

MINUTES OF MEETING

Agenda: The Meeting was convened to approve the Ordinance and Syllabus of Doctor of Pharmacy (Pharm.D & Pharm.D [Post Baccalaureate (PB)], M.Pharm (Pharmaceutics, Pharmacognosy, Pharmaceutical Chemistry, Pharmacology and Regulatory affairs) and Diploma in Pharmacy (D.Pharm) through the Member of Board of Studies (BOS) on dated 14/07/2019 (Sunday) from 12:30 PM at office of Head of the Department Pharmacy, Dr. Bhimrao Ambedkar University Agra, Khandari Campus for Institute of Pharmacy and Paramedical Sciences for the session 2020-21 onwards.


The Following Members concerned with Subject were invited as Mentioned below

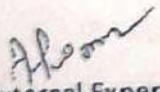
1. Head of the Department
(Department of Pharmacy)
2. Prof. A Pandurangan
(Maharishi Markandeshwar (Deemed to be University, Mullana Ambala (Haryana))
3. Prof. Pawan Gautam
(Department of Pharmacy, S.N Medical College, Agra)
4. Prof. Sudhir Kumar
(BBS Institute of Pharmaceuticals and Allied Health Sciences, Greater Noida)
5. Dr. Ravi Shekhar Sharma
(Department of Pharmacy)
6. Mr. Manoj Kr. Yadav
(Department of Pharmacy)
7. Dr. Jaybir Singh
(Department of Pharmacy)
8. Dr. Arshad Ahmad
(Department of Pharmacy)
9. Mrs. Pratibha Mishra
(Department of Pharmacy)
10. Mrs. Pooja Sharma
(Department of Pharmacy)


Resolution: Prof. Brijesh Kumar Tiwari, Head, Department of Pharmacy has Chaired meeting of Board of Studies, aforementioned Members were present in the meeting. Meeting was started with agenda to approve the ordinance and syllabus of Doctor of Pharmacy (Pharm.D & Pharm.D [Post Baccalaureate (PB)], M.Pharm (Pharmaceutics, Pharmacognosy, Pharmaceutical Chemistry, Pharmacology and Regulatory affairs) and Diploma in Pharmacy (D.Pharm) was adopted as per the regulations of Pharmacy Council of India. Also discussed that any amendments as per Pharmacy Council of India will be incorporated accordingly.


The appointment of faculty should be done on the basis of qualification and experience prescribed under the "Minimum Qualification for Teachers in Pharmacy Institutions Regulation 2014", as per the Gazette of India (notification no 325, Extraordinary), published on November 12 2014 by the Pharmacy Council of India
The Number of Seats will be according to Regulatory body (Pharmacy Council of India).
The resolution was passed with vote of thanks and approved.

The Following Members were Present



Prof. Brijesh Kumar Tiwari
(Head, Department of Pharmacy)

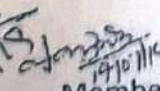

External Expert
(Prof. A Pandurangan)


External Expert
(Prof. Pawan Gautam)



External Expert
(Prof. Sudhir Kumar)

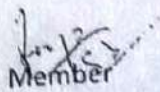

Member
(Dr. Ravi Shekhar)


Member
(Mr. Manoj Kr. Yadav)


Member
(Dr. Jaybir Singh)


Member
(Dr. Arshad Ahmad)


Member
(Mrs. Pratibha Mishra)


Member
(Mrs. Pooja Sharma)



डा० भीमराव आंबेडकर विश्वविद्यालय, आगरा (पूर्ववर्ती: आगरा विश्वविद्यालय, आगरा)

विद्या परिषद् की बैठक दिनांक 31.07.2019 का कार्यवृत्त

विद्या परिषद् की बैठक दिनांक 31.07.2019 को पूर्वाह्न 11:00 बजे जे०पी० सभागार, खन्दारी परिसर आगरा में सम्पन्न हुई, जिसमें निम्नलिखित सदस्य उपस्थित हुये :-

डा० अरविन्द कुमार दीक्षित (अध्यक्ष) - कुलपति

- | | |
|---------------------------------|------------------------------|
| 2. डा० विवेक द्विवेदी | 3. डा० जयप्रकाश सिंह |
| 4. डा० वाई०पी० सिंह | 5. प्रो० वी०पी० सिंह |
| 6. डा० के०के० शर्मा | 7. डा० एस०के० कटेरिया |
| 8. डा० हेमा पाठक | 9. डा० नीता गुप्ता |
| 10. प्रो० मनोज कुमार श्रीवास्तव | 11. डा० सुमन कुमार |
| 12. डा० प्रताप सिंह | 13. प्रो० दीपमाला श्रीवास्तव |
| 14. डा० के०पी० सिंह | 15. डा० यशपाल सिंह |
| 16. डा० आर०के०एस० धाकरे | 17. डा० अलका अग्रवाल |
| 18. डॉ० मंजूलता शर्मा | 19. डा० विपिन कुमार |
| 20. प्रो० हरबंस सिंह सौलकी | 21. डा० पीयूष त्यागी |
| 22. प्रो० मीनाक्षी श्रीवास्तव | 23. प्रो० विनीता सिंह |
| 24. डा० यदुवीर सिंह चौहान | 25. प्रो० वी०के० सारस्वत |
| 26. प्रो० मनुप्रताप सिंह | 27. डा० आर०के० सिंह |
| 28. डा० जी०के० गुप्ता | 29. प्रो० यू०एन० शुक्ला |
| 30. डा० एन०के० सिंह | 31. डा० अनिता गुप्ता |
| 32. डा० झिलमिल गुप्ता | 33. प्रो० मोहम्मद अरशद |
| 34. प्रो० यू०सी० शर्मा | 35. प्रो० अजय तनेजा |

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1. विद्या परिषद् की पूर्व बैठक दिनांक 27.09.2018, आकस्मिक बैठक दिनांक 21.12.2018 एवं दिनांक 19.06.2019 के कार्यवृत्त की सम्पुष्टि करना।

(परिशिष्ट-1)

निर्णय:-विद्या परिषद् द्वारा दिनांक 27.09.2018, आकस्मिक बैठक दिनांक 21.12.2018 एवं दिनांक 19.06.2019 के कार्यवृत्तों को सम्पुष्टि प्रदान की गई।

2. प्राचार्य, आर0बी0एस0 कालेज के पत्र दिनांक 25.09.2018 के द्वारा विश्वविद्यालय अनुदान आयोग, नई दिल्ली के द्वारा नेशनल स्किल क्वालीफिकेशन फ्रेमवर्क (एनएसक्यूएफ) स्कीम के अर्न्तगत महाविद्यालय द्वारा निम्न पाठ्यक्रमों को संचालित करने के अनुमोदन पर विचार करना:-

| Programme/Courses | |
|--|---|
| B.Voc. | Community College |
| 1. Multimedia Animation and Graphic Design | 1. Plant Nursery & Propagation Tech. |
| 2. Nutrition and Health Case Sci. | 2. Green House Tech. |
| 3. Analytical Instrumentation | 3. Holistic and Sustainable Agriculture |
| | 4. Dairy Products |

(परिशिष्ट-2)

निर्णय:-विद्या परिषद् द्वारा उपरोक्त पाठ्यक्रमों को अनुमोदन प्रदान किया गया।

3. विद्या परिषद् द्वारा फार्मेसी एण्ड पैरामैडिकल साइंसेज, खन्दारी आगरा की एकेडेमिक कमेटी की बैठक दिनांक 14.07.2019 की संस्तुतियों के अनुमोदन पर विचार।

(परिशिष्ट-3)

निर्णय:-विद्या परिषद् द्वारा फार्मेसी एण्ड पैरामैडिकल साइंसेज, खन्दारी आगरा की एकेडेमिक कमेटी की बैठक दिनांक 14.07.2019 की केवल अध्यादेश को अनुमोदन प्रदान कया गया। प्रशासनिक संस्तुतियों पर अलग से कार्यवाही किये जाने की संस्तुति की गयी।

4. विद्या परिषद् द्वारा भौतिक विज्ञान विभाग, खन्दारी, आगरा की एकेडेमिक कमेटी की बैठक दिनांक 30.07.2016, 10.11.2017 एवं 12.10.2018 की संस्तुतियों के अनुमोदन पर विचार।

(परिशिष्ट -4)

निर्णय:-विद्या परिषद् द्वारा भौतिक विज्ञान विभाग, खन्दारी, आगरा की एकेडेमिक कमेटी की बैठक दिनांक 30.07.2016, 10.11.2017 एवं 12.10.2018 की संस्तुतियों को अनुमोदन प्रदान किया गया।

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Institute of Pharmacy and Paramedical Sciences, Agra
(Dr. Bhim Rao Ambedkar University, Agra)

Preamble:

Institute of Pharmacy and Paramedical Sciences, Dr. Bhim Rao Ambedkar University, Agra imparting education and training in pharmaceutical sciences since 2002, started B. Pharm course in 2002. Pharm D (Post Baccalaureate), M.Pharm, D.Pharm programs were introduced in 2021. From the year 2002- 20, the institute was named as Department of pharmacy and in the year 2020 its name was changed to Institute of Pharmacy and Paramedical Sciences. 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 the University Regulations for Pharm.D. and Pharm.D. (Post Baccalaureate) programme 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 2016-2017.
- 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 Agra only.

