subject Code	Subject	Duration (Universit y exam -	Maximum Marks		Total
		hrs)	Sessional Exam	University exam	
12PD11T	Human Anatomy and Physiology	03	30	70	100
12PD11P	Human Anatomy and Physiology	04	30	70	100
12PD12T	Pharmaceutics	03	30	70	100
12PD12P	Pharmaceutics	04	30	70	100
12PD13T	Medicinal Biochemistry	03	30	70	100
12PD13P	Medicinal Biochemistry	04	30	70	100
12PD14T	Pharmaceutical Organic Chemistry	03	30	70	100
12PD14P	Pharmaceutical Organic Chemistry	04	30	70	100
12PD15T	Pharmaceutical Inorganic Chemistry	03	30	70	100
12PD15P	Pharmaceutical Inorganic Chemistry	04	30	70	100
12PD16T*	Remedial Mathematics <sup>+</sup> /	03	-	100	100

	Biology <sup>++</sup>					
12PD16P*	Remedial Biology <sup>++</sup>		04	-	100*	100
12PD17T*	Constitution of India		03	-	100	100
	TOTAL	Theory	500		Grand	1000
		Practical	500		Total	

<sup>+</sup> For mathematics deficient students ++ For Biology deficient students

# Second Year examination:

Subject Code	Subject		Duration (Universit		imum arks	Total
Code			y exam -	7416	ii K3	
			hrs)	Sessional	University	
			3)	Exam	exam	
12PD21T	Pathophysiology		03	30	70	100
12PD22T	Pharmaceutical		03	30	70	100
	Microbiology					
12PD22P	Pharmaceutical		04	30	70	100
	Microbiology					
12PD23T	Pharmacognosy &		03	30	70	100
	Phytopharmaceut	icals				
12PD23P	Pharmacognosy &		04	30	70	100
	Phytopharmaceut	icals				
12PD24T	Pharmacology-I		03	30	70	100
12PD25T	Community Pharr	nacy	03	30	70	100
12PD26T	Pharmacotherape	eutics-l	03	30	70	100
12PD26P	Pharmacotherape	eutics-l	04	30	70	100
12PD27T*	Human Rights, Ge	nder	03	-	100	100
	Equity and Environmental					
	Studies					
	TOTAL	Theory	600		Grand	900
		Practical	300		Total	

Total: Theory 600 Practical 300

Grand Total 900

<sup>\*</sup>College examination only

<sup>\*</sup>College examination only

# **Third Year examination:**

Subject Code	Subject		Subject		Duration (Universit y exam -		imum arks	Total
			hrs)	Sessional Exam	University exam			
12PD31T	Pharmacology-II		03	30	70	100		
12PD31P	Pharmacology-II		04	30	70	100		
12PD32T	Pharmaceutical A	nalysis	03	30	70	100		
12PD32P	Pharmaceutical Analysis		04	30	70	100		
12PD33T	Pharmacotherapeutics-II		03	30	70	100		
12PD33P	Pharmacotherapeutics-II		04	30	70	100		
12PD34T	Pharmaceutical Jurisprudence		03	30	70	100		
12PD35T	Medicinal Chemis	try	03	30	70	100		
12PD35P	Medicinal Chemis	try	04	30	70	100		
12PD36T	Pharmaceutical Formulations		03	30	70	100		
12PD36P	Pharmaceutical Formulations		04	30	70	100		
	TOTAL	Theory Practical	600 500		Grand Total	1100		

# Fourth Year examination:

Subject Code	Subject		Duration (Universit y exam -	Maximum Marks		Total
			hrs)	Sessional	University	
			,	Exam	exam	
12PD41T	Pharmacotherapeutics-III		03	30	70	100
12PD41P	Pharmacotherape	eutics-III	04	30	70	100
12PD42T	Hospital Pharmac	:y	03	30	70	100
12PD42P	Hospital Pharmacy		04	30	70	100
12PD43T	Clinical Pharmacy		03	30	70	100
12PD43P	Clinical Pharmacy	y	04	30	70	100
12PD44T	Biostatistics & Re	esearch	03	30	70	100
12PD45T	Biopharmaceutics Pharmacokinetics		03	30	70	100
12PD45P	Biopharmaceutics & Pharmacokinetics		04	30	70	100
12PD46T	Clinical Toxicology		03	30	70	100
	TOTAL	Theory Practical	600 400		Grand Total	1000

# Fifth Year examination:

Subject Code	Subject		Duration (Universit y exam -		imum arks	Total
			hrs)	Sessional	University	
			111 3)	Exam	exam	
12PD51T	Clinical Research		03	30	70	100
12PD52T	Pharmacoepidem	iology and	03	30	70	100
	Pharmacoeconom	iics				
12PD53T	Clinical Pharmaco	okinetics &	03	30	70	100
	Pharmacotherapeutic Drug					
	Monitoring					
12PD54	Clerkship *		03	30	70	100
12PD55P	Project work (Six Months)		04	-	100**	100
	TOTAL	Theory	300		Grand	500
		Practical	200		Total	

<sup>\*</sup> Attending ward rounds on daily basis.
\*\* 30 marks - viva-voce (oral)
70 marks - Thesis work

Pharm.D. (Post Baccalaureate)

# First Year examination:

Subject Code	Subject	:	Duration (Universit y exam -		imum arks	Total
			hrs)	Sessional	University	
			1113)	Exam	exam	
12PD41T	Pharmacotherape	utics-III	03	30	70	100
12PD41P	Pharmacotherape	utics-III	04	30	70	100
12PD42T	Hospital Pharmac	У	03	30	70	100
12PD42P	Hospital Pharmac	У	04	30	70	100
12PD43T	Clinical Pharmacy	/	03	30	70	100
12PD43P	Clinical Pharmacy	/	04	30	70	100
12PD44T	Biostatistics & Re Methodology	search	03	30	70	100
12PD45T	Biopharmaceutics Pharmacokinetics		03	30	70	100
12PD45P	Biopharmaceutics Pharmacokinetics		04	30	70	100
12PD46T	Clinical Toxicolog	<u>y</u>	03	30	70	100
12PD47T	Pharmacotherape & II	eutics I I	03	30	70	100
12PD47P	Pharmacotherape II	eutics I &	04	30	70	100
	TOTAL	Theory Practical	700 500		Grand Total	1200

# **Second Year examination:**

Subject Code	Subject		Duration (University	-	imum arks	Total
			exam - hrs)	Sessional	University	
				Exam	exam	
12PD51T	Clinical Research		03	30	70	100
12PD52T	Pharmacoepidemiology and		03	30	70	100
	Pharmacoeconomi	ics				
12PD53T	Clinical		03	30	70	100
	Pharmacokinetics					
	Pharmacotherapeutic					
	Drug Monitoring					
12PD54	Clerkship *		03	30	70	100
12PD55P	Project work (Six	Months)	04	-	100**	100
	TOTAL	Theory	300		Grand	500
		Practic al	200		Total	

Total: Theory 300

Practical 200

Grand Total 500

70 marks - Thesis work

# 15.2. Evaluation

Evaluation is based on formative evaluation (internal assessment) and summative evaluation (University examination).

# **15.2.1. Internal Assessment** (Formative Evaluation)

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

# 15.2.2. University examinations (Summative Evaluation):

1. Theory examination shall be of three hours and practical examination shall be of four hours duration.

<sup>\*</sup> Attending ward rounds on daily basis.

<sup>\*\* 30</sup> marks - viva-voce (oral)

- 2. Theory and practical of a particular subject are considered as individual subjects for the purpose of pass criteria.
- 3. Those candidates who fail in one or more subjects shall have to appear only in the subject so failed, in the subsequent examinations.
- 4. Practical examination shall also consist of a viva -voce (Oral) examination.
- 5. 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.

# 15.3 Criteria for Pass:

- a. Candidate shall be declared as pass if he secures 50% of marks (including internal assessment) in each subject in theory and practical examination separately except in the subjects for which examinations are conducted at the college level (by the college) for which the pass marks is 40%.
- b. Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.
- c. Those candidates who fail in one or more subjects shall have to appear only in the subject so failed, in the subsequent examinations i.e., if a candidate fails in theory or in practical of a subject, he has to appear only in theory or in practical as the case may be.

# 15.4 Carryover benefit:

A candidate of I Pharm.D. is permitted to carryover not more than two subjects of the first year to II Pharm.D and appear for II Pharm.D. However, failure in more than two subjects in any year shall debar him or her from promotion to the next year classes.

A candidate will not be permitted to go to III year unless he clears all the subjects of I year.

A candidate will not be permitted to go to IV year unless he clears all the subjects of II year

A candidate will not be permitted to go to V year unless he clears all the subjects of III year

A candidate will not be permitted to go for internship in VI year unless he clears all the subjects of IV year

#### 15.5 Internship:

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

(2) Every student has to undergo one-year internship as per the regulations of internship.

# 15.6 Rules for grace marks

The subject Grace of 1% of the maximum of the total marks in the examination subject to a maximum of 5 will be awarded to the failed course(s), provided on award of grace marks the candidate passes in that subject/examination. Award of grace marks shall not be applicable for compartmental examinations.

Subject grace awarded to a subject as per above shall be deducted from a subject which has the highest secured marks and on deduction the candidate should not fail in that subject. Secondly, if any one subject is not having marks more than the grace marks to be awarded than the minimum for passing, then the grace marks shall be awarded by deducting from two or more subjects such that total marks before gracing and after gracing shall remain the same. If there is no scope for deducting marks from other passed subjects to award marks for the failed subjects, grace marks shall not be awarded.

There shall be no provision to award grace marks for improvement of class.

# 15.7 Re-totaling

Re-totaling of marks is permitted for theory papers only. The university, on application within the stipulated time and remittance of a prescribed fee, shall permit a recounting of marks, for the subject(s) applied. The marks obtained after re-totaling shall be the final marks awarded.

# 15.8 Supplementary Examination:

Supplementary examination shall be conducted by the university for the benefit of unsuccessful candidates. The supplementary examination will be conducted within four to six weeks from the date of announcement of results.

A candidate detained for lack of attendance will be barred from appearing in any one or all subject(s) for the supplementary examination.

A Candidate dropping from appearance in any or all subjects at the regular examination is disallowed from taking dropped subject(s) at the supplementary examination.

A Candidate permitted to appear for the supplementary examination can improve his internal assessment marks before he takes the supplementary examination by subjecting himself to internal assessment procedure as practiced in the College.

# 16. Practical Training

**16.1 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 each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the

Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching shall be scheduled in the afternoon.

- **16.2 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 in fifth year / second year of Pharm.D and Pharm.D (Post Baccalaureate) respectively under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
- (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
- **16.3 Objectives of project work** The main objectives of the project work is to
- (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
- (ii) develop the students in data collection, analysis and reporting and interpretation skills.
- **16.4. Methodology** To complete the project work following methodology shall be adopted, namely:-
- (i) Students shall work in groups of not less than *two* but not more than *four* under an authorized teacher;
- (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
- (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilization reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
- (iv) project work shall be approved by the institutional ethics committee
- (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
- (vi) a write-up (synopsis) 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 before the commencement of the fifth and second year Pharm.D and Pharm.D (Post Baccalaureate) classes respectively.
- **16.5 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.
- **16.6 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 thirty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
	Total (30 marks)

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

a) Write up of the project work	(25.0)
b) Presentation of work	(15.0)
c) Communication skills	(15.0)
d) Question and answer skills	(15.0)
	Total (70 marks)

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

# 17. Declaration of class:

Class will be awarded only to those candidates who pass the examination in the first attempt.

17.1 Class shall be declared at the end of every year and will be on the basis of the aggregate of marks scored in that year.

75% and above - First class with Distinction

60% and above and less that 75% - First Class

50% and above and less that 60% - Second Class

Candidates who pass the examinations in more than one attempt shall be declared to have passed in 'Pass' class irrespective of the percentage of marks secured.

- 17.2 An attempt means the appearance of a candidate for one or more subjects either in part of full in a particular examination. If a candidate submits application for appearing for the examination but does not appear for any of the subjects either in full or part in the University examination, he can appear for supplementary examination provided other conditions such as attendance requirement, internal assessment marks, etc are fulfilled and his appearing in the supplementary examination shall be considered as the first attempt.
- 17.3 A candidate who passes one or more subjects or all subjects in the supplementary examination is not eligible for award of class or distinction. Passing in supplementary examination is considered as second attempt.

# 18. Award of Merit Certificate / Ranks

Merit certificate shall be awarded on the basis of aggregate marks of all the years of examination as per the duration of the course. In case lateral entry candidates are admitted, Merit Certificate shall be awarded on the basis of aggregate marks of the common years of study for both regular and lateral entry students.

Further Only those candidates who have completed the course and fulfilled all the requirements in the minimum number of years prescribed and who have passed each year in the first attempt are eligible for the award of ranks.

# 12PD11T: HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

1. Scope and Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

# Upon completion of the course the student shall be able to:

- 1. describe the structure (gross and histology) and functions of various organs of the human body;
- 2. describe the various homeostatic mechanisms and their imbalances of various systems;
- 3. identify the various tissues and organs of the different systems of the human body;
- 4. perform the hematological tests and also record blood pressure, heart rate, pulse and respiratory volumes;
- appreciate coordinated working pattern of different organs of each system;
- 6. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

#### 2. Course materials: Text books

- a) Gerard J. Tortora and Bryan Derrickson. Principles of anatomy and physiology, 14th ed.2013, HarperCollins College New York.
- b) Anne Waught & Allison Grant. Ross and Wilson's foundations of Anatomy and Physiology in Health and illness. 12<sup>th</sup> ed. 2014, Churchill Livingstone, Edinburg.

#### Reference books

- a) Guyton Arthur, C. *Physiology of human body*. 12<sup>th</sup>ed. 2010, Holtsaunders.
- b) Chatterjee, C.C. *Human physiology*. Volume I & II. 11<sup>th</sup> ed. 2016, medical allied agency, Calcutta.
- c) Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H. *Gray's anatomy*. 37<sup>th</sup> ed. Churchill Livingstone, London.
- d) K. Sembulingam & Prema Sembulingam, Medical Physiology, 6<sup>th</sup> ed.2014, Jaypee Brothers. Newdelhi.

# 3. Lecture wise program:

Topi	cs	Hrs
1.	Scope of anatomy and physiology, basic terminologies used in this	02
2.	subject (Description of the body as such planes and terminologies) General Physiology: Structure of cell - its components and their functions. Homeostasis, Mechanism of transport across cell membrane, Secondary messengers, Ion channels	04
3.	Elementary tissues of the human body: epithelial, connective, muscula and nervous tissues-their sub-types and characteristics	04
4.	<ul> <li>a) Osseous system - structure, composition and functions of the skeleton. (done in practical classes - 6hrs)</li> <li>b) Classification of joints, types of movements of joints and disorders (joints (Definitions only)</li> </ul>	01
5.	Haemopoetic system  a) Composition and functions of blood b) Haemopoesis and disorders of blood components (Definition only) c) Blood groups d) Clotting factors and mechanism e) Platelets and disorders of coagulation	05
6.	Lymph	04
7.	<ul> <li>a) Lymph and lymphatic system, composition, formation and circulatic</li> <li>b) Spleen: structure and functions, disorders</li> <li>c) Disorders of lymphatic system (Definition only)</li> <li>Cardiovascular system</li> <li>a) Anatomy and functions of heart</li> </ul>	06
	<ul> <li>b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)</li> <li>c) Electrocardiogram (ECG)</li> <li>d) Cardiac cycle and heart sounds</li> <li>e) Blood pressure - its maintenance and regulation</li> <li>f) Definition of the following disorders</li> <li>Hypertension, hypotension, arteriosclerosis, atherosclerosis, angina,</li> </ul>	
	myocardial infarction, congestive heart failure, cardiac arrhythmias	
8.	<ul> <li>Respiratory system</li> <li>a) Anatomy of respiratory organs and functions</li> <li>b) Mechanism / physiology of respiration and regulation of respiration</li> <li>c) Transport of respiratory gases</li> <li>d) Respiratory volumes and capacities, and definition of: hypoxia, asphyxia, oxygen therapy and resuscitation.</li> </ul>	05
9.	Digestive system  a) Anatomy and physiology of GIT  b) Anatomy and functions of accessory glands of GIT  c) Digestion and absorption d) Disorders of GIT (Definitions only)	06

10.	Nervous system	08
	a) Definition and classification of nervous system.	
	b) Synapse and neurotransmitter, ménages, ventricles of the brain and	
	CSF	
	c) Anatomy, physiology and functional areas of cerebrum	
	d) Anatomy and physiology of cerebellum	
	e) Anatomy and physiology of mid brain	
	f) Thalamus, hypothalamus and basal ganglia	
	g) Spinal card: Structure & reflexes - mono-poly-planter	
	h) Cranial nerves - names and functions	
	i) ANS - Anatomy & functions of sympathetic & parasympathetic N.S.	
11.	<u>Urinary system</u>	05
	a) Anatomy and physiology of urinary system	
	b) Formation of urine	
	c) Renin angiotensin aldosterone system - Juxtaglomerular apparatus -	
	acid base balance	
	d) Clearance tests and micturition	
12.		06
	a) Pituitary gland	
	b) Adrenal gland	
	c) Thyroid and Parathyroid glands	
_	d) Pancreas and gonads	
13.	Reproductive system	07
	a) Male and female reproductive system organs anatomy and physiolog	
	b) Their hormones - physiology of menstruation	
	c) Spermatogenesis & Oogenesis	
	d) Sex determination (genetic basis)	
	e) Pregnancy & maintenance. Parturition	
	f) Contraceptive devices	
14.		06
	a) Eye	
	b) Ear	
	c) Skin	
4 -	d) Tongue & Nose	00
15.	Skeletal muscles	03
	a) Histology	
	b) Physiology of Muscle contraction	
	c) Physiological properties of skeletal muscle and their disorders	
47	(Definitions only)	02
16	Sports physiology	03
	a) Muscles in exercise, Effect of athletic training on muscles and musc	
	performance, b) Perpiration in eversion CVS in eversion hadve heat in eversion had	
	b) Respiration in exercise, CVS in exercise, body heat in exercise, body	
	fluids and salts in exercise,	
	c) Drugs and athletics	

# 12PD11P: HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical: 3 Hrs/Week 75 Hours

**General Requirements:** Laboratory napkin, muslin cloth, record, observation book (100pages), stationery items, and blood lancet.

# Course materials: Textbooks

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, 2011 B.S Shah Prakashan, Ahmedabad.

# Reference books

- 1. Ranade VG, Textbook of practical physiology, 4<sup>rd</sup> edition, PVG, Pune
- 2. Anderson Experimental Physiology, Latest edition, Publisher: NA

# List of Experiments:

- 1. Study of a compound microscope.
- 2. Study of tissues of the human body
  - a) Epithelial tissue.
  - b) Muscular tissue.
- 3. Study of tissues of the human body
  - a) Connective tissue.
  - b) Nervous tissue.
- 4. Study of appliances used in hematological experiments.
- 5. Determination of total WBC count of blood.\*\*
- 6. Determination of total RBC count of blood.\*\*
- 7. Determination of differential leukocyte count of blood.\*
- 8. Determination of
  - a) Erythrocyte Sedimentation Rate. (ESR)\*
  - b) Hemoglobin content of blood.\*
  - c) Bleeding time & clotting time.\*
- 9. Determination of
  - a) Blood pressure.
  - b) Blood group.\*
- 10. Study of various systems with the help of charts, models & specimens
  - a) Skeleton system part I-axial skeleton.
  - b) Skeleton system part II- appendicular skeleton.
  - c) Cardiovascular system.
  - d) Respiratory system.
  - e) Digestive system.
  - f) Urinary system.
  - g) Nervous system.
  - h) Special Senses.
  - i) Reproductive system.
- 11. Study of different family planning appliances.
- 12. Study of pregnancy diagnosis test.
- 13. Study of appliances used in experimental physiology.
- 14. Study of record of simple muscle curve using gastroenemius sciatic nerve

- preparation.
- 15. Study of simple summation curve using gastroenemius sciatic nerve preparation.
- 16. Study of simple effect of temperature using gastroenemius sciatic nerve preparation.
- 17. Study of simple effect of load & after load using gastroenemius sciatic nerve preparation.
- 18. Study of fatigue curve using gastroenemius sciatic nerve preparation.

# Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment**	07	20
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).

# 12PD12T: PHARMACEUTICS (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope and objectives: This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

# Upon the completion of the course the student should be able to:

- 1. know the formulation aspects of different dosage forms;
- 2. do different pharmaceutical calculation involved in formulation;
- 3. formulate different types of dosage forms; and
- 4. appreciate the importance of good formulation for effectiveness.

# 2. Course materials:

# Text books

- a) Carter S.J, Cooper and Gunn's Dispensing for Pharmaceutical Students. 12ed. 2008, CBS Publishers & Distributors Pvt. Ltd.
- b) N.K.Jain and S.N.Sharma, A textbook Professional Pharmacy, 6<sup>th</sup> ed. 2016, Vallabha Prakashan, New Delhi.

# Reference books

- a) Introduction to Pharmaceutical dosage forms by Howard C. Ansel.3<sup>rd</sup>.ed, 1981
- b) Remington's Pharmaceutical Sciences. Vol 1-3, 22<sup>th</sup> ed. 2010
- c) Register of General Pharmacy by Cooper and Gunn. Popular Prakashan
- d) General Pharmacy by M.L. Schroff. Five Stars Enterprises

# 3. Lecture wise programme:

06
03
03
03
03
03
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06

Stabilizers, with examples. Study of Monophasic liquids (formulation aspects and examples) like gargles, mouthwashes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions. 7. Biphasic dosage forms: Suspensions and emulsions, Definition, 06 and disadvantages, classification and formulation of Suspensions and Emulsions. Test for the type of emulsion and stability problems in emulsions. 8. Suppositories: Definition, advantages and disadvantages, types of 03 base, a method of preparation, Displacement value and evaluation. 9. Galenicals: Definition, different extraction processes like infusion, 06 Decoction, Maceration and Percolation. Study of Maceration and Percolation processes 10. Surgical aids: Surgical dressings, sutures, ligatures and preparation of 04 surgical catgut. 11. Incompatibilities: Introduction, classification, Examples, and method 02 to overcome Physical and therapeutic incompatibilities.

# 12PD12P: PHARMACEUTICS (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

# List of Experiments:

# 1. Syrups

- a) Simple Syrup I.P
- b) Syrup of Ephedrine Hydrochloride NF
- c) Orange Syrup
- 2. Elixir
- a) Piperizine citrate elixir BP
- b) Paracetamol elixir BPC
- 3. Linctus
- a) Simple linctus BPC
- b) Pediatric simple linctus BPC
- 4. Solutions
- a) Solution of cresol with soap IP
- b) Aqueous Iodine Solution IP
- c) Strong solution of Iodine IP
- d) Strong solution of ammonium acetate IP
- 5. Liniments
- a) Liniment of turpentine IP\*
- b) Liniment of camphor IP
- 6. Suspensions\*
- a) Calamine lotion
- b) Magnesium Hydroxide mixture BP
- 7. Emulsions\*
- a) Cod liver oil emulsion
- b) Liquid paraffin emulsion
- 8. Powders<sup>1</sup>
- a) Eutectic powder
- b) Dusting powder
- c) Insufflations
- 9. Suppositories
- a) Boric acid suppositories
- b) Chloral suppositories

# 10. Incompatibilities

- a) Preparations having with Physical Incompatibilities (3 Nos)
- \* Colorless bottles required for dispensing Paper envelope (white), butter paper and white paper required for dispensing.

# 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).

# 12PD13T: MEDICINAL BIOCHEMISTRY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

Scope and Objectives: Biochemistry deals with complete understanding of the
molecular level of the chemical process associated with living cells in normal
and abnormal state. Clinical chemistry deals with the study of chemical
aspects of human life in health and illness and the application of chemical
laboratory methods to diagnosis, control of treatment and prevention of
diseases.

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy.

### Upon completion of the course student shall be able to -

- 1. understand the catalytic activity of enzymes and importance of enzymes in diagnosis of diseases and therapeutic agents;
- 2. know the metabolic pathways of biomolecules in health and illness (metabolic disorders);
- 3. understand the genetic organization of mammalian genome, protein synthesis, replication, mutation and repair mechanism.
- 4. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- 5. do the qualitative analysis and determination of biomolecules in the body fluids and their clinical significance.

### 2. Course Materials:

# Textbooks (Theory)

- a. Harper's Illustrated of biochemistry Robert K. Murray, Darryl K. Granner, Peter A. Mayes, 18<sup>th</sup> ed., 2003. Lange.
- b. Satyanarayana U and Chakrapani U, Biochemistry, 4<sup>th</sup> ed. 2016, Elsevier India PVT. LTD, Newdelhi
- c. Text book of clinical chemistry- Alex Kaplan &Laverve L.Szabo, 4<sup>th</sup> ed.1995, Williams and Wilkins Co.,

# Reference books (Theory)

- a. Principles of biochemistry Lehninger, 6<sup>th</sup> ed, 2014, W.H.Freeman and Co., New York
- b. Text book of biochemistry Ramarao, 2009, L.K and S. Publisher
- c. Practical Biochemistry-David T.Plummer.3<sup>rd</sup>. ed. 2014, Tata McGraw Hill Education Pvt. Ltd.
- d. Practical Biochemistry-Pattabhiraman.4<sup>th</sup> ed. 2015,All India Publisher and Distributers,

# 3. Lecture wise programme:

Topi		Hrs
1.	Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.	05
2.	Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.	10
3.	Carbohydrate metabolism: Glycolysis, citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, glycogenesis gluconeogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose tolerance test and its significance; hormonal regulation of carbohydrate metabolism.	11
4.	<b>Lipid metabolism:</b> Oxidation of saturated fatty acid; Ketogenesis and ketolysis; biosynthesis of fatty acids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).	09
5.	<b>Biological oxidation:</b> Enzymes and Coenzyme system involved in Biologicaloxidation. Electron transport chain (its mechanism in energy capture, regulation and inhibition); Oxidative phosphorylation and uncouplers of ETC.	04
6.	Protein and amino acid metabolism: protein turn over; nitrog balance; general reactions of catabolism of amino acid: (Tranamination deamination & decarboxylation). Urea cycle and metabolic disorders; production of bile pigment hyperbilirubinemia, porphorias, jaundice. Metabolic disorder Amino acids.	80
7.	<b>Nucleic acid metabolism:</b> Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; DNA damage and repair mechanism; DNA replication (semi conservative).	12
8.	The kidney function tests: Role of kidney; Laboratory tests for normal function includes- a) Urine analysis (macroscopic and physical examination, quantitative and semi quantitative tests.) b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood/urine creatinine, urea and uric acid) c) Urine concentration test d) Urinary tract calculi. (stones)	04
9.	Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.  a) Test for hepatic dysfunction-Bile pigments metabolism.	04

- b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
- c) Dye tests of excretory function.
- d) Tests based upon abnormalities of serum proteins.
- e) Selected enzyme activity determination tests.
- 10. **Lipid profile tests:** Lipoproteins, composition, functions. Determinatic of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 11. Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases. Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA).
- 12. **Electrolytes:** Body water, compartments, water balance, and electroly 03 distribution, Determination of sodium, calcium in the body fluids.

# 12PD13P: MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical: 3 Hrs. /Week 75 Hours

# Title of the Experiment:

- 1. Qualitative analysis of normal constituents of urine\*.
- 2. Qualitative analysis of abnormal constituents of urine\*.
- 3. Quantitative estimation of urine chlorides by Volhard's method\*\*.
- 4. Quantitative estimation of urine sugar by benedicts quantitative reagent method\*\*
- 5. Quantitative estimation of urine creatinine by Jaffe's method\*\*.
- 6. Quantitative estimation of urine calcium by precipitation method\*\*.
- 7. Quantitative estimation of serum cholesterol\*\*.
- 8. Preparation of Folin Wu filtrate from blood\*.
- 9. Quantitative estimation of blood creatinine\*\*.
- 10. Quantitative estimation of blood sugar Folin-Wu tube method\*\*.
- 11. Estimation of SGOT in serum\*\*.
- 12. Estimation of SGPT in serum\*\*.
- 13. Estimation of Urea in Serum\*\*.
- 14. Estimation of Proteins in Serum\*\*.
- 15. Determination of serum bilirubin\*\*
- 16. Determination of Glucose by means of Glucoseoxidase\*\*.
- 17. Enzymatic hydrolysis of Glycogen/Starch by Amylases\*\*.
- 18. Study of factors affecting Enzyme activity\*\*. (pH & Temp.)
- 19. Preparation of standard buffer solutions and its pH measurements (any two)\*

### 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).

# 12PD14T: PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

- **1. Scope and objectives:** This course is designed to impart a very good knowledge about
  - a) IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
  - b) Some important physical properties of organic compounds;
  - nucleophyllic radical/ [alkyl/ acvl/ / electrophyllic electrophyllic substitution free radical/ nucleophyllic addition, / oxidation and reduction elimination, reactions with mechanism, orientation the reaction, order of reactivity, stability of of compounds;
  - d) Some named organic reactions with mechanisms; and
  - e) Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

### 2. Course materials:

### Text books

- a. T.R. Morrison and R. Boyd Organic chemistry, 7<sup>th</sup> ed., 2012, Pearson Prentice Hall, Noida
- b. Bentley and Driver-Text book of Pharmaceutical chemistry, 8<sup>th</sup> ed. 2007, Oxford University Press, New York
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry, 6<sup>th</sup> ed. 2014, Pearson,

### Reference books

- a. Organic chemistry J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown, 8<sup>th</sup> ed. 2018, John wiley and sons Inc.
- c. Advanced organic chemistry- Jerry March, Wiley, 7<sup>th</sup> ed., 2013, Wiley India Pvt.Ltd, Newdelhi.
- d. Organic chemistry- Cram and Hammered, Pine Hendrickson, 5<sup>th</sup> ed., 2012, Tata Mc Graw Hill Publishing Pvt Ltd. Newdelhi

# 3. Lecture wise programme:

Topics Hrs

05

- 1. Structures and Physical properties:
  - a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion airs,
  - b. Acids and bases, Lowry bronsted and Lewis theories
  - c. Isomerism
- 2. Nomenclature of organic compound belonging to the following 08 classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides and Cycloalkanes.

- 3. Free radicals chain reactions of alkane: Mechanism, relative 02 reactivity and stability
- 4. Alicyclic compounds: Preparations of cyclo alkanes, Bayer strain 04 theory and orbital picture of angle strain.
- 5. Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN<sub>2</sub> reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, SN2 versus SN1.
- Dehydro halogenation of alkyl halides: 1,2 elimination, kinetic 6. 05 E2 and E1 mechanism, elimination via carbocation, evidence for mechanism, absence of rearrangement isotope effect, hydrogen exchange, the element effect, orientation E1, reactivity, E2 versus elimination versus substitutio dehydration of alcohol, ease of dehydration, acid catalys reversibility, orientation.
- 7. Electrophillic and free radicals addition: Reactions at carbon-06 double bond, electrophile, hydrogenation, heat of carbon. hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, orientation and reactivity, addition of halogen, rearrangement, mechanism, halohydin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- 8. Carbon-carbon double bond as substituents: Free radical 04 halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

05

- 9. Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals. conjugation, allyl cation as a resonance nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4 addition, 1,2-versus 1,4-addition, rate versus orientation and reactivity of free radical addition to conjugated dienes.
- 10. Elecrophilic aromatic substitution: Effect of substituent groups, 06 determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration,

acylation, reactivity and orientation, activating and deactivatir O,P,M directing groups, electron release via resonance, effect o halogen on electrophilic aromatic substitution in alkyl benzenside chain halogination of alkyl benzene, resonance stabilization of benzvl radical. 11. Nucleophilic addition reaction: Mechanism, ionisation of 05 carboxylic acids, acidity constants, acidity of acids, structure carboxylate ions, effect of substituent on acidity, nucleophilic ac substitution reaction, conversion of acid to acid chloride, esters, an and anhydride. Role of caboxyl group, comparison of alkyl nucleophi substitution with acyl nucleophilic substitution. Mechanism of aldol condensation, claisen condensation, cannizz 05 reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition. 13. Hoffman rearrangement: Migration to electron deficient nitrogen, 04 Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions. Nucleophilic aromatic substitution: Bimolecular displacement 03 mechanisms, orientation, comparison of aliphatic nucleophilic

Study of the following official compounds- preparation, test for puri

assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic ac aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimeth pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

02

05

substitution with that of aromatic.

Oxidation reduction reaction with examples

12.

15.

sulphonation, halogenation, friedel craft alkylation, friedel craft

# 12PD14P: PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

- I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):
  - 1. Acetanilde / aspirin (Acetylation)
  - 2. Benzanilide / Phenyl benzoate (Benzoylation)
  - 3. P-bromo acetanilide / 2,4,6 tribromo aniline (Bromination)
  - 4. Dibenzylidene acetone (Condensation)
  - 5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
  - 6. Benzoic acid / salicylic acid (Hydrolysis of ester)
  - 7. M-dinitro benzene (Nitration)
  - 8. 9, 10 Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
  - 9. M-phenylene diamine (Reduction of M-dinitrobenzene)/Aniline from nitrobenzene
  - 10. Benzophenone oxime
  - 11. Nitration of salicylic acid
  - 12. Preparation of picric acid
  - 13. Preparation of O-chlorobenzoic acid from O-chlorotolune
  - 14. Preparation of cyclohexanone from cyclohexanol
  - II. Identification of organic compounds belonging to the following classes by: Systematic qualitative organic analysis including preparation of derivatives phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones,

alcohols, esters, hydrocarbons, anilides, nitrocompounds.

### III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

### 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).

# 12PD15T: PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

Theory: 2 hrs/Week 50 Hours

1. Scope and objectives: This course mainly deals with fundamentals of analytical chemistry and also the study the Inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

Upon completion of course student shall be able to:

- 1. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceutical;
- 2. know the analysis of the inorganic pharmaceuticals their applications
- 3. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

### 2. Course materials:

#### Text books

- a. A.H.Beckett & J.B. Stenlake's -Practical Pharmaceutical Chemistry Vol I
- & II, Stahl one Press of University of London, 4th edition. 2007
- b. Text Book of Quantitative Inorganic analysis by Vogel, 10<sup>th</sup> ed. 2014, Pearson
- c. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao, 3<sup>rd</sup>, ed. 2017, Nirali prakashan, Newdelhi.