2. Definitions:

Unless the context otherwise requires

- *BOM means Board of Management*
- *AC means Academic Council*
- *BOS means Board of Studies (UG and PG) in Pharmaceutical Sciences*
- *College/Institute means Institute of Pharmacy and Paramedical Sciences, Agra*
- *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 Institute of Pharmacy and Paramedical Sciences, Agra*
- *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 S.N. MEDICAL COLLEGE,AGRA.*
- *University means Institute of Pharmacy and Paramedical Sciences, Agra*
- *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 31st 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 Institute of Pharmacy and Paramedical Sciences, Agra with not less than 45% marks with Physics and Chemistry as compulsory subjects along with one of the following subjects - Mathematics or Biology.

OR

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

OR

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

6.2 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 bebased 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 permittedto 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 stating 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 suchtemporary 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. Withdrawal of Admission:

- 8.2.1. As per University/ UGC norms.

addition to those mentioned in the clause above.

8.2.2. 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 behavior 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 behavior, 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 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:

- The Chairman may co-opt and/or invite more members.
- The senior most member in the Board shall act as chairman in the absence of chairperson
- 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 Code | Name of Subject | No. of hours/ Week | No. of hours of Tutorial |
|--------------|------------------------------------|--------------------|--------------------------|
| (1) | 2 | (3) | (4) |
| 22PD11T | Human Anatomy and Physiology | 3 | 1 |
| 22PD11P | Human Anatomy and Physiology | 3 | - |
| 22PD12T | Pharmaceutics | 2 | 1 |
| 22PD12P | Pharmaceutics | 3 | - |
| 22PD13T | Medicinal Biochemistry | 3 | 1 |
| 22PD13P | Medicinal Biochemistry | 3 | - |
| 22PD14T | Pharmaceutical Organic Chemistry | 3 | 1 |
| 22PD14P | Pharmaceutical Organic Chemistry | 3 | - |
| 22PD15T | Pharmaceutical Inorganic Chemistry | 2 | 1 |

| | | | |
|----------|--|---------------------------------------|---|
| 22PD15P | Pharmaceutical Inorganic Chemistry | 3 | - |
| 22PD16T* | Remedial Mathematics ⁺ / Biology ⁺⁺ | 3 | 1 |
| 22PD16P* | Remedial Biology ⁺⁺ | 3 | - |
| 22PD17T* | Constitution of India | 2 | - |
| | | 33 ⁺ /36 ⁺⁺ /30 | 6 |
| | Total hours - For Maths Deficient: 39For Biology Deficient: 42 For No Maths/Bio Deficiency: 35 | | |

+ For mathematics deficit students ++ For Biology deficit students

* College examination only

Second Year:

| Subject Code | Name of Subject | No. of hours/ Week | No. of hours of Tutorial |
|--------------|---|--------------------|--------------------------|
| 22PD21T | Pathophysiology | 3 | 1 |
| 22PD22T | Pharmaceutical Microbiology | 3 | 1 |
| 22PD22P | Pharmaceutical Microbiology | 3 | - |
| 22PD23T | Pharmacognosy & Phytopharmaceuticals | 3 | 1 |
| 22PD23P | Pharmacognosy & Phytopharmaceuticals | 3 | - |
| 22PD24T | Pharmacology-I | 3 | 1 |
| 22PD25T | Community Pharmacy | 2 | 1 |
| 22PD26T | Pharmacotherapeutics-I | 3 | 1 |
| 22PD26P | Pharmacotherapeutics-I | 3 | - |
| 22PD27T* | Human Rights, Gender Equity and Environmental Studies | 2 | - |
| | Total hours | 28 | 6 |
| | Grand Total | 34 | |

* College examination only

Third Year:

| Subject Code | Name of Subject | No. of hours/ Week | No. of hours of Tutorial |
|--------------|------------------------------|--------------------|--------------------------|
| 22PD31T | Pharmacology-II | 3 | 1 |
| 22PD31P | Pharmacology-II | 3 | - |
| 22PD32T | Pharmaceutical Analysis | 3 | 1 |
| 22PD32P | Pharmaceutical Analysis | 3 | - |
| 22PD33T | Pharmacotherapeutics-II | 3 | 1 |
| 22PD33P | Pharmacotherapeutics-II | 3 | - |
| 22PD34T | Pharmaceutical Jurisprudence | 2 | - |
| 22PD35T | Medicinal Chemistry | 3 | 1 |
| 22PD35P | Medicinal Chemistry | 3 | - |
| 22PD36T | Pharmaceutical Formulations | 2 | 1 |
| 22PD36P | 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 |
|--------------|--------------------------------------|--------------------|--------------------------|
| 22PD41T | Pharmacotherapeutics-III | 3 | 1 |
| 22PD41P | Pharmacotherapeutics-III | 3 | - |
| 22PD42T | Hospital Pharmacy | 2 | 1 |
| 22PD42P | Hospital Pharmacy | 3 | - |
| 22PD43T | Clinical Pharmacy | 3 | 1 |
| 22PD43P | Clinical Pharmacy | 3 | - |
| 22PD44T | Biostatistics & Research Methodology | 2 | 1 |
| 22PD45T | Biopharmaceutics & Pharmacokinetics | 3 | 1 |
| 22PD45P | Biopharmaceutics & Pharmacokinetics | 3 | - |
| 22PD46T | 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 |
|--------------|---|--------------------|--------------------------|
| 22PD51T | Clinical Research | 3 | 1 |
| 22PD52T | Pharmacoepidemiology and Pharmacoeconomics | 3 | 1 |
| 22PD53T | Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring | 2 | 1 |
| 22PD54 | Clerkship * | - | 1 |
| 22PD55P | Project work (Six Months) | 20 | - |
| | Total hours | 28 | 4 |
| | Grand Total | | 32 |

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in specialty units. Students 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 |
|--------------|--------------------------|--------------------|--------------------------|
| 22PD41T | Pharmacotherapeutics-III | 3 | 1 |
| 22PD41P | Pharmacotherapeutics-III | 3 | - |
| 22PD42T | Hospital Pharmacy | 2 | 1 |
| 22PD42P | Hospital Pharmacy | 3 | - |
| 22PD43T | Clinical Pharmacy | 3 | 1 |
| 22PD43P | Clinical Pharmacy | 3 | - |

| | | | |
|---------|--------------------------------------|-----------|-----------|
| 22PD44T | Biostatistics & Research Methodology | 2 | 1 |
| 22PD45T | Biopharmaceutics & Pharmacokinetics | 3 | 1 |
| 22PD45P | Biopharmaceutics & Pharmacokinetics | 3 | - |
| 22PD46T | Clinical Toxicology | 2 | 1 |
| 22PD47T | Pharmacotherapeutics I & II | 3 | 1 |
| 22PD47P | 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 |
|--------------|---|--------------------|--------------------------|
| 22PD51T | Clinical Research | 3 | 1 |
| 22PD52T | Pharmacoepidemiology and Pharmacoeconomics | 3 | 1 |
| 22PD53T | Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring | 2 | 1 |
| 22PD54 | Clerkship * | - | 1 |
| 22PD55P | Project work (Six Months) | 20 | - |
| | Total hours | 28 | 4 |
| | Grand Total | | 32 |

* Attending ward rounds on daily basis.

Third Year:

Internship or residency training including postings in specialty units. Students 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:

14.1. 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.

- 14.2. Each year shall be taken as a unit for the purpose of calculating attendance.
- 14.3. 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 (University exam - hrs) | Maximum Marks | | Total |
|--------------|----------------------------------|----------------------------------|----------------|-----------------|-------|
| | | | Sessional Exam | University exam | |
| 22PD11T | Human Anatomy and Physiology | 03 | 30 | 70 | 100 |
| 22PD11P | Human Anatomy and Physiology | 04 | 30 | 70 | 100 |
| 22PD12T | Pharmaceutics | 03 | 30 | 70 | 100 |
| 22PD12P | Pharmaceutics | 04 | 30 | 70 | 100 |
| 22PD13T | Medicinal Biochemistry | 03 | 30 | 70 | 100 |
| 22PD13P | Medicinal Biochemistry | 04 | 30 | 70 | 100 |
| 22PD14T | Pharmaceutical Organic Chemistry | 03 | 30 | 70 | 100 |

| | | | | | | |
|----------|--|----|-----------------------------|--------------------|------------------------|-------------|
| 22PD14P | Pharmaceutical Organic Chemistry | 04 | 30 | 70 | 100 | |
| 22PD15T | Pharmaceutical Inorganic Chemistry | 03 | 30 | 70 | 100 | |
| 22PD15P | Pharmaceutical Inorganic Chemistry | 04 | 30 | 70 | 100 | |
| 22PD16T* | Remedial Mathematics ⁺ / Biology ⁺⁺ | 03 | - | 100* | 100* | |
| 22PD16P* | Remedial Biology ⁺⁺ | 04 | - | 100* | 100* | |
| 22PD17T* | Constitution of India | 03 | - | 100* | 100* | |
| | TOTAL | | Theory Practical | 500 500 | Grand Total | 1000 |

+ For mathematics deficient students ++ For Biology deficient students

*College examination only

Second Year examination:

| Subject Code | Subject | Duration (University exam - hrs) | Maximum Marks | | Total | |
|--------------|---|----------------------------------|-----------------------------|--------------------|------------------------|------------|
| | | | Sessional Exam | University exam | | |
| 22PD21T | Pathophysiology | 03 | 30 | 70 | 100 | |
| 22PD22T | Pharmaceutical Microbiology | 03 | 30 | 70 | 100 | |
| 22PD22P | Pharmaceutical Microbiology | 04 | 30 | 70 | 100 | |
| 22PD23T | Pharmacognosy & Phytopharmaceuticals | 03 | 30 | 70 | 100 | |
| 22PD23P | Pharmacognosy & Phytopharmaceuticals | 04 | 30 | 70 | 100 | |
| 22PD24T | Pharmacology-I | 03 | 30 | 70 | 100 | |
| 22PD25T | Community Pharmacy | 03 | 30 | 70 | 100 | |
| 22PD26T | Pharmacotherapeutics-I | 03 | 30 | 70 | 100 | |
| 22PD26P | Pharmacotherapeutics-I | 04 | 30 | 70 | 100 | |
| 22PD27T* | Human Rights, Gender Equity and Environmental Studies | 03 | - | 100* | 100* | |
| | TOTAL | | Theory Practical | 600 300 | Grand Total | 900 |

Total: Theory 600 Practical 300

Grand Total 900

*College examination only

Third Year examination:

| Subject Code | Subject | Duration (University exam - hrs) | Maximum Marks | | Total |
|--------------|------------------------------|----------------------------------|--------------------|------------------------|-------------|
| | | | Sessional Exam | University exam | |
| 22PD31T | Pharmacology-II | 03 | 30 | 70 | 100 |
| 22PD31P | Pharmacology-II | 04 | 30 | 70 | 100 |
| 22PD32T | Pharmaceutical Analysis | 03 | 30 | 70 | 100 |
| 22PD32P | Pharmaceutical Analysis | 04 | 30 | 70 | 100 |
| 22PD33T | Pharmacotherapeutics-II | 03 | 30 | 70 | 100 |
| 22PD33P | Pharmacotherapeutics-II | 04 | 30 | 70 | 100 |
| 22PD34T | Pharmaceutical Jurisprudence | 03 | 30 | 70 | 100 |
| 22PD35T | Medicinal Chemistry | 03 | 30 | 70 | 100 |
| 22PD35P | Medicinal Chemistry | 04 | 30 | 70 | 100 |
| 22PD36T | Pharmaceutical Formulations | 03 | 30 | 70 | 100 |
| 22PD36P | Pharmaceutical Formulations | 04 | 30 | 70 | 100 |
| | TOTAL | Theory Practical | 600 500 | Grand Total | 1100 |

Fourth Year examination:

| Subject Code | Subject | Duration (University exam - hrs) | Maximum Marks | | Total |
|--------------|--------------------------------------|----------------------------------|--------------------|------------------------|-------------|
| | | | Sessional Exam | University exam | |
| 22PD41T | Pharmacotherapeutics-III | 03 | 30 | 70 | 100 |
| 22PD41P | Pharmacotherapeutics-III | 04 | 30 | 70 | 100 |
| 22PD42T | Hospital Pharmacy | 03 | 30 | 70 | 100 |
| 22PD42P | Hospital Pharmacy | 04 | 30 | 70 | 100 |
| 22PD43T | Clinical Pharmacy | 03 | 30 | 70 | 100 |
| 22PD43P | Clinical Pharmacy | 04 | 30 | 70 | 100 |
| 22PD44T | Biostatistics & Research Methodology | 03 | 30 | 70 | 100 |
| 22PD45T | Biopharmaceutics & Pharmacokinetics | 03 | 30 | 70 | 100 |
| 22PD45P | Biopharmaceutics & Pharmacokinetics | 04 | 30 | 70 | 100 |
| 22PD46T | Clinical Toxicology | 03 | 30 | 70 | 100 |
| | TOTAL | Theory Practical | 600 400 | Grand Total | 1000 |

Fifth Year examination:

| Subject Code | Subject | Duration (University exam - hrs) | Maximum Marks | | Total |
|--------------|---|----------------------------------|----------------|--------------------|------------|
| | | | Sessional Exam | University exam | |
| 22PD51T | Clinical Research | 03 | 30 | 70 | 100 |
| 22PD52T | Pharmacoepidemiology and Pharmacoeconomics | 03 | 30 | 70 | 100 |
| 22PD53T | Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring | 03 | 30 | 70 | 100 |
| 22PD54 | Clerkship * | 03 | 30 | 70 | 100 |
| 22PD55P | Project work (Six Months) | 04 | - | 100** | 100 |
| | TOTAL | | | Grand Total | 500 |
| | | Theory | 300 | | |
| | | Practical | 200 | | |

* 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 (University exam - hrs) | Maximum Marks | | Total |
|--------------|--------------------------------------|----------------------------------|----------------|-----------------|-------|
| | | | Sessional Exam | University exam | |
| 22PD41T | Pharmacotherapeutics-III | 03 | 30 | 70 | 100 |
| 22PD41P | Pharmacotherapeutics-III | 04 | 30 | 70 | 100 |
| 22PD42T | Hospital Pharmacy | 03 | 30 | 70 | 100 |
| 22PD42P | Hospital Pharmacy | 04 | 30 | 70 | 100 |
| 22PD43T | Clinical Pharmacy | 03 | 30 | 70 | 100 |
| 22PD43P | Clinical Pharmacy | 04 | 30 | 70 | 100 |
| 22PD44T | Biostatistics & Research Methodology | 03 | 30 | 70 | 100 |
| 22PD45T | Biopharmaceutics & Pharmacokinetics | 03 | 30 | 70 | 100 |
| 22PD45P | Biopharmaceutics & Pharmacokinetics | 04 | 30 | 70 | 100 |
| 22PD46T | Clinical Toxicology | 03 | 30 | 70 | 100 |

| | | | | | |
|---------|-----------------------------|------------------|------------|----|--------------|
| 22PD47T | Pharmacotherapeutics I & II | 03 | 30 | 70 | 100 |
| 22PD47P | Pharmacotherapeutics I & II | 04 | 30 | 70 | 100 |
| | TOTAL | Theory | 700 | | Grand |
| | | Practical | 500 | | Total |
| | | | | | 1200 |

Second Year examination:

| Subject Code | Subject | Duration (University exam - hrs) | Maximum Marks | | Total |
|--------------|---|----------------------------------|----------------|-----------------|--------------|
| | | | Sessional Exam | University exam | |
| 22PD51T | Clinical Research | 03 | 30 | 70 | 100 |
| 22PD52T | Pharmacoepidemiology and Pharmacoeconomics | 03 | 30 | 70 | 100 |
| 22PD53T | Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring | 03 | 30 | 70 | 100 |
| 22PD54 | Clerkship * | 03 | 30 | 70 | 100 |
| 22PD55P | Project work (Six Months) | 04 | - | 100** | 100 |
| | TOTAL | Theory | 300 | | Grand |
| | | Practical | 200 | | Total |
| | | | | | 500 |

Total: Theory 300 Practical 200 Grand Total 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral) 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 10 markwork, 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.
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.

Failure in two or more subjects in n^{th} year prevents the promotion to $(n + 2)^{\text{th}}$ year, though all subjects of $(n + 1)^{\text{th}}$ year are cleared.

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. Supplementary examinations will be

conducted within six weeks/six months from the date of announcement of results.

- A candidate detained for lack of attendance, internal assessment marks will be barred from appearing in any one or all course/s for the supplementary examination.
- A candidate dropping from appearance in any or all subjects /courses at regular examination is disallowed from taking dropped subject(s)/course(s) at the supplementary examinations.
- If a candidate submits application for appearing for the examination but does not appear for any of the subjects in the university examination, he can appear for supplementary examination provided other conditions such as attendance requirement, internal assessment marks, etc. are fulfilled.
- A candidate who is promoted to the next higher class as per carry over regulations (except where apex bodies do not permit), if he clears the lower year/semester/phase examinations in the main examination is allowed to appear for the higher class examination during supplementary examinations provided other conditions such as attendance requirement, internal assessment marks, etc. are fulfilled.

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 –

- a) 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 of Pharm. D Programme. 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.
- b) Every student shall be posted in constituent hospital for a period of not less than 200 working days in the first year of Pharm.D (PB) programme. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department

or Institution as prescribed. In the second year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching 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 pharmacoconomics;
- (iv) project work shall be approved by the institutional ethics committee
- (v) student shall present at least three seminars, one in the

beginning, one at middle and one at the end of the project work; and

- (vi) 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 TimesRoman 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 than 75% - First

Class 50% and above and less than 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 courses either in part or full in a particular examination.

17.3 A candidate who fails in main examination and 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 by such candidates shall be considered as attempt.