### Reference books

- a. A text book of Inorganic medicinal Chemistry by Surendra N. Pandey. 2011, K.G. Publisher, Varanasi
- b. Inorganic pharmaceutical Chemistry by M.L Schroff
- c. Bentely and Driver's Textbook of Pharmaceutical chemistry, 8<sup>th</sup> Ed., 2007 Oxford University Press, Newyork
- d. Pharmaceutical Analysis Vol I, Dr. A.V. Kasture et al., Nirali Prakashan, 13 Edition. 2016
- e. Inorganic Pharmaceutical Chemistry by Anand & Chatwal.5<sup>th</sup> ed. 2017, Himalaya Publication House, Mumbai
- f. Analytical chemistry principles by John H. Kennedy.3rd ed.
- g. Indian Pharmacopoeia 2018, 8th Edition (4 Volumes) . Govt. of India, Ministry of Health

# Lecture wise programme:

Topi	cs	Hrs
1.	Sources of errors, types of errors, methods of minimizing errors,	02
2.	accuracy, precision and significant figures.	04
۷.	Fundamentals of volumetric analysis, theories of indicators and methods of expressing concentrations. Primary and secondary	04
	standard. Preparation and standardization of various volumetic	
	solutions like sodium hydroxide, hydrochloric acid and sodium	
	thiosulphate.	
3.	Acid base titration: Classification and estimation of strong, weak, and	02
4	very weak acids and bases.	
4.	Principles of redox titrations: Concepts of oxidation and reduction.	03
	Redox reactions, strength and equivalent weights of oxidizing and reducing agents, theory of redox titrations, cerrimetry,	
	lodimetry, lodometry, bromometry, titrations with potassium	
	iodate	
5.	Non aqueous titration: Introduction to solvents, classification and	02
	estimation of Sodium benzoate.	
6.	<b>Principles of precipitation titrations:</b> Different methods-Mohr's,	03
	Modified Mohr's, Volhard's, Modified Volhard's, Fajans with example.	
7	Estimation of sodium chloride by modified volhards method.	02
7.	<b>Complexometric titration and its classification:</b> Estimation of Calcium Gluconate by complexometric method. Metal io n	03
	indicators.	
8.	<b>Gravimetry:</b> Introduction to gravimetric method, steps involved in	02
	gravimetric method, precipitants and estimation of Barium sulphate by	
	gravimetric method.	
9.	Limit test: Source and effect of impurities in pharmacopoeial	06
	substances, importance of limit test, general principle and procedures	
	for limit test, limit test for chloride, sulphate, iron, arsenic and lead and heavy metals. Special procedure for limit test for chloride and	
	sulphate	
	General methods of preparation, assays*, storage condition and	
	Medicinal uses of inorganic compounds belonging to the following	
	classes.	
4.0		•
10.	Medicinal gases: Oxygen, Nitrous oxide, Carbon dioxide	01
11. 12.	Acidifies: Dil HCl Antacid: Aluminum hydroxide gel, sodium bicarbonate*,	01 03
12.	Magnesium triisilicate, Magnesium carbonate (Light and Heavy),	U.S
	Magnesium hydroxide mixture*, Preparation containing combination of	
	antacids.	
13.	Cathartics: Magnesium sulphate*, Sodium orthophosphate	01
14.	Major extra and intracellular electrolytes: Functions of major	04
	physiological ions, Electrolytes used in the replacement therapy:	
	Sodium chloride*, Sodium chloride Injection, Sodium chloride	

Hrs

	compound injection, Potassium chloride, Potassium chloride injection, Calcium Gluconate and Electrolyte combination therapy and ORS, Physiological acid base balance.	
15.	, ,	01
16.	Antimicrobials: Potassium permanganate*, Hydrogen peroxide*,	03
	Chlorinated lime*, Iodine and its preparations, Boric acid*.	
17.	<b>Pharmaceutical aids:</b> Bentonite, sodium metabisulphite, Barium sulphate	01
18.	<b>Dental products:</b> Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium	02
	fluoride, Stannous fluoride, Zinc Eugenol cement.	
19.	Miscellaneous compounds:	04
	i) Expectorants: Potassium iodide*, Ammonium Chloride*	
	ii) Haematinics: Ferrous sulphate*, Ferrous gluconate, Ferrous fumarate,	
	iii) Emetics: Copper sulphate*, Sodium potassium tartarate	
	iv) Poison and Antidote: Sodium thoisulphate, Activated charcoal	
20.	Radiopharmaceuticals: Radio activity, natural radio activity and	02
	artificial radio activity. Measurement of radioactivity, $\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$	
	β, γ radiations, Half life, radio isotopes and study of radio isotopes	
	sodium iodide I-121, Ferric citrate Fe-59. Storage conditions, precautions	
	& pharmaceutical application of radioactive substances.	

# 12PD15P: PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hours/week 75 Hours

(Following experiments to be covered in 25 different practical classes)

- 1. Limit tests (7 exercises) \*
  - 1. Limit test for chlorides
  - 2. Limit test for sulphate
  - 3. Limit test for Iron
  - 4. Limit test for heavy metals
  - 5. Limit test for Arsenic
  - 6. Modifications in limit tests for chloride and sulphates in potassium permanganate,

sodium bicarbonate, sodium benzoate and sodium Salicylate.

- 2. Preparation and standardization of the following (3 exercises)\*.
  - 1. 0.IN NaOH
  - 2. 0.IN KMnO4
  - 3. 0.IN Cerric ammonium sulphate
  - 4. 0.IN HClO4
  - 5. 0.05M Di sodium EDTA
  - 6. 0.IN Sodium thiosulphate
- 3. Assay of the following compounds \*\*
  - 1. Ammonium chloride-acid base titration (Formal titration)
  - 2. Ferrous sulphate- (redox) Ceric ammonium sulphate titration
  - 3. Copper sulphate- (redox) Iodometry
  - 4. Calcium gluconate-complexometry
  - 5. Hydrogen peroxide- (redox -Permanganometry)
  - 6. Sodium benzoate-nonaqueous titration
  - 7. Sodium chloride-Modified Volhard's method
  - 8. Assay of KI-KIO<sub>3</sub> titration
  - 9. Assay of Zinc oxide (acid base back titration)
- 4. Test for identify for the following (2 exercises)\*

Sodium bicarbonate

Ferrous sulphate

Potassium iodide.

Calcium chloride

- 5. Test for purity for the following (2 exercises)\*
  - 1. Swelling power in Bentonite
  - 2. Ammonium salts in Potash alum.
  - 3. Presence of lodates in KI
- 6. Preparation of inorganic pharmaceuticals (2 exercises)\*
  - 1. Boric acid
  - 2. Potash alum
  - 3. Magnesium hydroxide.
  - 4. Magnesium sulphate

Scheme of Practical Examination	Sessional	Annual
Synopsis	05	15
Major Experiment(Experiment indicated by**)	10	25
Minor Experiment(Experiment indicated by*) 1&2	3	20
Viva-Voce	2	10
Max. Marks	20	70
Duration	03 hrs	04 hrs

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

# 12PD16T: REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

### **REMEDIAL MATHEMATICS:**

- **1. Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform. Upon completion of the course the student shall be able to:
  - Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
  - 2. solve the problems of different types by applying theory; and
  - 3. appreciate the important applications of mathematics in pharmacy.

### 2. Course materials:

### Text books

a. Differential calculus By Shantinarayan

b.Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

#### Reference books

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loncy

### 3. Lecture wise programme:

Topics Hrs

- 1. Matrices : Definition, Addition, Subtraction Algebra and 18 Multiplication of matrices, Determinants: Determinants of order two and three, Properties of determinants (without Proof). Inverse of square Matrices, Adjoint of square matrix, Solution of linear equation by Matrix method, Cramer's rule, Characteristic equation, Theorem Statement Cayley-Hamilton (Without of Proof) Pharmaceutical examples
- 2. **Trigonometry**: Relation between Sides and angles of a triangle, 05 solution of triangles Simple problems
- 3. Analytical Geometry: Points, Straight line, Types of straight lines Y= 15 mx + c, (y-y1) = m\*(x-x1), (y-y1) = ((y2-y1)/(x2-x1))\*(x-x1) Parallel and Perpendicular straight lines, Angle between two lines, Perpendicular distance from a point to theline, distance between parallel lines, Circle: General equation of circle, finding centre and radius of the circle, Parabo la: Equation of the parabola y2= 4ax, Simple problems
- 4. **Differential calculus:** Function, Limit, Differentiation, 16 Differentiation of sum, Product, Quotient, Composite, Parametric,

- exponential, trigonometric and Logarithmic function. Successive differentiation, simple problems.
- 5. **Integral Calculus:** Partial fractions, Definition of integration, 07 integration bysubstitution and integration by parts, Properties of definite integrals, Simple problems.
- 6. **Differential equations:** Definition, order, degree, variable separable, 10 homogeneous differential equation, linear differential equation, exact differential equation, Simple problems
- 7. **Laplace transform:** Definition, Laplace transform of elementary 04 functions, linearity and shifting property, simple problems

### **REMEDIAL BIOLOGY:**

1. Scope and objectives: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

### 2. Course materials:

#### Text books

- a. Textbook Of Pharmaceutical Biology, SB Gokhale CK Kokate, Vikash Gupta, 7<sup>th</sup> ed. Nirali Prakashan,
- b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

#### Reference books

- a. A Text book of Biology by B.V.Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C. Dutta.
- d. Outlines of Zoology by M. Ekambaranatha ayyer and T.N. Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B.Gokhale and
- C.K.Kokate, 7th ed. 2012, Nirali Prakahsan, Pune.

### 3. Lecture wise programme:

### PART - A

Topics		Hrs
1.	Introduction	02
2.	General organization of plants and its inclusions	04
3.	Plant tissues	04
4.	Plant kingdom and its classification	04
5.	Morphology of plants	04
6.	Root, Stem, Leaf and Its modifications	05
7.	Inflorescence and Pollination of flowers	04
8.	Morphology of fruits and seeds	04
9.	Plant physiology	04

10.	, ,	umbelliferae,	Solanaceae,	Lilliaceae,	06
	Zinziberaceae, Rubiaceae				
11.	Study of Fungi, Yeast, Penicillin	and Bacteria			04
PAR	Г-В				
Top	ics				Hrs
1.	Study of Animal cell				04
2.	Study animal tissues				04
3.	Detailed study of frog				80
4.	Study of Pisces, Reptiles, Aves				05
5.	General organization of mamma	ls			05
6.	Study of poisonous animals				04

# 12PD16P: REMEDIAL BIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

### Title of Experiments

- 1. Introduction of biology experiments (section cutting techniques, Mounting and staining, permanence slide preparation and Microscope)
- 2. Study of cell wall constituents and cell inclusions
- 3. Study of Stem modifications
- 4. Study of Root modifications
- 5. Study of Leaf modifications
- 6. Identification of Fruits and seeds
- 7. Preparation of Permanent slides
- 8. Simple plant physiological experiments
- 9. Identification of animals
- 10. Detailed study of Frog by using computer models
- 11. Computer based tutorials

### Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

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

# 12PD17T: CONSTITUTION OF INDIA (THEORY)

Theo	ry: 2 Hours per week  SYLLABUS	50 Hours
UNIT		
1.	Constitution of India  a. An introduction to Indian Polity  b. Meaning and importance of Constitution  c. Making of the Indian constitution - The Constituent Assembly  d. Salient features of the Indian Constitution  e. Preamble of the Indian Constitution and its significance	10 Hours
2.	Fundamental Rights and Directive Principles a. Fundamental Rights b. Directive Principles of the State Policy c. Fundamental Duties	08 Hours
UNIT 1.	<ul> <li>II</li> <li>Government of the Union</li> <li>a. The Union Executive- the President and the Vice-President- The Council of Ministers and the Prime Minister</li> <li>b. The Union Legislature - The Parliament- The Lok Sabha and the Rajya Sabha, composition, Powers and functions</li> <li>c. Important Committees -Privileges</li> <li>d. the Role of the Speaker</li> </ul>	06 Hours
2.	Government of the States  a. The Governor- The Council of Ministers and the Chief Minister  b. The State Legislature- composition powers and functions	06 Hours
3.	Democratic decentralization or Panchayath Raj in India	02 Hours
UNIT 1.	<ul> <li>III</li> <li>Federation in India</li> <li>a. Federal Features Indian federalism, Centre-State relations-distribution of legislative powers, Administrative and financial relations between the Union and the States</li> <li>b. The Finance Commission, The Planning Commission, National Development Council</li> <li>c. Military Features</li> </ul>	06 Hours
2.	<ul> <li>The Judiciary</li> <li>a. The Supreme Court - Organization, Jurisdiction and Role</li> <li>b. The High Court - Organization, Jurisdiction and Role</li> <li>c. Judicial Review, Judicial activism, Independence of Judiciary in India</li> </ul>	04 Hours

### **UNIT - IV**

- 1. Electoral Process in India Election Commission, Organization 04 Hours and Functions
- 2. Local Governments Rural and Urban Organization, Powers 04 Hours and Role

### **Books for Reference:**

- 1. D.D. Basu: Introduction to the Constitution of India, S C Sarkar & Sons, Kolkatta
- 2. M V Pylee: An Introduction to the Constitution of India, Vikas Publishing House Pvt Ltd, 2009
- 3. Granville Austin: The Indian Constitution. The Cornerstone of a Nation, Oxford University Press, New Delhi, 1966
- 1. C K Jain (ed): Constitution of India in Precept and Practice, Lok Sabha Secretariat, New Delhi
- 4. V.N. Shukla: Constitution of India, Jain Book Depot, New Delhi
- 5. Granville Austin: The working of a Democratic Constitution: The Indian Experience, New Delhi, Oxford University Press, New Delhi 1999
- 6. J C Johari: Indian Politics, Vishal Publications, Jalandhar
- 7. A P Avasthi: Indian Government and Politics, Lakshmi Narain Agarwal, Agra
- 8. Anup Chand Kapur: Indian Government and Politics, S. Chand and Company, New Delhi
- 9. V D Mahajan: The Constitution of India. S. Chand and Company, New Delhi.
- 10. J N Pandey: Constitution Law of India, Allahabad, Central Law Agency, 1998
- 11. J C Johari: The Constitution of India A Politico-Legal Study- Sterling Publication Pvt. Ltd. New Delhi
- 12. R C Agrawal: Constitutional Development and national Movement of India, S Chand & Co., New Delhi
- 13. M Hidayatullah: Democracy in India and the Judicial Process, Metropolitan, New Delhi
- 14. K C Markandan: Directive Principles in the Indian Constitution, Allied Publishers, Mumbai
- 15. Bidyut Chakrabarty and Rajendra Kumar Pandey: Indian Government and Politics, SAGE Publications New Delhi
- 16. India A Politico-Legal Study- Sterling Publication Pvt. Ltd, New Delhi

# 12PD21T: PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

**1. Scope and Objectives:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

Upon completion of the course student shall be able to -

- 1. Describe the etiology and pathogenesis of the selected disease states;
- 2. Name the signs and symptoms of the diseases; and
- 3. Mention the complications of the diseases.

# 2. Course Materials: Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins Elsiver India Pvt Ltd, Newdelhi, 2015, ed. 9 vol. 1-2
- b. Text book of Pathology- Harsh Mohan, 7<sup>th</sup> ed. 2015, Jaypee Brothers Medical Publishers (P) Ltd., New Delhi,
- c. Text book of Pathology- Y.M. Bhinde

# Reference books (Theory)

a. Clinical Pharmacy and Therapeutics; 5<sup>th</sup>.ed. 2012; Walker & Whittlesea, Churchill Livingstone publication

# 3. Lecture wise Programme:

Тор	ics	Hrs
1.	Basic principles of cell injury and Adaptation a) Causes, Pathogenesi s and morphology of cell injury b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen storage diseases	05
2.	Inflammation  a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation  b) Papairs of wounds in the skip, factors influencing healing of wounds.	05
3.	b)Repairs of wounds in the skin, factors influencing healing of wounds  Diseases of Immunity  a) Introduction to T and B cells  b) MHC proteins or transplantation antigens	10
	c) Immune tolerance - Hypersensitivity	
	Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs - Autoimmunity	

Criteria for autoimmunity, Classifications of autoimmune diseases

4.	in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.  - Acquired immune deficiency syndrome (AIDS)  - Amylodosis  Cancer	05
7.	Differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.	03
5.	Shock	03
	Types of shock, mechanisms, stages and management	
6.	Biological effects of radiation	02
7.	Environmental and nutritional diseases	04
	<ul> <li>i) Air pollution and smoking- SO2,NO, NO2, and CO</li> <li>ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation</li> </ul>	
8.	Pathophysiology of common diseases	30
	Parkinsonism Salainan hannia	
	Schizophrenia Depression and mania	
	Hypertension	
	Stroke (ischemic and hemorrhage)	
	Angina, CCF, Atherosclerosis, Myocardial infarction	
	Diabetes Mellitus  Pentis ulser and inflammatory boycel diseases	
	Peptic ulcer and inflammatory bowel diseases Cirrhosis and Alcoholic liver diseases	
	Acute and chronic renal failure	
	Asthma and chronic obstructive airway diseases	
9.	Infectious diseases:	11
	Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract	
	infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria, Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.	
	bysencery (bacteriat and ambebie), riepatitis- infective nepatitis.	
	Assignments:	
	1 Chemical Mediators of inflammation	
	<ul><li>2 Drug Hypersensitivity</li><li>3 Cigarette smoking &amp; its ill effects</li></ul>	
	4 Biological Effects of Radiation	
	5 Etiology and hazards of obesity	
	6 Complications of diabetes	
	7 Diagnosis of cancer	
	8 Disorders of vitamins	

- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

# 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.

# 12PD22T: PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

**1. Scope & Objectives:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. Its also discusses with sterilization of pharmaceutical products, equipment, media etc.

The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

Upon completion of the course student shall be able to

- 1. Know the anatomy, identification, growth factors and sterilization of microorganisms;
- 2. Know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- 3. Do estimation of RNA and DNA and there by identifying the source;
- 4. Do cultivation and identification of the microorganisms in the laboratory;
- 5. Do identification of diseases by performing the diagnostic tests; and
- 6. Depreciate the behavior of motility and behavioral characteristics of microorganisms.

#### 2. Course Materials:

### Text books (Theory)

- a) Vanitha Kale and Kishor Bhusari "Applied Microbiology" Himalaya Publishing house Mumbai.3rd., 2015.
- b) Mary Louis Turgeon "Immunology and Serology in Laboratory Medicines" 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri.
- c) Harsh Mohan, "Text book of Pathology" 3rd edition, 1998, B-3 Ansari Road Daryaganj N. Delhi.