17.4 If a candidate submits application for appearing for the regular examination but does not appear for any of the courses/subjects in the regular 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.

17.5 Candidates who pass the subjects in the supplementary examinations are not eligible for the award of Gold Medal or Merit Certificate.

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.

PROGRAM OUTCOMES

At the end of the program, graduates will be able to...

- PO1: Explain the chemistry and synthesis of medicinal compounds
PO2: Describe important organic reactions with mechanisms
- PO3: Describe the metabolic process of bio molecules in health and illness (metabolic disorders)
- PO4: Able to formulate, store and analyse various pharmaceutical dosage forms including herbal medicines in commercial production and research
- PO5: Discuss the source, active constituents and uses of crude drugs
- PO6: Develop patient care in the creation of individualized/assess, drug therapy management.
- PO7: Manage and document patient care activities efficiently.
- PO8: Analyze and apply legal and regulatory principles directing drug development. and approval and medication distribution, use and management systems.
- PO9: Identify methods for evaluating cost-effectiveness, cost-minimisation and cost-benefit of medication use.
- PO10: Demonstrate personal/professional development, through ongoing self- directed learning and self-reflection.
- PO11: Develop and maintain a collaborative and constructive pharmacist- patient relationship.
- PO12: Apply evidence-based practice, including knowledge of study design and statistics, to the care of individual patients and populations.
- PO13: Promote health improvement, wellness, and disease prevention.
- PO14: Provide preventive and primitive health care services to the community.
PO15: Exhibit knowledge of and confidence with the pharmacist's role in health care systems (eg. hospital, ambulatory care/community practice settings) and the provision of longitudinal car

22PD11T: HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week
Course Outcome

75 Hours

At the end of the course students will be able to...

| CO No. | Outcome statement |
|--------|---|
| CO1 | Explain the anatomy, physiology and functions of various Tissues and cell, organization of cellular system. . |
| CO2 | Classify different types of tissue and explain anatomy and physiology of skeletal system and joints |
| CO3 | Explain Haemopoetic and lymphatic system homeostatic and its altered physiology |
| CO4 | Explain the anatomy and Physiology of cardiovascular and respiratory system and its disorders |
| CO5 | Explain the anatomy and Physiology of digestive ,nervous, urinary and reproductive system and its disorders |
| CO6 | Explain the Anatomy and Physiology of endocrine system and sense organs and its disorders |
| CO7 | Describe the Physiology of muscle contraction and its disorders |
| CO8 | Explain sport physiology , drugs and athletics |

- 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, heartrate, pulse and respiratory volumes;
5. appreciate coordinated working pattern of different organs of eachsystem; and
6. appreciate the interlinked mechanisms in the maintenance of normalfunctioning (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. 12th ed. 2014, Churchill Livingstone, Edinburg.

Reference books

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

3. Lecture wise program:

| | Topics | Hrs |
|----|--|------------|
| 1. | Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies) | 02 |
| 2 | 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, muscular and nervous tissues-their sub-types and characteristics | 04 |

- 4 a) Osseous system - structure, composition and functions of the skeleton.(done in practical classes - 6hrs) 01
 b) Classification of joints, types of movements of joints and disorders of joints (Definitions only)
- 5 Haemopoetic system 05
 a) Composition and functions of blood
 b) Haemopoiesis and disorders of blood components (Definition only)
 c) Blood groups
 d) Clotting factors and mechanism
 e) Platelets and disorders of coagulation
- 6 Lymph 04
 a) Lymph and lymphatic system, composition, formation and circulation.
 b) Spleen: structure and functions, disorders
 c) Disorders of lymphatic system (Definition only)
- 7 Cardiovascular system 06
 a) Anatomy and functions of heart
 b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
 c) Electrocardiogram (ECG)
 d) Cardiac cycle and heart sounds
 e) Blood pressure – its maintenance and regulation
 f) Definition of the following disorders Hypertension, hypotension, arteriosclerosis, atherosclerosis, angina, myocardial infarction, congestive heart failure, cardiac arrhythmias
- 8 Respiratory system 05
 a) Anatomy of respiratory organs and functions
 b) Mechanism / physiology of respiration and regulation of respiration
 c) Transport of respiratory gases
 d) Respiratory volumes and capacities, and definition of: hypoxia, asphyxia, oxygen therapy and resuscitation
- 9 Digestive system 06
 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)
- 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 Urinary system 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 Endocrine system 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 physiology.
b) Their hormones – physiology of menstruation
c) Spermatogenesis & Oogenesis
d) Sex determination (genetic basis)
e) Pregnancy & maintenance. Parturition
f) Contraceptive devices
- 14 Sense organs 06
- a) Eye
b) Ear
c) Skin
d) Tongue & Nose

- | | | |
|----|--|----|
| 15 | <u>Skeletal muscles</u> | 03 |
| | a) Histology | |
| | b) Physiology of Muscle contraction | |
| | c) Physiological properties of skeletal muscle and their disorders (Definitions only) | |
| 16 | <u>Sports physiology</u> | 03 |
| | a) Muscles in exercise, Effect of athletic training on muscles and muscle performance, | |
| | b) Respiration in exercise, CVS in exercise, body heat in exercise, body fluids and salts in exercise, | |
| | c) Drugs and athletics | |

22PD11P: HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical: 3 Hrs/Week

75 Hours

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

Course materials: Textbooks

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

Reference books

1. Ranade VG, Textbook of practical physiology, 4rd 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 gastrocnemius sciatic nervepreparation.
15. Study of simple summation curve using gastrocnemius sciatic nervepreparation.
16. Study of simple effect of temperature using gastrocnemius sciatic nervepreparation.
17. Study of simple effect of load & after load using gastrocnemius sciatic nerve preparation.
18. Study of fatigue curve using gastrocnemius 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).

22PD12T: PHARMACEUTICS (THEORY)**Theory: 2 Hrs. /Week****50 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|--------|---|
| CO1 | Learn handling of prescription, posology & dose calculation of drug in children. Different types of dosage form |
| CO2 | Discuss history of the profession of Pharmacy in India & Pharmacopeia and its development. |
| CO3 | Explain the different pharmaceutical calculation involved in formulation |
| CO4 | Elaborate basic requirement and formulation of powder and liquid (monophasic & biphasic) dosages form |
| CO5 | Understand basic requirement, formulation and evaluation of suppositories and pessaries |
| CO6 | Explain different types of extraction process mainly maceration & percolation and their application. |
| CO7 | Explain the different types of surgical aids and their application |
| CO8 | Learn type of Pharmaceutical incompatibility |

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, 6th ed. 2016, Vallabha Prakashan, New Delhi.

Reference books

- a) Introduction to Pharmaceutical dosage forms by Howard C. Ansel. 3rd.ed, 1981
- b) Remington's Pharmaceutical Sciences. Vol 1-3, 22th 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:

| | Topics | Hrs |
|---|--|------------|
| 1 | a) Introduction to dosage forms - classification and definitions b) Prescription: definition, parts and handling c) Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses. | 06 |
| 2 | History of profession of Pharmacy in India in relation to pharmacy education, industry and organization in brief. | 03 |
| 3 | Development of Indian Pharmacopoeia. Salient features of latest edition of IP (IP 2008) and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian National formulary. | 03 |
| 4 | Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions. | 06 |
| 5 | Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules. | 05 |
| 6 | Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like Vehicles, Organoleptic additives and Stabilizers, with examples. Study of Monophasic liquids (formulation aspects and examples) like gargles, mouthwashes, Throat paint, Ear | 06 |

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

22PD12P: 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***
 - 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).

22PD13T: MEDICINAL BIOCHEMISTRY (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|--------|--|
| CO1 | Explain the concept of transport across cell membrane and energy rich compounds |
| CO2 | Describe the properties, classification, kinetics, inhibitors, importance of enzymes in diagnosis of diseases and therapeutic uses |
| CO3 | Describe the metabolism of carbohydrate and Glucose tolerance test |
| CO4 | Describe the metabolism of lipids in physiological and pathological condition |
| CO5 | Explain Electron transport chain, oxidative phosphorylation |
| CO6 | Describe the metabolism of Protein and amino acids in physiological and pathological condition |
| CO7 | Describe genetic organisation of mammalian genome, translation, replication, transcription, mutation metabolism of Nucleotides |
| CO8 | Explain kidney, liver, lipid profile test and immunochemical techniques |

1. 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, 18th ed., 2003. Lange.
- b. Satyanarayana U and Chakrapani U, Biochemistry, 4th ed. 2016, Elsevier India PVT. LTD, New Delhi
- c. Text book of clinical chemistry- Alex Kaplan & Laverne L. Szabo, 4th ed. 1995, Williams and Wilkins Co.,

Reference books (Theory)

- a. Principles of biochemistry – Lehninger, 6th 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. 3rd. ed. 2014, Tata McGraw Hill Education Pvt. Ltd.
- d. Practical Biochemistry-Pattabhiraman. 4th ed. 2015, All India Publisher and Distributors.