### Reference books (Theory)

- a) Prescot L.M., Jarley G.P Klein D.A "Microbiology" 2nd- edition Mc Graw Hill Company Inc.
- b) Rawlins E.A. "Bentley's Text Book of Pharmaceutics" Bailliere Tindals 24-28 London 1988.
- c) Forbisher "Fundamentals of Microbiology" Philadelphia W.B. Saunders. 9th ed.
- d) Prescott L.M. Jarley G.P., Klein D.A. "Microbiology." 2nd edition WMC Brown Publishers, Oxford. 1993.
- e) War Roitt, Jonathan Brostoff, David male, "Immunology"3rd edition 1996, Mosby-year book Europe Ltd, London.
- f) Indian Pharmacopoeia 2018, 8th Edition (4 Volumes). Govt. of India, Ministry of Health.

# 3. Lecture wise Programme:

Topi	ics	Hrs
1.	Introduction to the science of microbiology.	03
	Major divisions of microbial world and Relationship among them.	
2.	Morphology & Physiology of Microorganisms	07
	Different methods of classification of microbes and study of	
	Bacteria, Fungi, Virus, Rickettsiae, Spirochetes.	
3.	Growth & Nutrition	80
	Nutritional requirements	
	Growth and cultivation of bacteria and virus.	
	Culture Media for aerobic and anaerobic bacteria & fungi.	
	Maintenance of lab cultures.	
4.	Isolation and Identification of Bacteria	80
	Different methods-Staining reactions Biochemical reactions.	
	Counting of bacteria -Total and Viable counting techniques.	
5.	Sterilization	80
	Detailed study of different methods of sterilization with merits and	
	demerits. Sterilization methods for all pharmaceutical products.	
	Detailed study of sterility testing of different pharmaceutical	
,	preparations. Validation of various sterilization techniques.	07
6.	Disinfectants	07
	Study of disinfectants, antiseptics, fungicidal and virucidal agents.	
	Factors affecting their action and mechanism of action.	
	Evaluation of bactericidal, bacteriostatic, virucidal and preservatives in	
7.	pharmaceutical preparations.	12
7.	Immunology Definition, Classification, General principles of natural immunity,	ΙZ
	Phagocytosis, acquired immunity (active and passive).	
	Antigens, chemical nature of antigens structure and formation of	
	Antibodies, Antigen-Antibody reactions.	
	Bacterial exotoxins and endotoxins. Significance of toxoids in active	
	immunity, Immunization programme, and importance of booster dose.	
8.	Diagnostic tests	07
0.	Schick's Test, Elisa test, Western Blot test, Southern Blot PCR	07
	Widal, QBC, Mantaux Peripheral smear.	
	Study of malarial parasite.	
9.	Microbiological Assays	05
•	Microbial culture sensitivity Testing: Interpretation of results Principles	
	and methods of different microbiological assays. Microbiological assay	
	of Penicillin, Streptomycin and vitamin B2 and B12.	
	Standardization of vaccines and sera.	
10.	Study of infectious diseases	10
-	Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis,	-
	Syphilis & Gonorrhea and HIV	

# 12PD22P: PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical: 3 Hrs. /Week 75 Hours

### Title of the Experiment:

- 1. Study of apparatus used in experimental microbiology\*.
- 2. Sterilisation of glass ware's. Preparation and sterilisation of media\*
- 3. Staining techniques Simple staining; Gram's staining; Negative staining\*\*
- 4. Study of motility characters\*.
- 5. Enumeration of micro-organisms (Total and Viable)\*
- 6. Study of the methods of isolation of pure culture.\*
- 7. Bio chemical testing for the identification of micro\*-organisms.
- 8. Cultural sensitivity testing for some micro-organisms.\*
- 9. Sterility testing for powders and liquids.\*
- 10. Determination of minimum inhibitory concentration.\*
- 11. Microbiological assay of antibiotics by cup plate method.\*
- 12. Microbiological assay of vitamins by Turbidometric method\*\*
- 13. Determination of RWC.\*\*
- 14. Diagnostic tests for some common diseases, Widal, malarial parasite.\*\*

# Assignments:

- 1. Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
- 2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterization methods)

& study the activities and equipment/instruments used and reporting the same.

- 3. Library assignments
  - a. Report of recent microbial techniques developed in diagnosing some common diseases.
  - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

### Format of the assignment:

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

<sup>\*</sup> Indicate minor experiment & \*\* indicate major experiment

# Scheme of Practical Examination:

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

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

# 12PD23T: PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

# Theory: 3 Hours/Week 75 Hour

**1. Scope and objectives:** This subject has been introduced for the pharmacy course in order

to make the student aware of medicinal uses of various naturally occurring drugs their history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

# Upon completion of the course student shall be able to:

- 1. Understand the basic principles of cultivation, collection and storage of crude drugs
- 2. Know the source, active constituents and uses of crude drugs and
- 3. Appreciate the applications of primary and secondary metabolites of the plant.

### 2. Course materials:

#### Text books

- a. Pharmacognosy by G.E. Trease & W.C. Evans. 16<sup>th</sup> ed., 2009, Saunders Elsevier
- b. Pharmacognosy by C.K. Kokate, S.B. Gokhale & A.C. Purohit. 54<sup>th</sup> ed. 2017, Nirali Prakashan, Pune.

### Reference books

- a. Pharmacognosy by R. Brady & V.E. Tyler.9<sup>th</sup> ed.,1988, L E A and Febiger,
- b. Pharmacognosy by T.E. Wallis.5<sup>th</sup> ed. 2005, CBS Publishers and Distributors, New Delhi
- c. Pharmacognosy by C.S. Shah & J.S. Quadry.17<sup>th</sup> ed. 2014,B.S.shah Prakashan, Newdelhi.
- d. Pharmacognosy by M.A. Iyengar.11<sup>th</sup> ed. 2008, Manipal University, Manipal

### 3. Lecture wise programme:

Top	ics	Hrs
1.	Introduction.	01
2.	Definition, history and scope of Pharmacognosy	02
3.	Classification of crude drugs viz. alphabetical, morphological, taxonomical, chemical, pharmacological, and chemotaxonomical methods.	03
4.	Cultivation, collection, processing and storage of crude drugs. Conservation of medicinal plants.	06
5.	Detailed methods of cultivation, collection and storage of following crude drugs.	07
	a) Senna b) Cinchona c) Cardamom d) Opium e) Isapgol f) Ergot h) Ginger	
6.	Study of cell wall constituents and cell inclusions.	02
7.	Study of morphology and microscopy of different plants parts i. Leaf: Datura, Senna	10

	<ul> <li>ii. Bark: Cinnamon (Cassia), Cinchaona</li> <li>iii. Wood: Quassia</li> <li>iv. Stem: Ephedra</li> <li>v. Root: Rauwolfia, Liquorice</li> <li>vi. Rhizome: Ginger, Podophyllum.</li> <li>vii. Flower buds: Clove.</li> <li>viii. Fruits: Coriander, Fennel</li> <li>ix . Seeds: Isapgol, Nux Vomica.</li> </ul>	
8. 9.	Study of natural pesticides. Pyrethrum, Neem, Tobacco Carbohydrate:  a) Detailed study of Carbohydrates and related products. b) Biological source, method of production, chemical constituents, tests, uses and adulterants of i) Honey ii) Acacia iii) Agar iv) Sterculia v) Tragacanth vi) Cellulose and its products vii) Pectin viii) Guar gum ix) Sodium alginate.	02 07
10.	a) Definition classification, chemistry and method of analysis of proteins	03
11.	<ul> <li>b) Study of collagen, Gelatin and its products</li> <li>Lipids: <ul> <li>a) Definition, sources, method extraction, chemistry and method of analysis of Lipids.</li> <li>b) Study of method of production, chemical constituents, tests, uses and adulterants of the following drugs.</li> <li>i) Castor oil ii) Shark liver oil iii) Chaulmoogra oil iv) Wool fat v) Bees wax</li> </ul> </li> </ul>	07
12.	vi) Spermaceti vii) Cocoa butter viii) Olive oil Therapeutic application of herbal drugs, poisonous plants, herbal- drug interaction, edible vaccines, marine Pharmacognosy.	04
13.	Introduction, definition, classification, general properties, chemical tests and general method of isolation of Alkaloids, Glycosides, Essential Oils, Flavonoids, Resins and Tannins.	15
14. 15.	Study of plants fibers used in surgical dressings and related products.  Different methods of adulteration of crude drugs and general methods of detection of adulterants.	02 04

# 12PD23P: PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

**General Requirements:** Laboratory Napkin, Observation Book (150 pages), Zero brush, Needle, Blade, Match box.

### List of experiments:

- 1. Introduction of Pharmacognosy laboratory and experiments.
- 2. Macro, powder and microscopic study of Datura.
- 3. Macro, powder and microscopic study of Senna.
- 4. Macro, powder and microscopic study of Cassia Cinnamon.
- 5. Macro, powder and microscopic study of Cinchona
- 6. Macro, powder and microscopic study of Ephedra.
- 7. Macro, powder and microscopic study of Quassia.
- 8. Macro, powder and microscopic study of Clove
- 9. Macro, powder and microscopic study of Fennel.
- 10. Macro, powder and microscopic study of Coriander.
- 11. Macro, powder and microscopic study of Isapgol.
- 12. Macro, powder and microscopic study of Nux vomica.
- 13. Macro, powder and microscopic study of Rauwolfia.
- 14. Macro, powder and microscopic study of Liquorice.
- 15. Macro, powder and microscopic study of Ginger.
- 16. Macro, powder and microscopic study of Podophyllum.
- 17. Determination of Acid Value.
- 18. Determination of Saponification value and Iodine Value.
- 19. Chemical tests for Acacia and Tragacanth
- 20. Chemical tests for Agar and Starch
- 21. Chemical tests for Gelatin & Lipids (Castor oil, shark liver oil, Beer wax)
- 22. Isolation of Glycyrrhizin.
- 23. Isolation of Ouinine.
- 24. Isolation of Volatile oil.
- 25. TLC of Quinine.

### Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	04	10
Identification	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	2	7
Duration	03	04

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

# 12PD24T: PHARMACOLOGY - I (THEORY)

Theory: 3 Hrs. /Week 75 Hours

1. Scope & Objectives: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught.

Upon completion of the course student shall be able to:

- 1. Understand the pharmacological aspects of drugs falling under the above mentioned chapters.
- 2. Handle and carry out the animal experiments.
- 3. Appreciate the importance of pharmacology subject as a basis of therapeutics.
- 4. Correlate and apply the knowledge therapeutically.

# Text books (Theory)

- a) Tripathi, K. D. Essentials of medical pharmacology. 6<sup>th</sup> edition, 2008. Publisher: Jaypee, Delhi.
- b) Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and Pharmacotherapeutics. 20 edition, 2008. Publisher: Popular, Mumbai.
- c) Rang, H.P. & Dale, M.M. Pharmacology. 5th <sup>edition</sup>, 2003. Publisher: Churchill living stone.

### Reference books (Theory)

- a) Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological basis of therapeutics. 11<sup>th edition</sup>, 2006. Publisher McGraw Hill, Pergamon Press.
- b) Craig, C.R. & Stitzel, R.E. Modern Pharmacology. 5<sup>th</sup> edition, 1997. Publisher: Little Brown Co.
- c) Katzung, B.G. Basic and clinical pharmacology. 9<sup>th</sup> edition, 2004. Publisher: Prentice Hall, Int.
- d) Shargel and Leon. Applied Biopharmaceutics and Pharmacokinetics. Latest edition 2002. Publisher: Prentice Hall, London.

# 3. Lecture wise Programme:

Hrs

### **Topics**

### 1. General Pharmacology

16

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism & excretion)
- d) Pharmacodynamics

	e) Factors modifying drug effects	
	f) Drug toxicity - Basic concepts, acute, sub-acute & chronic toxicity.	
	g) Pre-clinical evaluation	
	h) Drug interactions	
	Note: The term Pharmacology used here refers to the classification,	
	mechanism of action, pharmacokinetics, pharmacodynamics, adverse	
	effects, contraindications, therapeutic uses, interactions and	
	dose and route of administration.	
2.	Pharmacology of drugs acting on ANS	09
	a) Introduction to neurotransmission	
	b) Adrenergic and antiadrenergic drugs	
	c) Cholinergic and anticholinergic drugs	
	d) Neuromuscular blockers	
	e) Mydriatics and miotics	
	f) Drugs used in myasthenia gravis g) Drugs used in Parkinsonism	
3.	Pharmacology of drugs acting on cardiovascular system	09
	a) Antihypertensives	
	b) Anti-anginal drugs	
	c) Anti-arrhythmic drugs	
	d) Drugs used for therapy of Congestive Heart Failure	
	e) Drugs used for hyperlipidaemias	
4.	Pharmacology of drugs acting on Central Nervous System	20
	a) Excitatory and inhibitory neurotransmitters of CNS	
	b) General anesthetics	
	c) Sedatives and hypnotics	
	d) Anticonvulsants	
	e) Analgesic and anti-inflammatory agents	
	f) Psychotropic drugs	
	g) Alcohol and methyl alcohol	
	h) CNS stimulants and cognition enhancers	
	i) Centrally acting skeletal muscle relaxants	
	j) Drug dependence, abuse and tolerance. List of drugs	
5.	causing such problems	02
5. 6.	Pharmacology of Local anaesthetics Pharmacology of Drugs acting on Respiratory tract	02
υ.	a) Bronchodilators b) Mucolytics	03
	c) Expectorants d) Antitussives	
	e) Nasal Decongestants	
7.	, , , , , , , , , , , , , , , , , , ,	08
, .	a) Thyroid and Antithyroid drugs	00
	b) Insulin, Insulin analogues and oral hypoglycemic agents c) Sex	
	hormones and oral contraceptives	
	d) Oxytocin and other stimulants and relaxants	
8.	Pharmacology of autocoids and their antagonists	06
-•	a) Histamines and Antihistaminics	
	b) 5-Hydroxytryptamine and its antagonists	
	c) Lipid derived autocoids and platelet activating factor	

# 12PD25T: COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope & Objectives: This course is designed to ensure that students are skilled and knowledgeable to provide various pharmaceutical care services to patients and general practitioners in the community setup.

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

- 1. Handle the prescriptions and manage the community pharmacies
- 2. Deliver the pharmaceutical care services in the community pharmacies.
- 3. Respond to minor ailments and provide health education
- 4. Promote rational drug therapy.
- 2. Course Materials:

### **Text Books:**

- a. Health Education and Community Pharmacy by N.S. Parmar. 1<sup>st</sup> ed. 2012, CBS
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.2017, CBS, **Publishers** & Distributors.

### Reference books:

- a. Handbook of pharmacy health care. Edt. Robin J Harman. 2<sup>nd</sup>. ed. 2001, The Pharmaceutical Press.
- b. Comprehensive Pharmacy Review 7<sup>th</sup> ed. Leon Shargel. Lippincott Williams & Wilkins.

# Special requirements:

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

### 3. Lecture wise programme:

Topics		Hrs
1.	Definition and scope of community pharmacy	02
	Roles and responsibilities of Community pharmacist	
2.	Community Pharmacy Management	04
	a) Selection of site, Space layout, and design	
	b) Staff, Materials- coding, stocking	
	c) Legal requirements	
	d) Maintenance of various registers	
	e) Use of Computers: Business and health care softwares	
3.	Prescriptions - parts of prescription, legality & identification of	02
	medication related problems like drug interactions.	
4.	Inventory control in community pharmacy	03
	Definition, various methods of Inventory Control ABC, VED, EOQ, Lead	
	time and safety stock	

5.	Pharmaceutical care. Definition and Principles of Pharmaceutical care	02
6.	Patient counseling Definition, outcomes, various stages, barriers, strategies to overcome barriers Patient information leaflets- content, design, layouts & advisory labels	04
7.	Patient medication adherence Definition, Factors affecting medication adherence and role of pharmacist in improving the adherence	02
8.	Health screening services  Definition, importance, methods for screening blood pressure/ blood sugar/lung function and Cholesterol testing	03
9. 10.	OTC Medication - Definition, OTC medication list & Counselling Health Education WHO Definition of health and health promotion, care for children, pregnant & breast feeding women and geriatric patients.	03 02
11.	Commonly occurring communicable diseases, causative agents, Clinical presentations and prevention of communicablediseases - Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS	09
12. 13. 14.	Balance diet, treatment & prevention of deficiency disorders Family planning - role of pharmacist Responding to symptoms of minor ailment Relevant pathophysiology and common drug therapy to Pain, Gl disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, onstipation), Pyrexia, Opthalmic symptoms and worms infestations.	02 01 08
15.	Essential Drugs concept and Rational Drug Therapy Role of community pharmacist	02
16	Code of ethics for community pharmacists	01

# 12PD26T: PHARMACOTHERAPEUTICS-I (THEORY)

Theory: 3 Hrs. /Week 75 Hours

**1. Scope and Objectives:** 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.

At completion of this course it is expected that students will be able to understand:

- 1. The pathophysiology of selected disease states and the rationale for drug therapy
- 2. The therapeutic approach to management of these diseases
- 3. The importance of preparation of individualized therapeutic plans based on diagnosis
- 4. 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)
- 5. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
- 6. Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
- 7. Discuss the controversies in drug therapy
- 8. Discuss the preparation of individualised therapeutic plans based on diagnosis
- 9. 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)

### 2. Course materials

#### **Text Books**

- a) Clinical Pharmacy and Therapeutics; 5<sup>th</sup>.ed. 2012; Walker & Whittlesea, Churchill Livingstone publication
- b) Pharmacotherapy: A Pathophysiology approach Joseph T. Dipiro et al. 10<sup>th</sup> ed., 2016, Appleton & Lange

### **Reference Books**

- a) Pathologic basis of disease by- Cotran, Kumar, Robbins Elsiver India Pvt Ltd, Newdelhi, 2015, ed. 9 vol. 1-2
- b) Pathology and Therapeutics for Pharmacists A Basis for Clinical Pharmacy Practice Green and Harris, 3<sup>rd</sup>. ed., Chapman and Hall publication
- c) Clinical Pharmacy and Therapeutics Eric T. Herfindal, 5<sup>th</sup> ed.

- 2016, Williams and Wilkins Publication
- d) Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA, 10<sup>th</sup> ed. 2013, Wolters Kluwer Lippincot williams &Wilkins, Newyork
- e) Avery's Drug Treatment, 4th Ed., 1997, Adis International Limited.
- f) Relevant review articles from recent medical and pharmaceutical literature.

# 3. Lecture wise Programme

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Top	pics	Hrs
1.	Cardiovascular system Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidemia,	26
ว	Electrophysiology of heart and Arrhythmias	12
2.	Introduction to Pulmonary function test, Asthma, Chronic	12
2	obstructive airways disease, Drug induced pulmonary diseases	47
3.		16
	Diabetes, Thyroid diseases, Oral contraceptives, Hormone	
	replacement therapy, Osteoporosis	
4.	General prescribing guidelines for	10
	4.1 Paediatric patients	
	4.2 Geriatric patients	
	4.3 Pregnancy and breast feeding	
5.	o ,	06
6.	Introduction to rational drug use	05
	Definition, Role of pharmacist in promoting rational drug use and essential drug concept.	

#### 12PD26P: PHARMACOTHERAPEUTICS-I (PRACTICAL)

Practical: 3 Hrs. /Week 75 Hours

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 15 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.

#### **Assignments**

#### Format of the assignment

- Minimum & Maximum number of pages.
   It shall be computer draft copy
   Reference(s) shall be included at the end.
   Name and signature of the student
- Assignment can be a combined presentation at Time allocated for presentation may be the end of the academic year 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	2	7
Duration	03hrs	04hr

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

### 12PD27T: HUMAN RIGHTS, GENDER EQUITY AND ENVIRONMENTAL STUDIES (THEORY)

50 Hours

Theory: 2 Hours per Week **UNIT - I: HUMAN RIGHTS** 1. Human Rights - Meaning; Universal Declaration of Human Rights 04 Hours 2. **Human Rights Advocacy:** Global Advocacy of Human Rights; 07 Hours Amnesty International and other organization; People's Union for Civil Liberty (PUCL); Human Rights Commission in India; Minority Commission in India; Remedies against violation of Human Rights in India 3. **United Nations and Human Rights:** Civil and Political Rights: 04 Hours Economic, Social and Cultural Rights **UNIT II: GENDER EQUITY** Sex and Gender - Masculinity and Feminity - Patriarchy, 1. 04 Hours Matriarchy, Gender Roles and Attributes, Gender Division of Labour - Gender bias, Gender Stereotypes - Need for Gender Sensitization 2. Women's Status in India: Important indicators - sex ratio, 04 Hours education, health, nutrition, maternal and infant mortality, work participation rates, political participation 3. **Contemporary Women's issues:** Discrimination against girl child: 04 Hours Violence against women; Problems of Health and Nutrition; Women's Education and gender bias in education; Trafficking of Women; Globalization and impact on women 4. **State Initiative on Gender Issues:** Constitution rights of women; 04 Hours Laws pertaining to women; National and State Commission for women **UNIT III: ENVIRONMENTAL STUDIES Environment:** Components of Environment Concepts of Ecology; 05 Hours 1. Ecological factors: Soil, air, water; Eco System - Pond and Forest as Ecosystem; Human Population Growth 2. **Environmental Pollutions:** Types of Pollution - a) soil, air, water 07 Hours b) noise and radioactive pollution; Sources of Pollution and their effects; Control measures: Legal and administrative 3. Conservation and Preservation of Environment: Natural 07 Hours resources and their conservation - water, soil and forest; Agencies involved in environmental protection in India; Environmental Movements in India; Legal and administrative measures for environmental protection

#### **BOOKS FOR REFERENCE:**

#### A. Human Rights

- 1. S. Davidson: Human Rights, Buckingham, Open University,
- 2. Nirmal Chiranjivi: Human Rights in India, New Delhi, Oxford University Press

#### B. Gender Equity

- 1. Usha Sharma (ed): Gender Mainstreaming and Women's Rights, Authors press, New Delhi, 2004
- 2. Mohini Chatterjee: Feminism and Gender Equity, Aavishkar Publishers Jaipur
- 3. Neera Desai and Maithreyi Krishnaraaj, Women's Studies in India: Some perspectives. Popular Prakashan, Mumbai, 1986
- 4. Desai Neera and Thakkar Usha: Women in Indian Society, National Book Trust, India, 2001
- 5. Tharabai S.B: Women's Studies in India, APH Publication Corporation, New Delhi, 2000
- 6. Sushma Yadav and Anil Datta: Gender Issues in India, Radha Publications, New Delhi, 2003

#### C. Environmental Studies

- 1. N.K. Chakravarthy: Environmental Protection and Law, Ashis Publishing House, New Delhi
- 2. Eugene P. Odum: Basic Ecology, Savndus College, London
- 3. Kumar N: Air Pollution and Environmental Protection, Mittal Publication, New Delhi
- 4. Trivedi R K and Singh, UK: Environmental Laws on Wild Life, Mittal Publication, New Delhi
- 5. K.A. Agarwal: Wild Life in Indian Conservation and Management, Nishi Publications
- 6. Erach Baruch: Text Book For Environmental Studies, UGC, New Delhi and Bharati Vidyapeeth Institute Environment Education and Research, Pune
- 7. Erach Baruch: The Biodiversity of India, Mapin Publishing Pvt Ltd., Ahmedabad
- 8. Jadhav H & Bhosale, VM: Environmental Protection and Laws, Himalaya Publishing House, New Delhi
- 9. Trivedi R K and PK Goel: Introduction to Air Pollution, Techno- Science Publication

#### 12PD31T: PHARMACOLOGY - II (THEORY)

Theory: 3 Hrs. /Week 75 Hours

Scope and Objectives: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic aspects, adverse effects, pharmacokinetic uses, dose, administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune hormones, pharmacology of autocoids and different aspects of will be concentrated. ln addition, pharmacology genes of toxicology are also taught. In chemotherapeutic agents and principles addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

Upon completion of the subject student shall be able to:

- 1. Understand the pharmacological aspects of drugs falling under the above mentioned chapters.
- 2. Carry out the animal experiments confidently.
- 3. Appreciate the importance of pharmacology subject as a basis of therapeutics.
- 4. Correlate and apply the knowledge therapeutically.
- 5. Understand different aspects of genes and their regulatory functions.

#### 2. Course materials:

#### Text books (Theory)

- a) Tripathi, K. D. Essentials of medical pharmacology. 8th edition, 2018. Publisher: Jaypee, Delhi.
- b) Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and Pharmacotherapeutics. 24th edition (single volume), 2015. Publisher: Popular, Mumbai.
- c) Rang, H.P. and Dale, M.M. Pharmacology. 8th edition, 2016. Publisher: Churchill Living stone.
- d) Alberts, B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD Molecular Biology of the Cell by, 6<sup>th</sup>. Edition, 2012, Publisher: Garland Science.

#### Reference books (Theory)

- a) Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological basis of therapeutics. 12th edition, 2014. Publisher: McGraw Hill, Pergamon press.
- b) b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. 6th edition 2012. Publisher: Little Brown and company.
- c) Katzung, B.G. Basic and clinical pharmacology. 14th edition 2014. Publisher: Prentice Hall, International.
- d) Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. 2010. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.
- e) Crommelin, DJA and Sindelar RD. Pharmaceutical Biotechnology. 3rd edition 2008. Publisher: Infarma Healthcare.
- f) Watson, JD., Gilman, M., et al. Recombinant DNA. 3nd edition 2008. Publisher:

Scientific America.

- g) g. Walsh, G. Biopharmaceutical: Biochemistry and Biotechnology. 2013. Publisher: John Wily.
- h) Derelanko MG. Handbook of toxicology. 3rd edition 2014; Publisher: CRC Press.

#### Text books (Practical)

a Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. 2012, Vallabha prakashan, Delhi.

#### Reference books (Practical)

- a) Macleod, L.J. Pharmacological experiments on intact preparations 1970: Churchill livingstone.
- b) Macleod, L.J. Pharmacological experiments on isolated preparations., 1970,: Churchill livingstone.
- c) Ghosh, M.N. Fundamentals of experimental pharmacology. 6rd edition, 2015; Publisher: Scientific book agency, Kolkata.
- d) Ian Kitchen. Textbook of in vitro practical pharmacology. 1984. Publisher: Black well Scientific.

### 3. Lecture wise Programme:

э.	Lecture wise Programme.	
To	pics	Hrs
1.	Pharmacology of drugs acting on Blood and blood forming agent	06
	a) Anticoagulants	
	b) Thrombolytics and antiplatelet agents	
	c) Haemopoietics and plasma expanders	
2.	Pharmacology of drugs acting on Renal System	03
	a) Diuretics	
	b) Antidiuretics	
3.	Pharmacology of drugs acting on Gastrointestinal Tract	06
	a) Antiulcer drugs, Antacids b) Laxatives and purgatives	
	c) Emetics and antiemetics	
	d) Appetizers, digestants and carminatives	
4.	Chemotherapy	22
	a) Introduction	
	b) Sulfonamides and co-trimoxazole	
	c) Penicillins and Cephalosporins	
	d) Tetracyclins and Chloramphenicol	
	e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics	
	f) Quinolines and Fluroquinolines	
	g) Antifungal antibiotics	
	h) Antiviral agents	
	i) Chemotherapy of tuberculosis and leprosy	
	j) Chemotherapy of Malaria	
	k) Chemotherapy of protozoal infections (amoebiasis, giardiasis)	
	l) Pharmacology of Anthelmintic drugs	

m) Chemotherapy of cancer (Neoplasms)

<ul> <li>a) Acute, subacute and chronic toxicity.</li> <li>b) Principles involved in the various toxicity screening methods available for drugs in the laboratory animals.</li> <li>7. The dynamic cell: The structures and functions of the components of the cell <ul> <li>a) Cell and macromolecules: Cellular classification, subcellularorganelles, macromolecules, large macromolecular assemblies</li> <li>b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatinstructure, genome complexity, the flow of genetic information.</li> <li>c) DNA replication: General, bacterial and eukaryotic DNA replication.</li> <li>d) The cell cycle: Restriction point, cell cycle regulators and modifiers.</li> <li>e) Cell signaling: Communication between cells and their</li> </ul> </li> </ul>	02
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modifiers. e) Cell signaling: Communication between cells and their	
e) Cell signaling: Communication between cells and their	
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environment, ion-channels, signal transduction pathways	
(MAP kinase, P38 kinase, JNK, Ras and PI3-kinase	
pathways, biosensors.	
	18
a. Gene structure: Organization and elucidation of genetic code.	
b. Gene expression: Expression systems (pro and eukaryotic),	
genetic elements that control gene expression (nucleosomes,	
histones, acetylation, HDACS, DNA binding protein families.	
c. Transcription and Transcription factors: Basic principles of	
transcription in pro and eukaryotes. Transcription factors that	
regulate transcription in pro and eukaryotes.	
d. RNA processing: rRNA, tRNA and mRNA processing.	
e. Protein synthesis: Mechanisms of protein synthesis, initiation in	
eukaryotes, translation control and post-translation events	
f. Altered gene functions: Mutations, deletions,	
amplifications, LOH, translocations, trinucleotide repeats	
and other genetic abnormalities. Oncogenes and tumor	
suppressor genes.	
g. The gene sequencing, mapping and cloning of human disease	
genes.	
h. Introduction to gene therapy and targeting.	
i. Recombinant DNA technology: principles. Processes (gene	
transfer technology) and applications  9. Bio-assay methods	)4
Scope, principles involved in general methods, bioassay designing,	<b>7</b> →
applications and limitations.	

#### 12PD31P: PHARMACOLOGY - II (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

#### List of Experiments:

- 1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
- 2. Study of physiological salt solutions used in experimental pharmacology.
- 3. Study of laboratory appliances used in experimental pharmacology.
- 4. Study of use of anesthetics in laboratory animals.
- 5. To record the dose response curve of Acetylcholine using isolated rat ileum/rectus abdominis muscle preparation.
- 6. To carry out bioassay of Ach using isolated rat ileum/rectus abdominis muscle preparation by interpolation method.
- 7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
- 8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
- 9. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
- 10. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
- 11. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
- 12. To study different routes of administration of drugs in animals (Rats, Mice, Rabbits).
- 13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
- a. Analgesic property of drug using analgesiometer (tail flick and hotplate).
- b. Antiinflammatory effect of drugs using rat-paw edema method.
- c. Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
- d. Antidepressant activity of drugs using pole climbing apparatus.
- e. Pentobarbitone induced sleeping time in mice.
- f. Locomotor activity of drugs using actophotometer.
- g. Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.
- h. Skeletal muscle relaxant activity of the drugs using rotarod.
- i. Drugs effect on the blood pressure, heart rate and respiratory rate of dog.

#### 14. Simulated experiments

- a) Effect of drugs on frog's isolated heart.
- b) Effect of drugs on rabbit eye.
- c) Effect of drugs on ciliary motility of frog's esophagus.

### Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment	04	10
(Interpretation of given Graph/ simulated		
Viva	02	10
Max Marks	20	70
Duration	3 hrs	4 hrs

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

#### 12PD32T: PHARMACEUTICAL ANALYSIS (THEORY)

75 Hours Theory: 3 Hrs. /Week

1. Scope and objectives: This course is designed to impart a fundamental knowledge on the art and science of testing drugs by various instrumental methods of analysis. This focuses on various modern instruments that are used for testing the purity of drugs in various dosage forms. This course also gives idea about modern instruments that are used for drug testing like NMR, IR, Mass, HPLC, HPTLC forms etc. It prepares the students for most basics of the applied field of pharmacy.

At the end of course, students are able

- 1. To understand the construction and working of various analytical instruments.
- 2. To know principle and mechanism of instrumentation.
- 3. To understand the different modern techniques of drug analysis.
- 4. To appreciate the advantages of instrumental methods of drug analysis.

#### 2. Course materials:

#### Text books

- a. Instrumental methods of analysis by Willard, Merrit, Dean and Settlle 7thed. 2005, CBS publishers and distributors, Newdelhi
- b. A.H.Beckett & J.B. Stenlake's -Practical Pharmaceutical Chemistry Vol I & II, Stahl one Press of University of London, 4th edition. 2007

#### Reference books

- a. Text Book of Quantitative Inorganic analysis by Vogel, 10<sup>th</sup> ed. 2014, Pearson
- b. Text book of Pharmaceutical Analysis by K.A. Cannors 3<sup>rd</sup> ed. 2007, Wiely,
- c. Pharmaceutical analysis by Skoog and West. d. 9th. Ed., 2010, William Kemp-Spectroscopy methods. Cengage

#### 3. Lecture wise Programme

**Topics** Hrs 06

#### **Quality Assurance:** 1.

- a. Introduction, sources of quality variation, control of quality variation.
- b. Validation methodsquality of equipment, validation equipment and validation of analytical instruments and calibration.
- 2. Chromatography: Introduction, history, classification, separation 27 techniques, choice methods. The following techniques relevant examples of pharmaceutical products discussed with involving principles and techniques of separation of drugs from excipients.
  - a. Column Chromatography: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis.

- Factors affecting column efficiency, applications and partition chromatography.
- b. TLC: Introduction, principle, techniques, Rf value and applications.
- c. PC: Introduction, principle, types of paper chromatography, techniques, development techniques, applications. preparation
- d. Ion-exchange chromatography: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. HPLC: Introduction, theory, instrumentation, and applications.
- f. HPTLC: Introduction, theory, instrumentation, and applications.
- Chromatography: Introduction, theory, instrumentationcarrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, **Typical** thermal conductivity detector. gas chromatogram, derivatisation techniques, programmed temperature chromatography, applications.
- h. Electrophoresis: Principles of for separation, equipment and gel electrophoresis, and application. paper
- i. Gel filtration and affinity chromatography: Introduction, technique, applications.

#### 3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra analytical applications be discussed on the following topics. and

- Potentiometry: Electrical potential, electrochemical reference electrodes indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. Conductometry: Introduction, conductivity cell, conductometric titrations and applications.
- c. Amperometric Titrations: Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over Potentiometry Pharma applications.