3. Lecture wise programme:

| | Topics | 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 | 11 |

- carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose tolerance test and its significance; hormonal regulation of carbohydrate metabolism.
- 4 **Lipid metabolism:** Oxidation of saturated fatty acid; 09
Ketogenesis and ketolysis; biosynthesis of fatty acids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Enzymes and Coenzyme 04
system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture, regulation and inhibition); Oxidative phosphorylation and uncouplers of ETC.
- 6 **Protein and amino acid metabolism:** protein turn 08
over; nitrogen balance; general reactions of catabolism of amino acids (Transamination deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphyras, jaundice. Metabolic disorder of Aminoacids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and 12
pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; DNA damage and repair mechanism; DNA replication (semi conservative).
- 8 **The kidney function tests:** Role of kidney; Laboratory 04
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)
- 9 **Liver function tests:** Physiological role of liver, 04
metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
- a) Test for hepatic dysfunction-Bile pigments metabolism.
 - 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. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. 02
- 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). 03
- 12 **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution, Determination of sodium, calcium in the body fluids. 03

22PD13P: 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 reagentmethod**
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:

| | Sessional | 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).

**22PD14T: PHARMACEUTICAL ORGANIC CHEMISTRY
(THEORY)**

Theory: 3 Hrs. /Week

75 Hours

Course Outcome

At the end of the course students will be able to...

| CO No. | Outcome statement |
|--------|--|
| CO1 | Learn IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds |
| CO2 | Explain physical properties of organic compounds |
| CO3 | Understand free radical/ nucleophilic [alkyl/acyl/aryl] /electrophilic substitution orientation of the reaction, order of reactivity, stability of compounds |
| CO4 | Learn free radical/ nucleophilic / electrophilic addition orientation of the reaction, order of reactivity, stability of compounds |
| CO5 | Learn free radical/ nucleophilic / electrophilic elimination orientation of the reaction, order of reactivity, stability of compounds |
| CO6 | Describe oxidation and reduction reactions |
| CO7 | Explain some named organic reactions with mechanisms |
| CO8 | Discuss the methods of preparation test for purity, principle involved in the assay, important medicinal uses of some important organic compounds. |

- 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;
 - c) Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability 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

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

Reference books

- Organic chemistry – J.M.Cram and D.J.Cram
- Organic chemistry- Brown, 8th ed. 2018, John Wiley and Sons Inc.
- Advanced organic chemistry- Jerry March, Wiley, 7th ed., 2013, Wiley India Pvt.Ltd, New Delhi.
- Organic chemistry- Cram and Hammond, Pine Hendrickson, 5th ed., 2012, Tata Mc Graw Hill Publishing Pvt Ltd. New Delhi

3. Lecture wise programme:

| | Topics | Hrs |
|---|---|------------|
| 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 pairs, b) Acids and bases, Lowry Bronsted and Lewis theories c) Isomerism | 05 |
| 2 | Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides and Cycloalkanes. | 08 |
| 3 | Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability | 02 |
| 4 | Alicyclic compounds: Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain. | 04 |
| 5 | Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN2 | 06 |

- 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.
- 6 Dehydro halogenation of alkyl halides: 1,2 elimination, 05 kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 Electrophillic and free radicals addition: Reactions at 06 carbon - carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, orientation and reactivity, addition of halogen, mechanism, halohydrin 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, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- 9 Theory of resonance: Allyl radical as a resonance hybrid, 05 stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophilic 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 equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

- 10 Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel-Craft alkylation, Friedel-Craft acylation, reactivity and orientation, activating and deactivating O, P, M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkylbenzene, side chain halogenation of alkylbenzene, resonance stabilization of benzyl radical. 06
- 11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution. 05
- 12 Mechanism of aldol condensation, Claisen condensation, Cannizzaro reaction, crossed aldol condensation, crossed Cannizzaro reaction, benzoin condensation, Perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition. 05
- 13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer-Tiemann's reactions. 04
- 14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic. 03
- 15 Oxidation reduction reaction with examples 02
- 16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glycerol trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin. 05

**22PD14P: 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. Acetanilide / 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-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (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-chlorotoluene
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).

22PD15T: PHARMACEUTICAL INORGANIC CHEMISTRY
(Theory)

Theory: 2 hrs/Week

50 Hours

Course Outcome

At the end of the course students will be able to...

| CO No. | Outcome statement |
|---------------|---|
| CO1 | Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures. |
| CO2 | Explain the various methods of expressing concentration and requirement of primary standards and Describe the preparation and standardization of different reagents used in volumetric analysis |
| CO3 | Explain the principle of acid base, redox, nonaqueous titration with examples. |
| CO4 | Describe the principle of precipitation, complexometric and gravimetric estimation with examples |
| CO5 | Explain the sources of impurities and methods to determine the impurities in inorganic pharmaceuticals |
| CO6 | Explain the method of preparation, assay, properties, medicinal uses of Medicinal Gases, acidifiers, antacids, cathartics, Major extra and intracellular electrolytes. |
| CO7 | Explain the method of preparation, assay, properties, medicinal uses of, antimicrobials, trace elements, pharmaceutical aids, dental products and miscellaneous compounds |
| CO8 | Describe the properties, storage condition and application of radiopharmaceuticals. |

- 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, 10th ed. 2014, Pearson
- c. Inorganic Pharmaceutical Chemistry III-Edition P. GunduRao, 3rd, 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. Bentley and Driver's Textbook of Pharmaceutical chemistry, 8th 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. 5th 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.

3. Lecture wise programme :

| | Topics | Hrs |
|---|--|------------|
| 1 | Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures. | 02 |
| 2 | Fundamentals of volumetric analysis, theories of indicators and methods of expressing concentrations. Primary and secondary standard. Preparation and standardization of various volumetric solutions like sodium hydroxide, hydrochloric acid and sodiumthiosulphate. | 04 |
| 3 | Acid base titration: Classification and estimation of strong, weak, and very weak acids and bases. | 02 |

| | | |
|----|--|----|
| 4 | Principles of redox titrations: Concepts of oxidation and reduction. | 0 |
| | 3Redox reactions, strength and equivalent weights of oxidizing and reducing agents, theory of redox titrations, cerriometry, Iodimetry, Iodometry, bromometry, titrations with potassium iodate | |
| 5 | Non aqueous titration: Introduction to solvents, classification and estimation of Sodium benzoate. | 02 |
| 6 | Principles of precipitation titrations: Different methods-Mohr's, Modified Mohr's, Volhard's, Modified Volhard's, Fajans with example. Estimation of sodium chloride by modified volhardsmethod. | 03 |
| 7 | Complexometric titration and its classification: Estimation of Calcium Gluconate by complexometric method. Metal ionindicators. | 03 |
| 8 | Gravimetry: Introduction to gravimetric method, steps involved in gravimetric method, precipitants and estimation of Barium sulphateby gravimetric method. | 02 |
| 9 | Limit test: Source and effect of impurities in pharmacopoeial 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 testfor chloride and sulphate | 06 |
| | General methods of preparation, assays*, storage condition andMedicinal uses of inorganic compounds belonging to the following classes. | |
| 10 | Medicinal gases: Oxygen, Nitrous oxide, Carbon dioxide | 01 |
| 11 | Acidifies: Dil HCl | 01 |
| 12 | Antacid: Aluminum hydroxide gel, sodium bicarbonate*, Magnesium triisilicate, Magnesium carbonate (Light and Heavy),Magnesium hydroxide mixture*, Preparation containing combination of antacids. | 03 |
| 13 | Cathartics: Magnesium sulphate*, Sodium orthophosphate | 01 |
| 14 | Major extra and intracellular electrolytes: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Sodium chloride Injection, Sodium chloride compound injection, Potassium chloride, Potassium chloride injection, Calcium Gluconate and Electrolyte combination therapy and ORS, Physiological acid base balance. | 04 |
| 15 | Essential trace elements: Copper, Iron, Iodine and Zinc | 01 |

- 16 **Antimicrobials:** Potassium permanganate*, Hydrogen peroxide*, 03
Chlorinated lime*, Iodine and its preparations, Boric acid*.
- 17 **Pharmaceutical aids:** Bentonite, sodium metabisulphite, Barium 01
Sulphate
- 18 **Dental products:** Dentifrices, role of fluoride in the treatment of 02
dental caries, Desensitizing agents, Calcium carbonate,
Sodium 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 thioisulphate, Activated charcoal
- 20 **Radiopharmaceuticals:** Radio activity, natural radio activity and 02
artificial radio activity. Measurement of radioactivity,
Properties of α , 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.