#### 4. Spectroscopy:

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a) Absorption Spectroscopy:

Theory of electronic, atomic and molecular spectra. Fundamental laws photometry, Beer-Lambert's Law, application and its deviation, of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra isolated of chromophores, auxochromes, bathochromic shift. hypsochromic shift. hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

**Instrumentation** - Photometer, U.V.-Visible spectrophotometer of U.V.- Visible radiations, collimating sources systems,

12

30

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monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

Infrared Spectroscopy: Vibrational transitions, frequency - structure correlations, Infrared absorption bands, Instrumentation-IR spectrometer - sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors-Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

**Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, \ quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

- b) Flame Photometry: Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- **c) Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d) Atomic Emission Spectroscopy: Spectroscopic sources, atomic emissionspectrometers, photographic and photoelectric detection.
- e) NMR (introduction only):Introduction,theoretical aspects and applications
- **f)** Mass Spectroscopy: (Introduction only) Fragmentation, types of ionsproduced, mass spectrum and applications.
- **g) Polarimetry:** (Introduction only) Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h) X-RAY Diffraction: (Introduction only) Theory, reciprocal lattice concept, diffraction patterns and applications

#### 12PD32P: PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

#### List of Experiments:

- 1. Separation and identification of Amino Acids by Paper Chromatography\*.
- 2. Separation and identification of Dyes by radial paper chromatography\*.
- 3. Separation and identification of Sulpha drugs by TLC technique\*.
- 4. Effect of pH and solvent on the UV spectrum of given compound\*.
- 5. Determination of dissociation constant of indicators using UV-Visible spectroscopy\*.
- 6. Conductometric titration of mixture of acids with a strong base\*\*.
- 7. Potentiometric titration of strong acid with a strong base\*\*.
- 8. Estimation of drugs by Fluorimetric technique\*\*.
- 9. Study of quenching effect in fluorimetry\*\*.
- 10. Colorimetric estimation of Supha drugs using BMR reagent\*\*.
- 11. Simultaneous estimation of two drugs present in given formulation\*\*.
- 12. Assay of Dextrose by colorimetry\*\*
- 13. Colorimetric estimation of Ferrous ions using 1,10-Phenonthroline\*\*.
- 14. UV spectroscopic estimation of Paracetamol tablets\*
- 15. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method\*\*.
- 16. Determination of Na/K by Flame Photometry\*\*.
- 17. Determination of pKa using pH meter\*.
- 18. Infrared spectral graphs/ peak identiofication of samples with different functional groups (-COOH, -COOR, -NH2, -NHR, -OH, -CHO, -C=O)
- 19. Demonstration of HPLC.

#### SCHEME OF PRACTICAL EXAMINATION:

	Sessional	Annual
Synopsis	05	10
Major Experiment (Experiment indicated by**)	10	30
Minor Experiment (Experiment indicated by*)	3	20
Viva-Voce	2	10
Max. Marks	20	70

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

#### 12PD33T: PHARMACOTHERAPEUTICS-II (THEORY)

Theory: 3 Hrs. /Week 75 Hours

**1. Scope and Objectives:** 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.

#### Upon completion of the course student shall be able to

- 1. know the pathophysiology of selected disease states and the rationale for drug therapy
- 2. know the therapeutic approach to management of these diseases
- 3. know the controversies in drug therapy
- 4. know the importance of preparation of individualised therapeutic plans based on diagnosis
- 5. 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)

#### 2. Course Materials: Text books (Theory)

a. Clinical Pharmacy and Therapeutics; 5<sup>th</sup>.ed. 2012; Walker & Whittlesea, Churchill Livingstone publication

#### Reference books (Theory)

- a) a. Pharmacotherapy: A Pathophysiology approach Joseph T. Dipiro et al. 10<sup>th</sup> ed., 2016, Appleton & Lange
- g) b. Clinical Pharmacy and Therapeutics Eric T. Herfindal, 5<sup>th</sup> ed. 2016, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA, 10<sup>th</sup> ed. 2013, Wolters Kluwer Lippincot williams &Wilkins, Newyork

#### 3. Lecture wise programme

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

Topics

1. Infectious diseases: Guidelines for the rational use of antibiotics 35 and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections,
Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections,
Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis

2. Musculoskeletal disorders
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.

10

3.	Renal system	10
	Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug	
	induced renal disorders	
4.	Oncology: Basic principles of Cancer therapy, General introduction to	12
	cancer chemotherapeutic agents, Chemotherapy of breas	
	cancer, leukemia. Management of chemotherapy induced nausea	
	and emesis	
5.	Dermatology: Psoriasis, Scabies, Eczema, Impetigo	80

#### 12PD33P: PHARMACOTHERAPEUTICS-II (PRACTICALS)

Practical: 3 Hrs./Week 75 Hours

Hospital postings for a period of at least one month 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.

#### **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

- Minimum & Maximum number of pages. It shall be computer draft
- Reference(s) shall be included at the end. student
- Name and signature of the
- Assignment can be a combined presentation Time allocated for presentation may be at the end of the academic year 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)

#### 12PD34T: PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope and Objectives: This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments is the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

# Upon completion of the subject student shall be able to (Know, do, and appreciate) -

- 1. practice the Professional ethics;
- 2. understand the various concepts of the pharmaceutical legislation in India;
- 3. know the various parameters in the Drug and Cosmetic Act and rules;
- 4. know the Drug policy, DPCO, Patent and design act;
- 5. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
- 6. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
- 7. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

#### 2. Course materials

#### Text books (Theory)

Mithal, B.M. Textbook of Forensic Pharmacy. Calcutta: National; 10th ed. 2014, vallabha Prakashan, Newdelhi.

#### Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad:Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. 8<sup>th</sup> ed. 2015, Delhi: Vallabh Prakashan;
- c. Reports of the Pharmaceutical enquiry Committee d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

## 3. Lecture wise programme:

Topi	ics	Hrs
1.	Pharmaceutical Legislations - A brief review. Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee	02
2.	Code of Pharmaceutical Ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath	02
3.	Drugs and Cosmetics Act, 1940 and its rules 1945.  Objectives, Definitions, Legal definitions of schedules to the act and rules Import of drugs - Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs - Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Detailed study of schedule M, N and Y. Offences and penalties.	22
	Sale of Drugs - Wholesale, Retail sale and Restricted license. Offences and penalties.	
	Labeling & Packing of drugs - General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties Administration of the act and rules - Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government analysts, Licensing authorities, controlling authorities, Drug Inspectors	
4.	Pharmacy Act -1948.  Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; its constitution and functions, Registration of Pharmacists, Offences and Penalties.	05
5.	Medicinal and Toilet Preparation Act -1955. Objectives, Definitions, Licensing, Manufacture in bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations. Offences and Penalties.	04
6.	Narcotic Drugs and Psychotropic substances Act-1985 and Rules. Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	04

7.	Study of Salient Features of Drugs and magic remedies Act and its rules.	02
	Objectives, Definitions, Prohibition of certain advertisements, Classes of	
	Exempted advertisements, Offences and Penalties	
8.	Drug Price Control Order & National Drug Policy (Current).	02
	Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled	
	formulations, Implementation of prices Fixed/ revised.	
	Pharmaceutical Policy 2002: Objectives, Approaches in the review,	
	Salient features of Pharmaceutical Policy 2002.	
9.	Prevention of Cruelty to animals Act-1960.	03
	Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties	
10.	· · · · · · · · · · · · · · · · · · ·	03
	<ul> <li>Objectives, definitions, Types of patent, PCT, Patentable and not patentable inventions, Applications for patents, Term of patent, revocation of patents, compulsory licensing, Offences and penalties.</li> <li>Registration of designs, copyright, prohibition of certain designs, cancellation of designs, Offences and penalties.</li> </ul>	
11.	<b>9</b> /	01
<b>Assi</b>	gnments.	

#### Format of the assignment

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

#### Case studies relating to

- 1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
- 2. Various prescription and non-prescription products.
- 3. Medical and surgical accessories.
- 4. Diagnostic aids and appliances available in the market.

#### 12PD35T: MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

1. Scope and Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the different drugs. The course gives details of Chemistry, Mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR) and uses of Chemotherapeutic Agents, Cardiovascular Drugs and synthesis of some important drugs. The course also covers modern techniques of drug design, which include Prodrug concept and combinatorial chemistry.

At the end of the course, students are able

- 1. To understand the chemistry of drugs with respect to their biological activity.
- 2. To know the metabolism, adverse effect and therapeutic activity of drugs.
- 3. To understand the different modern techniques of drug design.
- 4. To appreciate the SAR of some important drug classes.

#### 2. Course materials:

#### Text books

- a. Wilson and Giswolds, Text book of Organic and pharmaceutical chemistry, 12<sup>th</sup> . 2015, Wolter Kluwer
- b. Principles of Medicinal chemistry- William O. Foye, 7<sup>th</sup> ed. 2012, wolter kluwer,

#### Reference books

- a. A I Vogel Text book of Practical Organic Chemistry, 5<sup>th</sup> ed, Pearson
- b. Text Book of organic chemistry by I. L. Finar, 6<sup>th</sup> ed. 2014, Pearson.
- c. A text book of Inorganic medicinal Chemistry by Surendra N. Pandey. 2011, K.G. Publisher, Varanasi

#### 3. Lecture wise Programme:

Topics Hrs

- I. Modern concept of rational drug design: 06 introduction to Quantitative Structure Activity prodrug, combinatorial Relationaship (QSAR), chemistry drug design and computer aided (CADD) and concept of antisense molecules.
  - II. A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

15

#### Anti-infective agents:

Local anti-infective agents: Alcohols: isopropyl alcohol

Phenols: cresols, hexyl resorcinol

Oxidizing agents: Hydrogen peroxide solution, hydrous benzoyl peroxide.

Halogen containing compounds: Iodine Tincture

Dyes-Gentian Violet, Methylene blue.

Cationic surfactants: benzalkonium chloride, cetyl pyridinium bromide Nitrofurans: nitrofurazone, furazolidone.

#### **Preservatives:**

- a. Methylparaben, Propylparaben, Ethyl paraben, Chlorobutanol, Benzyl alcohol, Phenylethyl alcohol, Sodium benzoate, Phenyl mercuric nitrate, Phenyl mercuric acetate.
- b. Antifungal agents:

Azoles: miconazole, ketoconazole, fluconazole, clotrimazole.

Miscellaneous: tolnaftate\*, naftifine

Antifungal Antibiotics: amphotericin, nystatin, griseofulvin.

- c. Urinary tract anti-infectives:
  - SAR of quinolone antibacterial agents, Norfloxacin, ciprofloxacin\*, sparfloxacin, ofloxacin, nitrofurantoin\*.
- d. Antitubercular agents: Management of tuberculosis, Synthetic anti TB agents: PAS\*, INH\*, Pyrizinamide, ethambutol, Anti TB antibiotics: rifampin, capreomycin
- e. Antiviral agents and Anti AIDS agents: amantadine, acyclovir, iodoxuridine, trifluridine, zidovudine, stavudine
- f. Antiprotozoal agents: Introduction to protozoal diseases and causative organisms. Metronidazole\*, diloxanide furoate\*, dehydroemetine, nifurtimox
- g. Anthelmentics: Benzimidazoles: mebendazole, albendazole Piperazine, diethylcarbamazine\*, ivermectin

#### 2. Sulfonamides and sulfones

04

History and development of sulfonamides, SAR and mechanism of action of Sulfonamides, pK<sub>a</sub> of Sulfas and Crystalluria.
Sulfamethoxazole\*, sulfisoxazole, sulfacetamide\*, sulfasalzine Folate

reductase inhibitors: trimethoprim\*, synergistic action of cotrimoxazole. Sulfones: dapsone\*

#### 3. Antimalarials:

05

Etiology of malaria, SAR and mechanism of action of quinoline Antimalarials Quinine sulphate, Chloroquine phosphate, amodiaquine, pamaquine\*, primaquine, Quinacrine Chloroguanide, cycloguanil, pyrimethamine\*

#### 4. Antibiotics 12

Historical background and classification of antibiotics.

Beta lactam antibiotics: development of acid resistant and extended spectrum Penicillins. Penicillin G, ampicillin, amoxicillin, cloxacillin Beta lactamase inhibitors: clavulanic acid, thienamycin Cephalosporins: cephelexin, cefadroxil, cefuroxime

Aminoglycosids: streptomycin, neomycin, amikacin, gentamicin

	Antimetabolites: mercaptopurine, flurouracil, methotrexate Antibiotics: dactinomycin, mitomycin, streptozocin Plant products: etoposide, taxol, vincristine and vinblastine Miscellaneous: cisplatin, interferons	
6.	Cardiovascular agents  a) Antianginal agents and vasodilators Nitrovasodilators: amyl nitrite, isosorbide dinitrate Calcium channelblockers: verapamil, diltiazem	12
	b) Antiarrhythmic agents: Class I: quinidine, phenytoin*, lidocaine, encainide Class II: beta blockers- propranolol Class III: amiodarone Class IV: Calcium channel blockers: verapamil*, diltiazem	
	c) Antihypertensive agents: betablockers: propranolol*, ACE inhibitors: captopril, enalapril Angiotensin antagonists: losartan Calcium channel blockers: nifedipine, amlodepine Adrenergic agents: clonidine, methyl dopa Adrenergic antagonists: prazosin, reserpine	
	d) Antihyperlipidemic agents: types of hyperlipoproteinemia clofibrate*, fenofibrate, cholestyramine, lovastatin, simvastatin	
	e) Anticoagulants: warfarin*, dicumarol*, anisindione	
7.	Hypoglycemic agents: History, development and SAR of sulfonylureas: tolbutamide*, chlorpropamide*, glipizide Metaglinides: repaglinide Thiazolindiones: rosiglitazone, pioglitazone	03

Tetracyclines: Chemistry and SAR of tetracyclines, chlortetracycline,

Alkylating agents: cyclophosphamide\*, mechlorethamine, cholrambucil\*

06

doxycycline, Minocycline.

**Antineoplastic agents** 

5.

Macrolides: erythromycin, azithromycin

Miscellaneous: clindamycin, bacitracin, chloramphenicol\*

Historical background and classification of antineoplastic agents

Biguanides: metformin, phenformin Miscellaneous: acarabose, miglitol

8.	Thyroid and Antithyroid agents L-thyroxine, L-threonine Propyl thiouracil, methimazole	01
9.	Diuretics: Carbonic anhydrase inhibitors: acetazolmide* Thiazide diuretics: SAR of thiazide diuretics, chlorthiazide, benzthiazide, xipamide, chlorthalidone Loop diuretics: frusemide*, ethacrynic acid* Potassium sparing diuretics: spiranolactone, amiloride Miscellaneous: mannitol	05
10.		01
11.	Steroidal Hormones and Adrenocorticoids Estrogens: estradiol, DES Progestines: progesterone, norethindrone Testosterone, nandralone Betamethasone, prednisolone, beclomethasone	05

#### 12PD35P: MEDICINAL CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

#### List of experiments

#### A. Assays of important drugs from the course content.

- 1. Assay of ascorbic acid by cerimetry
- 2. Assay of metronidazole by NAT
- 3. Assay of chloroquine phosphate by NAT
- 4. Assay of dapsone by diazotization
- 5. Assay of INH by bromometry
- 6. Assay of benzyl penicillin by iodometry
- 7. Assay of analgin by iodimetry
- 8. Assay of diclofenac by alkalimetry

# B. Preparation of medicinally important compounds or intermediates required for synthesis of drugs

- 1. Preparation of 7-hydroxy 4-methyl coumarin
- 2. Preparation of phenytoin from benzoin
- 3. Preparation of phenothiazine from diphenyl amine
- 4. Preparation of benzyl alcohol from benzaldehyde
- 5. Preparation of chlorbutanol
- 6. Preparation of eosin from resorcinol
- 7. Preparation of fluorescein from eosin
- 8. Preparation of triphenyl imidazole from benzoin
- 9. Preparation of 2,3 diphenyl guinoxaline from OPDA
- 10. Preparation of benztriazole from OPDA
- 11. Preparation of benzimidazoles from OPDA
- 12. Preparation of sulfanilamide from acetanilide
- 13. Preparation of INH
- 14. Preparation of cinnamic acid

#### C. Monograph analysis of important drugs.

- 1. Monograph analysis of ibuprofen
- 2. Monograph analysis of aspirin
- 3. Monograph analysis of caffeine
- 4. Monograph analysis of sulfanilamide
- 5. Monograph analysis of paracetamol
- **D.** Determination of partition coefficients, dissociation constants of drug substances.

### **Scheme of Practical Examination**

	Sessionals	Annual
Synopsis	04	10
Assay/Estimation	06	30
Preparation	06	20
Viva	04	10
Max Marks	20	70
Duration	03hrs	04hr

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

#### 12PD36T: PHARMACEUTICAL FORMULATIONS (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope and Objective: Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

Upon completion of the course student shall be able to (Know, do, appreciate) -

- 1. understand the principle involved in formulation of various pharmaceutical dosage forms;
- 2. prepare various pharmaceutical formulation;
- 3. perform evaluation of pharmaceutical dosage forms; and
- 4. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

#### 2. Course materials

#### Text books

- a) Pharmaceutical dosage forms, Vol, I, II and III by Liberman & Lachman, 1989, Marcel Dekker, Newyork
- b) Rowlings Text book of Pharmaceutics, Rawlins E.A, 8th. Ed. 2010Elsevier Saunders, Philedelphia
- c) Tutorial Pharmacy Cooper & Gun, 6th 1986, poplur Prakashan,

#### Reference books

- a) Remington's Pharmaceutical Sciences, Vol. 1-3, 22nd ed.2010. Wolter Kluwer and Lippincott,
- b) USP, The United States Pharmacopoeia, 36th 2018, ed. Vol. 1-3, supp1-2, Govt. of India, Ministry of Health
- c) MHRA, British Pharmacopoeia 2017, Vol. 1-5+Vet, Govt. of India, Ministry of Health
- d) Indian Pharmacopoeia 2018, 8th Edition (4 Volumes) . Govt. of India, Ministry of Health

#### 3. Lecture wise programme:

Topics Hrs

10

- 1. **Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques, Tablet coating, Type of coating, quality control tests and evaluation for uncoated and coated tablets.
- 2. **Capsules:** Production and filling of hard gelatin capsules, Raw 07 materials for shell, finishing. Production and filling of soft gelatin capsules, Importance of base adsorption, quality control tests for hard and soft gelatin capsules.
- 3. **Liquid orals:** Formulation, Manufacturing and evaluation of 06 suspensions, emulsions and solutions. Instability problems in suspensions and emulsions.

- 4. Parenterals: Definition, types, advantages and limitation, general formulation, vehicles, production procedure, production facilities, and controls. Formulation of injections, sterile powders, implants and long acting parenterals, emulsions and suspensions. Containers and closures pertinent to sterile preparations and Pharmacopoeial quality control tests, Sterilization and evaluation.
- 5. **Semi Solids**: Introduction and classification Factors affecting ab: 06 Packaging, storage and labeling. Ointments: Types of Ointment Base Pre of ointment. Gels: Types and formulation of Gels
- 6. **Definition and concept of Controlled and novel Drug delivery** 08 **systems** with available examples, viz. transdermal, buccal, vaginal, nasal, implantable, ocular drug delivery systems

#### 12PD36P: PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

#### List of Experiments:

#### 1. Manufacture of Tablets

- a. Ordinary compressed tablet-wet granulation
- b. Tablets prepared by direct compression.
- c. Soluble tablet.
- d. Chewable tablet.

#### 2. Formulation and filling of hard gelatin capsules

#### 3. Manufacture of parenterals

- a. Ascorbic acid injection
- b. Calcium gluconate injection
- c. Sodium chloride infusion.
- d. Dextrose and Sodium chloride injection/infusion.

#### 4. Evaluation of Pharmaceutical formulations (QC tests)

- a. Tablets
- b. Capsules
- c. Injections

#### 5. Formulation of two liquid oral preparations and evaluation by assay

- a. Solution: Paracetamol Syrup
- b. Antacid suspensions- Aluminum hydroxide gel

#### 6. Formulation of semisolids and evaluation by assay

- a. Salicyclic acid and benzoic acid ointment
- b. Gel formulation Diclofenac gel

#### 7. Cosmetic preparations

- a. Lipsticks
- b. Cold cream and vanishing cream
- c. Clear liquid shampoo
- d. Tooth paste and tooth powders.

#### 8. Tablet coating (demonstration)

#### Scheme of Practical Examination:

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

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

#### 12PD41T: PHARMACOTHERAPEUTICS - III (THEORY)

Theory: 3 Hrs. /Week 75 Hours

1. Scope and Objectives: 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.

At completion of this course it is expected that students will be able to understand:

- 1. The pathophysiology of selected disease states and the rationale for drug therapy
- 2. The therapeutic approach to management of these diseases
- 3. The importance of preparation of individualised therapeutic plans based on diagnosis
- 4. 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)
- 5. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
- 6. Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence
- 7. Discuss the controversies in drug therapy
- 8. Discuss the preparation of individualised therapeutic plans based on diagnosis
- 9. 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)

#### 2. Course Materials:

#### **Text Books**

- a) Clinical Pharmacy and Therapeutics; 5<sup>th</sup>.ed. 2012; Walker & Whittlesea, Churchill Livingstone publication
- b) Pharmacotherapy: A Pathophysiology approach Joseph T. Dipiro et al.10th ed.,2016, Appleton & Lange

#### **Reference Books**

- a) Pathologic basis of disease by- Cotran, Kumar, Robbins Elsiver India Pvt Ltd, Newdelhi, 2015, ed. 9 vol. 1-2
- b) Pathology and Therapeutics for Pharmacists A Basis for Clinical Pharmacy Practice Green and Harris, 3rd. ed., Chapman and Hall publication
- c) Clinical Pharmacy and Therapeutics Eric T. Herfindal, 5th ed. 2016, Williams and Wilkins Publication
- d) Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA, 10th ed. 2013, Wolters Kluwer Lippincot williams &Wilkins, Newyork
- e) Avery's Drug Treatment 4th Ed., 1997, Adis International Limited.
- f) Relevant review articles from recent medical and pharmaceutical literature.

#### 3. Lecture wise Programme

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Тор	pics	Hrs
1.	Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.	20
2.	<b>Haematological system:</b> Anaemias, Venous thromboembolism, Drug induced blood disorders.	12
3.	Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease	16
4.	<b>Psychiatry disorders:</b> Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders	14
5.	Pain management including Pain pathways, neuralgias, headaches	80
6.	Evidence Based Medicine	05

#### 12PD41P: PHARMACOTHERAPEUTICS - III (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

#### **Practicals:**

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

#### **Assignments:**

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

#### Format of the assignment:

- 1. Minimum & Maximum number of pages
- 2. Reference(s) shall be included at the end.
- 3. Assignment can be a combined presentation at the end of 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).

#### 12PD42T: HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope and Objectives: 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 counseling, and therapeutic drug monitoring for improved patient care.

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

- 1. Know various drug distribution methods;
- 2. Know the professional practice management skills in hospital pharmacies;
- 3. Provide unbiased drug information to the doctors;
- 4. Know the manufacturing practices of various formulations in hospital set up;
- 5. Appreciate the practice based research methods; and
- 6. Appreciate the stores management and inventory control.

#### 2. Course materials:

#### Text books: (latest editions)

- a) Hospital pharmacy by William .E. Hassan, 5th ed. 1990, K.M. Varghese, Mumbai.
- b) 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. Ed. Robin J Harman. The Pharmaceutical press.

#### 3. Lecture wise programme:

- Infection committee

Top	ics	Hrs
1.	Hospital - its Organisation and functions	01
2.	Hospital pharmacy-Organisation and management  a) Organizational structure-Staff, Infrastructure & work load statistics b) Management of materials and finance c) Roles & responsibilities of hospital pharmacist	04
3. 4.	The Budget - Preparation and implementation Hospital drug policy	01 10
<b>4.</b>	a) Pharmacy and Therapeutic Committee (PTC) b) Hospital formulary c) Hospital committees	10

	- Research and ethical committee	
	d) Development of therapeutic guidelines	
	e) Hospital pharmacy communication - Newsletter	
5.	Hospital pharmacy services	10
	a) Procurement & warehousing of drugs and Pharmaceuticals	
	b) Inventory control: Definition, various methods of Inventory Control	
	ABC, VED, EOQ, Lead time and 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	10
	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	02
	Education and training	
8.	Radio Pharmaceuticals - Handling and packaging	02
9.	Professional Relations and practices of hospital pharmacist	02

#### 12PD42P: HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs. /Week 75 Hours

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

#### List of Assignments:

- 1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
- 2. Pharmacy and Therapeutics committee Organization, functions, and limitations.
- 3. Development of a hospital formulary for 300 bedded teaching hospital
- 4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
- 5. Different phases of clinical trials with elements to be evaluated.
- 6. Various sources of drug information and systematic approach to provide unbiased drug information.
- 7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

#### Special requirements:

- 1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
- 2. Well equipped with various resources of drug information.

#### Scheme of Practical Examination:

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

#### 12PD43T: CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week 75 Hours

 Scope and Objectives: This course is designed to impart the basic knowledge and skills that required for practice of pharmacy including provision of various clinical pharmacy services to patients and healthcare professionals in clinical settings.

Upon completion of the course, student shall be able to

- 1. Monitor drug therapy and resolve drug related problems
- 2. Counsel the patients for safe and effective use of medications
- 3. Assist healthcare professionals in detecting and managing medication errors including ADR
- 4. Provide unbiased drug and poison information services
- 5. Interpret, analyze and correlate the lab investigations

#### 2. Course Materials

#### Text books (Theory)

- a. Practice Standards and Definitions, the Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data, Scott LT, 2<sup>nd</sup>. Ed. 1996, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics, Leon Shargel, 6<sup>th</sup> ed. 2013, Prentice Hall Publication
- d. Textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr.
- G. Parthasarathi, Karin Nyfort-Hansen, Milap Nahata, 2<sup>nd</sup> ed. 2015, Orient Longman Pvt. Ltd.

#### Reference Books

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 4<sup>th</sup> ed. 2010.
- c. Pharmaceutical statistics. Practical and clinical applications.4<sup>th</sup> ed. 2003, Sanford Bolton, Marcel Dekker, Inc

#### 3. Lecture wise programme

Top	pics	Hrs
1. ·	Definitions, development and scope of clinical pharmacy	03
2.	Introduction to daily activities of a clinical pharmacist	13
	a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)	
	b. Ward round participation	

	g. Drug utilisation evaluation (DUE) and review (DUR) h. Quality assurance of clinical pharmacy services	
3.	<ul> <li>Patient data analysis</li> <li>The patient's case history, its structure and use in evaluation of drug therapy &amp; understanding common medical abbreviations and terminologies used in clinical practices</li> </ul>	03
4.	<ul> <li>Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results</li> <li>Haematological, Liver function, Renal function, thyroid function tests</li> <li>Tests associated with cardiac disorders</li> <li>Fluid and electrolyte balance</li> <li>Microbiological culture sensitivity tests</li> <li>Pulmonary Function Tests</li> </ul>	15
5.	<ul> <li>Drug &amp; Poison information</li> <li>Introduction to drug information resources available</li> <li>Systematic approach in answering DI queries</li> <li>Critical evaluation of drug information and literature</li> <li>Preparation of written and verbal reports</li> <li>Establishing a Drug Information Centre</li> <li>Poisons information- organization &amp; information resources</li> </ul>	08
6.	<ul> <li>Pharmacovigilance</li> <li>Scope, definition and aims of pharmacovigilance</li> <li>Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used],</li> <li>Reporting, evaluation, monitoring, preventing &amp; management of ADRs</li> <li>Role of pharmacist in management of ADR.</li> </ul>	10
7.	Communication skills, including patient counseling techniques, medication history interview, presentation of cases.	10
8. 9. 10.	Pharmaceutical care concepts Critical evaluation of biomedical literature Medication errors	04 06 03

c. Adverse drug reaction managementd. Drug information and poisons information e. Medication history

f. Patient counselling

#### 12PD43P: CLINICAL PHARMACY (PRACTICALS)

Practical: 3 Hrs. /Week 75 Hours

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

Answering drug information questions (4 Nos) Patient medication counseling (4 Nos) Case studies related to laboratory investigations (4 Nos) 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 interview, history Patient medication counseling, Problem solving in Clinical Pharmacokinetics, Therapeutic drug monitoring and Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

#### Format of the assignment

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

## 12PD44T: BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope and Objective: This is an introductory course in statistics, research methodology and Computer application in hospital and community Pharmacy. This subject deals with Research methodology, Biostatics, epidemiology and Computer application and clinical studies.

Research methodology deal about types of clinical study, designing, sample size determination and power of study Statistics deals about frequency distribution, graphics, averages, measures of dispersion, Correlation, regression, Parametric and non-parametric tests. Incidence and prevalence, relative risk, attributable risk

Computer Application deals with application of Computer System in Hospital Pharmacy and Community Pharmacy

## Upon completion of the course the student shall be able to:

- 1. Know the various statistical methods to solve different types of problems
- 2. Operate various statistical software packages
- 3. Appreciate the importance of Computer in hospital and Community Pharmacy
- 4. Appreciate the statistical technique in solving the pharmaceutical problems

#### 2. Course material:

#### Reference books:

- a) Pharmaceutical statistics. Practical and clinical applications.4<sup>th</sup> ed. 2003, Sanford Bolton, Marcel Dekker, Inc.
- b) Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich, 5rd edition, McGraw Hill Publications 2014
- c) Computer Application in Pharmacy William E. Fassett, publisher Lea & Febiger. Philadelphia

#### 3. Lecture wise Programme

Topics Hrs

#### 1. Research Methodology

10

- a) Types of clinical study designs: Case studies, observational studies, interventional studies,
- b) Designing the methodology
- 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.	<ul><li>2.1 Biostatistics</li><li>a) Introduction</li><li>b) Types of data distribution</li><li>c) Measures describing the central tendency distributions- average, median, mode</li></ul>	10
	d) Measurement of the spread of data-range, mean deviation, standard deviation, variance, coefficient of variation, standard error of mean.	02
	2.2 <b>Data graphics</b> : Construction and labeling of graphs, histogram, Pie charts, scatter plots, semi-logarithmic graphs	UZ.
	<ul> <li>2.3 Basics of testing hypothesis:</li> <li>a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.</li> <li>b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)</li> <li>c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall's test (one way ANOVA)</li> <li>d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.</li> <li>e) Introduction to statistical software: SPSS, Epi Info, SAS.</li> <li>2.4 Statistical methods in epidemiology Incidence and prevalence, relative risk, attributable risk</li> </ul>	05
3.	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	08

ledger system

Drug Information Retrieval & Storage:

Introduction - Advantages of Computerized Literature Retrieval, Use of Computerized Retrieval

## 12PD45T: BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week 75 Hours

1. Scope and Objectives: This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

At completion of this course it is expected that students will be able to -

- 1. Define the basic concepts in biopharmaceutics and pharmacokinetics.
- 2. Use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- 3. Critically evaluate biopharmaceutic studies involving drug product equivalency
- 4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- 5. Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

#### 2. Course Materials

#### **Text Books**

- a) Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.4<sup>th</sup> ed. 2005, Pharma Med Press
- b) Biopharmaceutics and Pharmacokinetics; By Robert F Notari, 2010, Marcel Dekker,
- c) Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 7th edition, 2016, Prentice-Hall Inernational edition. USA
- d) Bio pharmaceutics and Pharmacokinetics-A Treatise, D. M. Brahmankar and Sunil B. Jaiswal, 3<sup>rd</sup>. ed. 2015, Vallabh Prakashan Pitampura, Delhi

#### Reference Books

- a) Pharmacokinetics: By Milo Gibaldi Donald, R.4<sup>th</sup>. ed. 2005, Mercel Dekker Inc.
- b) Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott, 2005, 4<sup>th</sup>.ed., by ADIS Health Science Press.
- c) Biopharmaceutics; By Swarbrick, Encyclopedia of Pharmaceutical Technology, Vol. 1-3, 2<sup>nd</sup>. Ed. 2002,
- d) Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 4<sup>th</sup> ed. 2010.
- e) Dissolution, Bioavailability and Bioequivalence, By Abdou H.M. Mack, Publishing Company, Pennsylvania 1989.
- f) Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4<sup>th</sup> edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- g) Remington's Pharmaceutical Sciences. Vol. 1-3, 22<sup>th</sup> ed. 2010

## 3. Lecture wise programme

Topi	<b>CS</b>	Hrs
·	I Biopharmaceutics	
1. 2.	Introduction to biopharmaceutics <b>Absorption;</b> Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non <i>per OS</i> extra-vascular routes	01 08
3.	<b>Distribution of drugs</b> Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, protein binding of drugs, factors affecting protein - drug binding. Kinetics of protein binding, Clinical significance of protein bin-drug binding	80
4.	<b>Drug Elimination.</b> Biotransformation of drugs, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs	06
5.	<b>Bioavailability and Bioequivalence:</b> Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, <i>in-vitro</i> drug dissolution models, <i>in-vitro in-vivo</i> correlations, bioequivalence studies, methods to enhance the bioavailability	10
	II Pharmacokinetics	
6.	Introduction to Pharmacokinetics. Mathematical model. Drug levels in blood. Pharmacokinetic models, Compartment models, Noncompartment models, physiological models	05
7.	One compartment open model.  a. Intravenous Injection (Bolus) b. Intravenous infusion. c. extra vascular administrations, calculations of Ka, KE from plasma	15
	and urinary excretion data	
8.	Multicompartment models: Two compartment open model.IV bolus, IV infusion and oral administration	80
9.	Multiple - Dosage Regimens: a). Repititive Intravenous injections - One Compartment Open Model	05
	b). Repititive Extravascular dosing - One Compartment Open model	
10.	c). Multiple Dose Regimen - Two Compartment Open Model Nonlinear Pharmacokinetics. a. Introduction,	05
11.	<ul> <li>b. Factors causing Non-linearity.</li> <li>c. Michaelis-menton method of estimating parameters</li> <li>Noncompartmental Pharmacokinetics. Statistical Moment Theory,.</li> <li>MRT for various compartment models. Physiological Pharmacokinetic model</li> </ul>	04

## 12PD45P: BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

## List of experiments

- 1. Improvement of dissolution characteristics of slightly soluble drugs by cosolvency
- 2. Improvement of dissolution characteristics of slightly soluble drugs by solid dispersion
- 3. Improvement of dissolution characteristics of slightly soluble drugs by use of surfactant
- 4. Comparison of dissolution studies of two different marketed products of same drug.
- 5. Influence of polymorphism on solubility and dissolution
- 6. Protein binding studies of a drug.
- 7. Calculation of bioavailability
- 8. Calculation of Ka, Ke,  $t_1/2$  Cmax, AUC, AUMC, MRT etc. from blood profile data.
- 9. Calculation of bioavailability from urinary excretion data for two drugs.
- 10. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data
- 11. Calculation of AUC and bioequivalence from the given data for two drugs
- 12. Absorption studies in animal inverted intestine using various drugs.
- 13. Studying metabolic pathways for different drugs based on elimination kinetics data
- 14. Calculation of renal clearance

## 12PD46T: CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope and Objectives: This course is designed to impart a thorough knowledge in the management of various poisoning cases thereby enabling the students to assist healthcare professionals / toxicologists in handling and managing the emergency cases.

Upon completion of the course student shall be able to:

- 1. Understand and deal with general principles involved in the management of poisoning
- 2. Recognize the clinical symptoms and manage poisoning cases
- 3. Educate public and healthcare professionals in the management of emergency cases
- 4. Minimize/ prevent the poisoning cases in local population

#### 2. Course materials

#### **Reference Books:**

- a) Matthew J Ellenhorn. Ellenhorns Medical Toxicology Diagnosis and Treatment of Poisoning. 2nd ed., 1997, Williams and Willkins publication, London
- b) Modern medical toxicology, Author V. V. Pillay, 4<sup>th</sup> ed. 2013, Publisher: JP Brothers
- c) Pediatric toxicology diagnosis and management of the poisoned child, Timothy B, Erickson, William R. Athrens, Steven.E. AK, Cart K.Baun, Louis J.Ling. Mcgraw-Hill; 2005.
- d) Lindsay Murray, Frank Dary, Mark little, Mikes Cadogan, editors. Toxicology handbook. Australia: Churchil Livingstone, Elsevier; 2007

#### 3. Lecture wise programme

ics	Hrs
General principles involved in the management of poisoning	02
Antidotes and the clinical applications	01
Supportive care in clinical Toxicology	02
Gut Decontamination	02
Elimination Enhancement	01
Toxicokinetics	02
Clinical symptoms and management of acute poisoning with the	21
following agents	
a) Pesticide poisoning: organophosphorous compounds, carbamates,	
organochlorines, pyrethroids	
b) Opiates overdose.	
c) Antidepressants	
	General principles involved in the management of poisoning Antidotes and the clinical applications Supportive care in clinical Toxicology Gut Decontamination Elimination Enhancement Toxicokinetics Clinical symptoms and management of acute poisoning with the following agents a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids b) Opiates overdose.