**22PD15P: 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. 0.1N NaOH
 2. 0.1N KMnO₄
 3. 0.1N Ceric ammonium sulphate
 4. 0.1N HClO₄
 5. 0.05M Di sodium EDTA
 6. 0.1N 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-KIO₃ 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 Iodates 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 | Sessiona 1 | Annua 1 |
|--|-----------------------|--------------------|
| 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)

22PD16T: 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 :

1. 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 Shantinakaran
- 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 | Algebra : Matrices : Definition, Addition, Subtraction & 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, Statement of Cayley-Hamilton Theorem (Without Proof) – Pharmaceutical examples | 18 |
| 2 | Trigonometry : Relation between Sides and angles of a triangle, solution of triangles – Simple problems | 05 |

- 3 **Analytical Geometry** :Points, Straight line, Types of straight lines – $Y = mx + c$, $(y-y_1) = m(x-x_1)$, $(y-y_1) = ((y_2-y_1)/(x_2-x_1))(x-x_1)$ Parallel and Perpendicular straight lines, Angle between two lines, Perpendicular distance from a point to the line, distance between parallellines, Circle: General equation of circle, finding centre and radius of the circle, Parabola: Equation of the parabola $y^2 = 4ax$, Simple problems 15
- 4 **Differential calculus:** Function, Limit, Differentiation, Differentiation of sum, Product, Quotient, Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, simple problems. 16
- 5 **Integral Calculus:** Partial fractions, Definition of integration, integration by substitution and integration by parts, Properties of definite integrals, Simple problems. 07
- 6 **Differential equations:** Definition, order, degree, variable separable, homogeneous differential equation, linear differential equation, exact differential equation, Simple problems 10
- 7 **Laplace transform:** Definition, Laplace transform of elementary functions, linearity and shifting property , simple problems 04

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 introduced 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, VikashGupta, 7th 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 Prakashan, 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. Taxonomy of Leguminosae, umbelliferae, Solanaceae Lilliaceae, Zinziberaceae, Rubiaceae | 06 |
| 11. Study of Fungi, Yeast, Penicillin and Bacteria | 04 |

PART-B**Topics**

| | Hrs |
|------------------------------------|------------|
| 1. Study of Animal cell | 04 |
| 2. Study animal tissues | 04 |
| 3. Detailed study of frog | 08 |
| 4. Study of Pisces, Reptiles, Aves | 05 |
| 5. General organization of mammals | 05 |
| 6. Study of poisonous animals | 04 |

22PD16P: REMEDIAL BIOLOGY (PRACTICAL)**Practical : 3 Hrs./Week****75 Hours****Title of Experiments**

1. Introduction of biology experiments (sectioncutting techniques, Mounting andstaining, 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:

| | Sessional | Annua |
|------------------|------------------|--------------|
| | s | l |
| 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).

22PD17T: CONSTITUTION OF INDIA (THEORY)

| | |
|---|-----------------|
| Theory: 2 Hours per week | 50 Hours |
| SYLLABU | |
| SUNIT – I | |
| 1. Constitution of India | 10 Hours |
| 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 | |
| 2. Fundamental Rights and Directive Principles | 08 Hours |
| a. Fundamental Rights | |
| b. Directive Principles of the State Policy | |
| c. Fundamental Duties | |
| UNIT – II | |
| 1. Government of the Union | 06 Hours |
| a. The Union Executive- the President and the Vice-President- The Council of Ministers and the Prime Minister | |
| b. The Union Legislature - The Parliament- The Lok Sabha and the Rajya Sabha, composition, Powers and functions | |
| c. Important Committees -Privileges | |
| d. the Role of the Speaker | |
| 2. Government of the States | 06 Hours |
| a. The Governor- The Council of Ministers and the Chief Minister | |
| b. The State Legislature- composition powers and functions | |
| 3. Democratic decentralization or Panchayath Raj in India | 02 Hours |
| UNIT – III | |
| 1. Federation in India | 06 Hours |
| a. Federal Features Indian federalism, Centre-State relations distribution of legislative powers, Administrative and financial relations between the Union and the States | |

- b. The Finance Commission, The Planning Commission, National Development Council
- c. Military Features
- 2. The Judiciary 04 Hours
 - a. The Supreme Court – Organization, Jurisdiction and Role
 - b. The High Court – Organization, Jurisdiction and Role
 - c. Judicial Review, Judicial activism, Independence of Judiciary in India

UNIT – IV

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

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
4. C K Jain (ed): Constitution of India in Precept and Practice, Lok Sabha Secretariat, New Delhi
5. V.N. Shukla: Constitution of India, Jain Book Depot, New Delhi
6. Granville Austin : The working of a Democratic Constitution: The Indian Experience, New Delhi, Oxford University Press, New Delhi 1999
7. J C Johari: Indian Politics, Vishal Publications, Jalandhar
8. A P Avasthi: Indian Government and Politics, Lakshmi Narain Agarwal, Agra
9. Anup Chand Kapur: Indian Government and Politics, S. Chand and Company, New Delhi
10. V D Mahajan: The Constitution of India. S. Chand and Company, New Delhi.
11. J N Pandey: Constitution Law of India, Allahabad, Central Law Agency, 1998
12. J C Johari: The Constitution of India – A Politico-Legal Study- Sterling Publication Pvt. Ltd, New Delhi
13. R C Agrawal: Constitutional Development and national Movement of India, S Chand & Co., New Delhi
14. M Hidayatullah: Democracy in India and the Judicial Process,

Metropolitan, New Delhi

15. K C Markandan: Directive Principles in the Indian Constitution, AlliedPublishers, Mumbai
16. Bidyut Chakrabarty and Rajendra Kumar Pandey: Indian Government andPolitics, SAGE Publications New Delhi
17. India – A Politico-Legal Study- Sterling Publication Pvt. Ltd, New Delhi

22PD21T: PATHOPHYSIOLOGY (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|--|
| CO1 | Describe Basic principles of Cell injury Adaptation and explain the concept of inflammation and repair |
| CO2 | Describe Diseases of Immunity a) Introduction to T and B cells b) MHC proteins or transplantation antigens c) Immune tolerance – Hypersensitivity, |
| CO3 | Describe autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, allograft, and graft rejection mechanism AIDS, amyloidosis |
| CO4 | Classify and explain the etiology and pathogenesis of cancer |
| CO5 | Describe the etiology and pathogenesis of shock , describe the biological effects of radiation Explain the pathogenesis of Environmental and nutritional diseases |
| CO6 | Effects of i) Air pollution and smoking- SO ₂ ,NO, NO ₂ , and CO ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation. |
| CO7 | Describe the etiology and pathogenesis of Pathophysiology of common diseases a. Parkinsonism b. Schizophrenia c. Depression and mania d. Hypertension, e. Stroke (ischaemic and hemorrhage) f. Angina, CCF, Atherosclerosis, Myocardial infarction g. Diabetes Mellitus h. Peptic ulcer and inflammatory bowel diseases i. Cirrhosis and Alcoholic liver diseases j. Acute and chronic renal failure k. Asthma and chronic obstructive airway diseases |

| | |
|-----|---|
| CO8 | Describe the etiology and pathogenesis of Infectious diseases Sexually transmitted diseases (HIV, Syphilis, Gonorrhoea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis. |
|-----|---|

- 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 Elsevier India PvtLtd, Newdelhi, 2015, ed. 9 vol. 1-2
- b. Text book of Pathology- Harsh Mohan, 7th ed. 2015, JaypeeBrothers Medical Publishers (P) Ltd., New Delhi,
- c. Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; 5th.ed. 2012; Walker & Whittlesea, Churchill Livingstone publication

3. Lecture wise Programme:

| | Topics | Hrs |
|---|--|------------|
| 1 | Basic principles of cell injury and Adaptation a) Causes, Pathogenesis 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) Repairs of wounds in the skin, factors influencing healing of wounds | 05 |
| 3 | Diseases of Immunity a) Introduction to T and B cells b) MHC proteins or transplantation antigens c) Immune tolerance - Hypersensitivity Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs | 10 |

| | | |
|---|---|----|
| | - Autoimmunity Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft. | |
| | - Acquired immune deficiency syndrome (AIDS) | |
| | - Amyloidosis | |
| 4 | Cancer 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. | 05 |
| 5 | Shock Types of shock, mechanisms, stages and management | 03 |
| 6 | Biological effects of radiation | 02 |
| 7 | Environmental and nutritional diseases i) Air pollution and smoking- SO ₂ , NO, NO ₂ , and CO ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation | 04 |
| 8 | Pathophysiology of common diseases Parkinsonism Schizophrenia Depression and mania Hypertension Stroke (ischemic and hemorrhage) Angina, CCF, Atherosclerosis, Myocardial infarction Diabetes Mellitus Peptic ulcer and inflammatory bowel diseases Cirrhosis and Alcoholic liver diseases Acute and chronic renal failure Asthma and chronic obstructive airway diseases | 30 |
| 9 | Infectious diseases: Sexually transmitted diseases (HIV, Syphilis, Gonorrhoea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria, Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis. | 11 |

Assignments:

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 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.