	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	05
	following agents - Heavy metals: Arsenic, lead, mercury, iron, copper	
9.	Venomous snake bites: Families of venomous snakes, clinical effects of	02
	venoms, general management as first aid, early	
	manifestations, complications and snakebite injuries	
10.	Plants poisoning. Mushrooms, Mycotoxins	02
11.	Food poisonings	01
	Envenomations - Arthropod bites and stings	01
13.		80
	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	

## 12PD47T: PHARMACOTHERAPEUTICS I & II (THEORY)

Theory: 3 Hrs. /Week 75 Hours

1. Scope and Objectives: 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.

At completion of this course it is expected that students will be able to understand:

- 1. The pathophysiology of selected disease states and the rationale for drug therapy.
- 2. The therapeutic approach to management of these diseases.
- 3. The controversies in drug therapy.
- 4. The importance of preparation of individualized therapeutic plans based on diagnosis.
- 5. 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).
- 6. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy.
- 7. Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence.
- 8. Discuss the controversies in drug therapy.
- 9. Discuss the preparation of individualized therapeutic plans based on diagnosis.
- 10. 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).

#### 2. Course materials

### **Text Books**

- a) Clinical Pharmacy and Therapeutics; 5<sup>th</sup>.ed. 2012; Walker & Whittlesea, Churchill Livingstone publication.
- b) Pharmacotherapy: A Pathophysiology approach Joseph T. Dipiro et al.10<sup>th</sup> ed., 2016, Appleton & Lange

#### Reference Books

- a) Pathologic basis of disease by- Cotran, Kumar, Robbins Elsiver India Pvt Ltd, Newdelhi, 2015, ed. 9 vol. 1-2.
- b) Pathology and Therapeutics for Pharmacists A Basis for Clinical Pharmacy Practice Green and Harris, 3rd. ed., Chapman and Hall publication

- c) Clinical Pharmacy and Therapeutics Eric T. Herfindal, 5th ed. 2016, Williams and Wilkins Publication
- d) Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA, 10th ed. 2013, Wolters Kluwer Lippincot williams &Wilkins, Newyork
- e) Avery's Drug Treatment, 4th Ed, 1997, Adis International Limited.
- f) Relevant review articles from recent medical and pharmaceutical literature.

## 3. Lecture wise Programme

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

Top	ics	Hrs
1.	Cardiovascular system Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidemia,	13
	Electrophysiology of heart and Arrhythmias	
2.	1. Respiratory system	06
	Introduction to Pulmonary function test, Asthma, Chronic	
	obstructive airways disease, Drug induced pulmonary diseases.	
3.	Endocrine system	80
	Diabetes, Thyroid diseases, Oral contraceptives, Hormone	
	replacement therapy,Osteoporosis	
4.	General prescribing guidelines for	04
	4.1 Paediatric patients	
	4.2 Geriatric patients	
	4.3 Pregnancy and breast feeding	
5.	Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial.	03
6.	Introduction to rational drug use	02
	Definition, Role of pharmacist Essential drug concept Rational drug	
	formulations.	
7.	Infectious disease: Guidelines for the rational use of antibiotics	18
	and surgical	
	Prophylaxis, Tuberculosis, Meningit is, Respiratory tract in	
	Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, F	
	infection- Malaria, HIV & Opportunistic infections, Fungal infectior	
•	infections, Gonarrhoea and Syphillis.	٠.
8.	5. Musculoskeletal disorders	06
	Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic	
^	lupus erythematosus.	٥.
9.	6. Renal system	05
	Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug	
40	induced renal disorders.	01
10.	Oncology: Basic principles of Cancer therapy, General introduction	06
	to cancer chemotherapeutic agents, Chemotherapy of breast cancer,	
4.4	leukemia. Management of chemotherapy nausea and emesis.	0.4
11.	Dermatology: Psoriasis, Scabies, Eczema, Impetigo.	04

## 12PD47P: PHARMACOTHERAPEUTICS I & II (PRACTICAL)

Practical: 3 Hrs./Week 75 Hours

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 15 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.

## **Assignments**

## Format of the assignment

- Minimum & Maximum number of pages It shall be computer draft copy
- Reference(s) shall be included at the end.
- Assignment can be a combined presentation Time allocated for presentation at the end of the academic year
- Name and signature of the student
  - 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)

## 12PD51T: CLINICAL RESEARCH (THEORY)

Theory: 2 Hrs. /Week 50 Hours

1. Scope and Objectives: This course is designed to make the students to understand the principles and gain adequate knowledge regarding the various approaches to drug discovery including clinical phase of development. Also enables the students to understand and implement all regulatory and ethical requirements that are required during the process of drug development.

At completion of this course, it is expected that students will be able to:

- 1. Know the concept of new drug development process.
- 2. Understand the regulatory and ethical requirements.
- 3. Conduct the clinical trials in accordance to regulatory and ethical requirements.
- 4. Coordinate the clinical trials and promote quality drug trial research.

#### 2. Course material

#### **Text Books:**

- a) Principles and practice of pharmaceutical medicine, 3rd edition. Lionel. D. Edward, Aadrew. J. Flether Anthony W Fos, Peter D Sloaier Wiley;
- b) Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
- c) Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes. 2001, Director of CCA 2000 Ltd, East Horsley, UK.

## **References:**

- a) Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b) International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.
- c) Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d) Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, ed. 2, March 2010, John Wiley and Sons.
- e) Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes. 2001, Director of CCA 2000 Ltd, East Horsley, UK.
- f) Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. 2nd. Edition, Jan 2000, Wiley Publications.
- g) Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological basis of therapeutics. 11th edition, 2006. Publisher McGraw Hill, Pergamon Press.

## 3. Lecture wise programme

Top	pics	Hrs
1.	Drug development process: Introduction	10
	Various Approaches to drug discovery	
	i. Pharmacological	
	ii. Toxicological	
	iii. IND Application	
	iv. Drug characterization	
	v. Dosage form	
2.	Clinical development of drug:	
	1. Introduction to Clinical trials.	04
	2. Various phases of clinical trial.	06
	3. Methods of post marketing surveillance.	03
	4. Abbreviated New Drug Application submission.	
	5. Good Clinical Practice - ICH, GCP, Central drug standard control	03
	organization (CDSCO) guidelines.	80
	6. Challenges in the implementation of guidelines.	03
	7. Ethical guidelines in Clinical Research.	02
	8. Composition, responsibilities, procedures of IRB / IEC.	02
	9. Overview of regulatory environment in USA, Europe and India.	10
	10. Role and responsibilities of clinical trial personnel as per ICH GCP	07
	a. Sponsor	07
	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	06
	assignment).	02
	12. Informed consent Process.	
	13. Data management and its components.	05
	14. Safety monitoring in clinical trials.	04

## 12PD52T: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs./Week 75 Hours

1. Scope and Objectives: This course is designed to impart knowledge regarding various methods and applications of pharmacoepidemiology and pharmacoeconomics in drug safety monitoring, drug approval and regulations.

Upon completion of this course, it is expected that students will be able to -

- 1. Understand drugs use pattern and their outcome measures
- 2. Conduct pharmacoepidemiological studies
- 3. Adopt the tools effectively in evaluating risk and benefit of therapy
- 4. Conduct pharmacoeconomic studies and evaluate the cost-benefit ratio

### 2. Course Materials: Reference Books

- a) Pharmacoeconomics and outcomes: Applications for patient care, case studies, Graer DW, Lee J, OdomTD, et al. American college of clinical pharmacy-2003.
- b) Introduction to Applied Pharmacoeconomics, F. Randy Vogenberg, New York; London: McGraw-Hill,
- c) Pharmacoepidemiology Editor Brian L Storm, John Wiley and Sons, Ltd 4<sup>th</sup> edition,
- d) Clinical epidemiology- How to do clinical Practice Research. 3<sup>rd</sup> edition, Brian Haynes, David L Sachett, Lippinkot

### 3. Lecture wise programme

Top	pics	Hrs
1.	Pharmacoepidemiology:	06
	Definition and scope:	
	Origin and evaluation of Pharmacoepidemiology, need for	
	pharmacoepidemiology, aims and applications of Pharmacoepidemiology	
2.	Measurement of outcomes in pharmacoepidemiology	06
	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	
3.	Concept of risk in pharmacoepidemiology	06
	Measurement of risk, attributable risk, relative risk, time-risk	
	relationship and odds ratio	
4.	Pharmacoepidemiological methods	21
	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,	

	prescription event monitoring and record linkage system.	
5.	Sources of data for pharmacoepidemiological studies  Ad Hoc data sources and automated data systems.	04
6.	Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth defects.	80
7.	Phrmacoeconomics: Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions Pharmacoeconomic evaluation Outcome assessment and types of evaluation, Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost - minimization, cost- benefit, cost - effectiveness and cost utility Applications of Pharmacoeconomics Software and case studies (assignment discussion)	24

# 12PD53T: CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs./Week 50 Hours

1. Scope and Objectives: This course is designed to make the students to understand and apply pharmacokinetic principles in designing / individualizing dosage regimen. Also, enable the students to interpret the plasma drug range, and hepatic / renal function in optimizing the drug therapy.

On completion of the course, the student shall be able to

- 1. Design the drug therapy regimen for individual patient
- 2. Interpret and correlate the plasma drug concentration with patient's therapeutic outcome.
- 3. Recommend dosage adjustment for patients with renal/ hepatic impairment
- 4. Detect and manage drug -drug interactions

## 2. Course materials: Reference Books

- a) Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring; Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans Lippincott Williams & Wilkins, 4<sup>th</sup>., ed. 2005,
- b) Handbook of Analytical Therapeutic Drug Monitoring and Toxicology By Steven How-Yan Wong, Irving Sunshine, Published by CRC Press, 1996
- c) Clinical pharmacokinetics, Author: Soraya Dhillon, Andrzej Kostrzewski, Publisher: Pharmaceutical Press
- d) Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 4<sup>th</sup> ed. 2010
- e) Biopharmaceutics and Applied Pharmacokinetics, Leon Shargel, 6<sup>th</sup> ed. 2013, Prentice Hall Publication

### 3. Lecture wise Programme:

Гор	ics	Hrs
1.	Introduction to Clinical pharmacokinetics.	01
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	07
3.	Pharmacokinetics of Drug Interaction:  a. Pharmacokinetic drug interactions  b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary  Excretion.	03
4.	Therapeutic Drug monitoring:  a) Introduction  b) Individualization of drug dosage regimen (Variability - Genetic, age.	20

weight, disease and Interacting drugs). c) Indications for TDM, Protocol for TDM. d) Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e) TDM of drugs used in the following conditions: Cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations. Dosage adjustment in Renal and hepatic Disease.

## 5.

10

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

#### Population Pharmacokinetics. 6.

05

- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with feed back.
- c. Analysis of Population pharmacokinetic Data.

#### 7. **Pharmacogenetics**

04

- a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- b. Genetic Polymorphism in Drug Transport and Drug Targets.
- c. Pharmacogenetics and Pharmacokinetics / Pharmacodynamic considerat

#### Pharm. D. - Sixth Year

# INTERNSHIP (See regulation 16.1.6)

## 1) SPECIFIC OBJECTIVES:

- i. to provide patient care in cooperation with patients, prescribers, and other members of an inter-professional 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. manage and use resources of the health care system, prescribers, cooperation with patients, other health care providers, and supportive personnel, to promote health; to administrative 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 cooperation with patients, communities, at-risk population, and other members of an inter-professional 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	SCORE 0-5
	management	
2.	The competency in skills expected for providing Clinical	SCORE 0-5
	Pharmacy Services	
3.	Responsibility, punctuality, work up of case, involvement	SCORE 0-5
	in patient care	
4.	including medical doctors, nursing staff and	SCORE 0-5
5.	Initiative, participation in discussions, research	SCORE 0-5

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

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

#### PCI NOTIFICATION - I

Ref.No.50-100(R)/2009-PCI/28059-92

Dated-17/01/2011

## All the State Pharmacy Councils/Registration Tribunals

Sub: Registration procedure of Pharm.D. (Doctor of Pharmacy) passed out students.

Sir/Madam

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 vide Notification No.19, Part III - Section 4, dated 10<sup>th</sup> - 16<sup>th</sup> May, 2008 had published Pharm.D. Regulations, 2008 in the Gazette of India.

Under the said Pharm.D. Regulations -

- a) Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.
- b) 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.
- c) The eligibility criteria for admission to Pharm.D. course is as follows -

Level Qualification	Duration of the Course
• 10 + 2 Science academic stream Or	6 years
D.Pharm	
B.Pharm	3 years

d) The above Pharm.D. course includes one year of internship in hospital as per Pharm.D. Regulations, 2008.

The first batch of Pharm.D students admitted during 2008-2009 with B.Pharm entry level qualification will pass the Pharm.D. course in 2010-2011 academic session. These students will approach the State Pharmacy Council for registration as a pharmacist u/s 32(2) of the Pharmacy Act, 1948.

In view of above, it is requested to -

- a) register these Pharm.D. students as "Doctor of Pharmacy" u/s 32(2) of the Pharmacy Act, 1948.
- b) maintain separate register for Pharm.D. registrations and forward the same to PCI for Central Register.

- c) ensure that following conditions of section 32(2) of the Pharmacy Act, 1948 are strictly complied with
  - i. the candidate shall be of 18 years or more.
  - ii. he/she should reside or carry on the business or profession of pharmacy in the State.
- iii. he/she should have pass an approved examination i.e. he/she should have pass the Pharm.D. course from an institution approved by the PCI u/s 12 of the Pharmacy Act.
- iv. the approval status of such institutions can be verified from -
  - Council's website "www.pci.nic.in".
  - Council's Notifications issued from time to time.

Please note that if the course is approved only for the "conduct of study" and not u/s 12 of the Pharmacy Act for the purpose of registration as a pharmacist, students are not eligible for registration. Further please find enclosed herewith the registration procedure in detail for strict compliance at your end.

Yours faithfully Sd/-

(ARCHNA MUDGAL) Registrar-cum-Secretary

### **PCI NOTIFICATION - II**

Dated: 30.9.2011

Ref. No. 14-126/2010-PCI / 28844-947

To All Universities

Sub: Clarification on Pharm.D qualification.

Sir/Madam

With reference to the subject cited above, I directed to inform that subject cited issue was considered by the 88<sup>th</sup> /CC in its meeting held in August, 2011 & decided to forward a clarification to all universities that Pharm.D is a PG qualification and passed out students can directly register for Ph.D.

This is for information.

Yours faithfully

Sd/-(ARCHNA MUDGAL) Registrar-cum-Secretary

Nav/14-126 letter /hd-2/p-11/7.9.1/27.9.11

#### PCI NOTIFICATION - III

Ref. No. 14-126/2010-PCI/34094-36202 21.11.2011 Dated

## All D.Pharm, B.Pharm & Pharm.D institutions approved

- u/s 12 of the Pharmacy Act, 1948
- for conduct of "course of study"

Sub: Pharm.D an approved qualification for teaching.

Sir/Madam

It may kindly be recalled that vide notification published in Gazette of India, Part-III, Section-4, No. 19, May 10- May 16, 2008, the Pharmacy Council of India has introduced Pharm.D qualification as a registrable qualification under the Pharmacy Act, 1948.

In this connection, I am directed to inform that Pharm.D. qualification from an institution approved by the PCI u/s 12 of the Pharmacy Act 1948 is an approved qualification for teaching D.Pharm, B.Pharm, M.Pharm and Pharm.D./ Pharm.D (Post Baccalaureate) courses. As such a candidate holding Pharm.D. qualification from an institution approved by the PCI u/s 12 of the Pharmacy Act, 1948 shall be eligible for consideration for teaching posts at appropriate level in pharmacy institutions.

This is for information.

Yours faithfully

Sd/-(ARCHNA MUDGAL) Registrar-cum-Secretary

#### **PCI NOTIFICATION - IV**

Ref.No.14-126/2012-PCI/46595-618 Dated: 16<sup>th</sup> February 2012

To

All Universities/Examining Authorities approved by the PCI in respect of Pharm.D/Pharm.D (Post Baccalaureate) course.

Sub: <u>Pharm.D Course - Clarification regarding nomenclature of</u> Pharm.D/Pharm.D (Post Baccalaureate) on pass certificates.

Ref: Council's circular No. 14-126/2012-PCI/46011-36 dt.8.2.2012.

Sir/Madam

This has a reference to the subject cited above.

It has been brought to the notice of the Council that some Universities are not prefixing "Dr." before the name of the candidate in the provisional as well as final degree pass certificate issued by the university in respect of students passing Pharm.D/Pharm.D (Post Baccalaureate) from an institution approved by the Pharmacy Council of India u/s 12 of the Pharmacy Act, 1948.

In view of above, it is requested to use the prefix "Dr." before the name of the candidate while awarding the degree of Doctor of Pharmacy under regulation 18 of the Pharm.D. Regulations, 2008.

This is for information and necessary action at your end.

Yours faithfully

--sd--(ARCHNA MUDGAL) Registrar-cum-Secretary