22PD22T: PHARMACEUTICAL MICROBIOLOGY (THEORY)
Theory: 3 Hrs. /Week **75 Hours**
Course Outcome

At the end of the course students will be able to...

| CO No. | Outcome statement |
|--------|--|
| CO1 | Explain the anatomy, identification, growth factors of microorganisms which include bacteria, virus, and fungus. |
| CO2 | Discuss the cultivation and identification of the microorganisms in the laboratory |
| CO3 | Explain different methods of sterilization and its properties and applications in pharmaceutical microbiology |
| CO4 | Discuss the concepts and types, antibody, antigen -antibody reactions |
| CO5 | Define the terms bacterial vaccines, toxoids, immunization programme, importance of booster dose. |
| CO6 | Identification of diseases by performing the diagnostic tests |
| CO7 | Estimation of potency of antibiotic by various microbial assay |
| CO8 | Understand infectious diseases its history, pathogenesis, treatment and control |

- 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. It 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 thereby 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
7. 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) Prescott L.M., Jarley G.P Klein D.A “Microbiology” 2nd- edition Mc GrawHill 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:

| | Topics | Hrs |
|----|--|------------|
| 1. | Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them. | 03 |
| 2. | Morphology & Physiology of Microorganisms Different methods of classification of microbes and study of Bacteria, Fungi, Virus, Rickettsiae, Spirochetes. | 07 |
| 3. | Growth & Nutrition Nutritional requirements Growth and cultivation of bacteria and virus. Culture Media for aerobic and anaerobic bacteria & fungi. Maintenance of lab cultures. | 08 |

- | | | |
|-----|---|----|
| 4. | Isolation and Identification of Bacteria Different methods-Staining reactions Biochemical reactions.Counting of bacteria -Total and Viable counting techniques. | 08 |
| 5. | Sterilization Detailed study of different methods of sterilization with meritsand demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations. Validation of varioussterilization techniques. | 08 |
| 6. | Disinfectants Study of disinfectants, antiseptics, fungicidal and virucidal agents. Factors affecting their action and mechanism of action. Evaluation of bactericidal, bacteriostatic, virucidal andpreservatives in pharmaceutical preparations. | 07 |
| 7. | Immunology Definition, Classification, General principles of natural immunity, 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 ofbooster dose. | 12 |
| 8. | Diagnostic tests Schick’s Test, Elisa test, Western Blot test, Southern BlotPCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite. | 07 |
| 9. | Microbiological Assays 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. | 05 |
| 10. | Study of infectious diseases Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhoea and HIV | 10 |

22PD22P: 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; Negativestaining**
 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.**
- * Indicate minor experiment & ** indicate major experiment

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 year.
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).

**22PD23T: PHARMACOGNOSY & PHYTOPHARMACEUTICALS
(THEORY)**

Theory : 3 Hours/Week

75 Hour

Course Outcome

At the end of the course students will be able to...

| CO No. | Outcome statement |
|---------------|---|
| CO1 | Describe the history and scope of Pharmacognosy |
| CO2 | Describe the Cultivation, Collection, Processing, Storage and Conservation of Medicinal Plants |
| CO3 | Describe the various cell wall constituents and cell inclusions |
| CO4 | Describe the morphology and microscopy of different plant parts |
| CO5 | Discuss regarding natural pesticides and their sources; describe the various plant fibers used in surgical dressings and related products |
| CO6 | Describe the pharmacognosy and chemistry of carbohydrates, lipids, proteins and elaborate on their sources |
| CO7 | Discuss the various therapeutic applications of herbs, poisonous plants; describe Herb-drug interaction, Edible Vaccines and Marine Pharmacognosy |
| CO8 | Describe different types of secondary metabolites (Alkaloids, Glycosides, Essential oils, Flavonoids, Resins and Tannins), their general properties, classification, test for identification and isolation techniques |

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. 16th ed., 2009, SaundersElsevier
- b. Pharmacognosy by C.K. Kokate, S.B. Gokhale & A.C. Purohit. 54thed. 2017,Nirali Prakashan, Pune.

Reference books

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

3. Lecture wise programme:

| Topics | Hrs |
|---|------------|
| 1. Introduction. | 01 |
| 2. Definition, history and scope of Pharmacognosy | 02 |
| 3. Classification of crude drugs viz. alphabetical, morphological, 03 taxonomical, chemical, pharmacological, and chemotaxonomical methods. | |
| 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 | 10 |
| i. Leaf: Datura, Senna | |
| ii. Bark: Cinnamon (Cassia), Cinchaona | |
| iii. Wood: Quassia | |
| iv. Stem: Ephedra | |
| v. Root: Rauwolfia, Liquorice | |
| vi. Rhizome: Ginger, Podophyllum. | |
| vii. Flower buds: Clove. viii.Fruits: Coriander, Fennel | |

| | | |
|-----|--|----|
| | ix . Seeds: Isapgol, Nux Vomica. | |
| 8. | Study of natural pesticides. Pyrethrum, Neem, Tobacco | 02 |
| 9. | Carbohydrate: | 07 |
| | 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. | |
| 10. | Proteins: | 03 |
| | a) Definition classification, chemistry and method of analysis of proteins | |
| | b) Study of collagen, Gelatin and its products | |
| 11. | Lipids: | 07 |
| | a) Definition, sources, method extraction, chemistry and method of analysis of Lipids. | |
| | b) Study of method of production, chemical constituents, tests, uses and adulterants of the following drugs. | |
| | i) Castor oil ii) Shark liver oil iii) Chaulmoogra oil iv) Wool fat | |
| | v) Bees wax vi) Spermaceti vii) Cocoa butter viii) Olive oil | |
| 12. | 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. | Study of plants fibers used in surgical dressings and related products. | 02 |
| 15. | Different methods of adulteration of crude drugs and general methods of detection of adulterants. | 04 |

**22PD23P: PHARMACOGNOSY & PHYTOPHARMACEUTICALS
(PRACTICAL)**

Practical: 3 Hrs./Week

75 Hours

General Requirements: Laboratory Napkin, Observation Book (150 pages), Zerobrush, 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 Quinine.
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 | 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).

22PD24T: PHARMACOLOGY – I (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|---|
| CO1 | Describe the history and scope of pharmacology, general pharmacology, pharmacokinetics, and pharmacodynamics. |
| CO2 | Explain neurotransmission and the pharmacology of drugs acting on ANS |
| CO3 | Describe the pharmacology of drugs acting on Cardio Vascular System |
| CO4 | Explain the pharmacology of drugs acting on Central Nervous System |
| CO5 | Explain the pharmacology of Local Anaesthetics. |
| CO6 | Explain the pharmacology of drugs acting on Respiratory System |
| CO7 | Explain the pharmacology of Hormones and their antagonist. |
| CO8 | Explain the pharmacology of Autocoids and their Antagonist |

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 aspect of drugs falling under the abovementioned 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. 6th edition, 2008. Publisher: Jaypee, Delhi.
- b) Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and Pharmacotherapeutics. 20th edition, 2008. Publisher: Popular, Mumbai.
- c) Rang, H.P. & Dale, M.M. Pharmacology. 5th edition, 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. 11th edition, 2006. Publisher McGraw Hill, Pergamon Press.
- b) Craig, C.R. & Stitzel, R.E. Modern Pharmacology. 5th edition, 1997. Publisher: Little Brown Co.
- c) Katzung, B.G. Basic and clinical pharmacology. 9th 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: Topics Hrs**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 causing such problems
- 5. **Pharmacology of Local anaesthetics** 02
- 6. **Pharmacology of Drugs acting on Respiratory tract** 05
 - a) Bronchodilators
 - b) Mucolytics
 - c) Expectorants
 - d) Antitussives
 - e) Nasal Decongestants
- 7. **Pharmacology of Hormones and Hormone antagonists** 08
 - a) Thyroid and Antithyroid drugs
 - b) Insulin, Insulin analogues and oral hypoglycemic agents
 - c) Sex hormones and oral contraceptives
 - d) Oxytocin and other stimulants and relaxants
- 8. **Pharmacology of autocooids and their antagonists** 06
 - a) Histamines and Antihistaminics
 - b) 5-Hydroxytryptamine and its antagonists
 - c) Lipid derived autocooids and platelet activating factor

22PD25T: COMMUNITY PHARMACY (THEORY)**Theory: 2 Hrs. /Week****50 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|---|
| CO1 | Describe the business and professional practice management skills in community pharmacies |
| CO2 | Analyse and manage the prescriptions in the community pharmacy |
| CO3 | Management of various inventory control techniques in community pharmacy |
| CO4 | Explain the pharmaceutical care services |
| CO5 | Understand various methods of patient counselling. |
| CO6 | Describe the methods of health screening |
| CO7 | Recognize the minor ailments and develop the health promotions in the community |
| CO8 | Explain the rational drug therapy |

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. 1st 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. 2nd. ed. 2001, The Pharmaceutical Press.
- b. Comprehensive Pharmacy Review – 7th 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 medication related problems like drug interactions. | 02 |
| 4. Inventory control in community pharmacy | 03 |
| Definition, various methods of Inventory Control | |
| ABC, VED, EOQ, Lead time and safety stock | |
| 5. Pharmaceutical care. | 02 |
| Definition and Principles of Pharmaceutical care | |
| 6. Patient counselling | 04 |
| Definition, outcomes, various stages, barriers, strategies to overcome barriers | |
| Patient information leaflets- content, design, layouts & advisory labels | |
| 7. Patient medication adherence | 02 |
| Definition, Factors affecting medication adherence and role of pharmacist in improving the adherence | |
| 8. Health screening services | 03 |
| Definition, importance, methods for screening blood pressure/ blood sugar/lung function and Cholesterol | |

| | | |
|-----|---|----|
| | testing | |
| 9. | OTC Medication - Definition, OTC medication list & Counselling | 03 |
| 10. | Health Education | 02 |
| | WHO Definition of health and health promotion, care for children, pregnant & breast feeding women and geriatric patients. | |
| 11. | Commonly occurring communicable diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS | 09 |
| 12. | Balance diet, treatment & prevention of deficiency disorders | 02 |
| 13. | Family planning – role of pharmacist | 01 |
| 14. | Responding to symptoms of minor ailment Relevant | 08 |
| 15. | pathophysiology and common drug therapy to Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms and worms infestations. | |
| 16. | Essential Drugs concept and Rational Drug Therapy Role of community pharmacist | 02 |
| 17 | Code of ethics for community pharmacists | 01 |

22PD26T: PHARMACOTHERAPEUTICS-I (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|--|
| CO1 | Describe the etiopathogenesis of selected disease states |
| CO2 | Discuss the various methods involved in the diagnosis of selected disease state |
| CO3 | Interpret and analyze the selected laboratory results of specific disease states |
| CO4 | Describe the therapeutic approach to manage the selected diseases |
| CO5 | Discuss the rationale for drug therapy of the selected disease |
| CO6 | Identify the controversies in drug therapy |
| CO7 | Develop the individualized therapeutic plans based on diagnosis |
| CO8 | Describe the general prescribing guidelines for special population |
| CO9 | Explain role of pharmacist in promoting rational drug use and essential drug concept |

- 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; 5th.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 Elsevier 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

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

22PD26P: 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

| | Sessional | Annual |
|------------------|------------------|---------------|
| Synopsis | 05 | 15 |
| Major Experiment | 10 | 25 |
| Minor Experiment | 03 | 15 |
| <i>Viva</i> | 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)

22PD27T: HUMAN RIGHTS, GENDER EQUITY AND ENVIRONMENTAL STUDIES (THEORY)

Theory: 2 Hours per Week

50 Hours

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

1. **Sex and Gender** – Masculinity and Femininity – Patriarchy, 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

1. **Environment:** Components of Environment Concepts of Ecology; 05 Hours
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 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, Savandus 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

22PD31T: PHARMACOLOGY – II (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|--------|---|
| CO1 | Explain the pharmacology drugs acting on blood and blood forming agents |
| CO2 | Explain the drugs acting on urinary system |
| CO3 | Discuss pharmacology drugs acting on GI system |
| CO4 | Explain pharmacology of chemotherapeutic agents |
| CO5 | Explain pharmacology drugs acting on immune system |
| CO6 | Discuss principles of toxicology and bioassay |
| CO7 | Discuss Structure and functions of the components of the cell. |
| CO8 | Discuss different aspects of genes and their regulatory functions. |

1. Scope and 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, drugs acting on autacoids, respiratory system, GIT, immune system, hormones, pharmacology of autocoids and different aspects of genes will be concentrated. In addition, pharmacology of chemotherapeutic agents and principles of toxicology are also taught. In 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, 6th. Edition, 2012, Publisher: GarlandScience.

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) 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. 3rd edition 2008. Publisher: Scientific America.
- 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:

| Topics | 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) | |

- | | | |
|----|---|----|
| 5. | Immunopharmacology Pharmacology of immunosuppressants and stimulants | 03 |
| 6. | Principles of Animal toxicology a) Acute, subacute and chronic toxicity. b) Principles involved in the various toxicology screening methods available for drugs in the laboratory animals. | 02 |
| 7. | The dynamic cell: The structures and functions of the components of the cell a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information. c) DNA replication: General, bacterial and eukaryotic DNA replication. d) The cell cycle: Restriction point, cell cycle regulators and modifiers. e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors. | 11 |
| 8. | The Gene: Genome structure and function: 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. | 18 |

- i. Recombinant DNA technology: principles. Processes (gene transfer technology) and applications
- 9. **Bio-assay methods** 04
Scope, principles involved in general methods, bioassay designing, applications and limitations.

22PD31P: 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:

| | Sessional | Annual |
|--|------------------|---------------|
| Identification | 02 | 10 |
| Synopsis | 04 | 10 |
| Major Experiment (Bioassay) | 08 | 30 |
| Minor Experiment (Interpretation of given Graph/ simulated experiment) | 04 | 10 |
| 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).

22PD32T: PHARMACEUTICAL ANALYSIS (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|--|
| CO1 | Understand the construction and working of various analytical instruments |
| CO2 | Know principle and mechanism of instrumentation |
| CO3 | Understand the different modern techniques of drug analysis |
| CO4 | Evaluate the advantages of instrumental methods of drug analysis |
| CO5 | Estimate the drugs by Fluorimetric technique, Colorimetric technique & Nepheloturbidimetric Method |
| CO6 | Perform Separation and identification of mixture of compounds using different Chromatography technique |
| CO7 | Understand Potentiometric titration and Conductometric titration |
| CO8 | Understand the advantage of calibration, validation & quality assurance |

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 will be 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 Settle 7th ed. 2005, CBS publishers and distributors, New Delhi
- 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, 10th ed. 2014, Pearson
- b. Text book of Pharmaceutical Analysis by K.A. Cannors 3rd 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 |
|---|--|------------|
| 1 | Quality Assurance: a. Introduction, sources of quality variation, control of quality variation. b. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration. | 06 |
| 2 | Chromatography: Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products 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, preparation techniques, development techniques, applications. 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. | 27 |

- f. HPTLC: Introduction, theory, instrumentation, and applications.
- g. Gas Chromatography: Introduction, theory, instrumentation carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. Electrophoresis: Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. Gel filtration and affinity chromatography: Introduction, technique, applications.

3 **Electrometric Methods:** 12

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

- a. **Potentiometry:** Electrical potential, electrochemical cell, 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:** 30

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

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.- Visible radiations, collimating systems, monochromators, sample 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 andphotoelectric 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

22PD32P: 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 Sulpha 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-Phenanthroline**.
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 identification of samples with different functional groups (-COOH, -COOR, -NH₂, -NHR, -OH, -CHO, -C=O)
19. Demonstration of HPLC.

SCHEME OF PRACTICAL EXAMINATION:

| | Sessiona 1 | 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)

22PD33T: PHARMACOTHERAPEUTICS-II (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|--|
| CO1 | Describe the etiopathogenesis of selected disease states |
| CO2 | Discuss the various methods involved in the diagnosis of selected disease states |
| CO3 | Interpret and analyze the selected laboratory results of specific disease states |
| CO4 | Describe the therapeutic approach to manage the selected diseases |
| CO5 | Discuss the rationale for drug therapy of the selected diseases |
| CO6 | Identify the controversies in drug therapy |
| CO7 | Develop the individualized therapeutic plans based on diagnosis |
| CO8 | Identify the patient-specific parameters relevant in initiating the drug therapy |

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; 5th.ed. 2012; Walker & Whittlesea, Churchill Livingstone publication

Reference books (Theory)

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

3. Lecture wise programme

Etio pathogenesis and pharmacotherapy of diseases associated with following systems / diseases

| | Topics | Hrs |
|---|--|------------|
| 1 | Infectious diseases: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis | 35 |
| 2 | Musculoskeletal disorders Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus. | 10 |
| 3 | Renal system Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders | 10 |
| 4 | Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy induced nausea and emesis | 12 |
| 5 | Dermatology: Psoriasis, Scabies, Eczema, Impetigo | 08 |

22PD33P: 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 copy
- Reference(s) shall be included at the end.
- Name and signature of the student
- 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

| | Sessional | Annual |
|------------------|------------------|---------------|
| Synopsis | 05 | 15 |
| Major Experiment | 10 | 25 |
| Minor Experiment | 03 | 15 |
| <i>Viva</i> | 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)

22PD34T: PHARMACEUTICAL JURISPRUDENCE (THEORY)**Theory: 2 Hrs. /Week****50 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|--|
| CO1 | Acquire knowledge in practice the Professional ethics |
| CO2 | Understand the various concepts of the pharmaceutical legislation in India; |
| CO3 | Learn the knowledge on schedules and functioning of various committees in the Drug and Cosmetic Act and rules |
| CO4 | Understand the labelling requirements and packaging guidelines for drugs and cosmetics |
| CO5 | Understand the Drug policy, DPCO, Patent and Design Act |
| CO6 | Know about narcotic and psychotropic drugs, its productions and drug abuse, its controlling. |
| CO7 | Understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise Duties Act |
| CO8 | Explain other laws as prescribed by the Pharmacy Council of India from time to time including International Laws |

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)

- a. Mithal, B M. Textbook of Forensic Pharmacy. Calcutta: National; 10th ed. 2014, Vallabha Prakashan, New Delhi.

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. 8th ed. 2015, Delhi: Vallabh Prakashan;
- c. Reports of the Pharmaceutical enquiry Committee d. I.D.M.A., Mumbai. DPCO 1995
- d. Various reports of Amendments.
- e. Deshpande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- f. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Lecture wise programme:

| | Topics | 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 | 22 |

- 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.
- 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.** 05
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.
- 5 **Medicinal and Toilet Preparation Act –1955.** 04
Objectives, Definitions, Licensing, Manufacture in bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- 6 **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** 04
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
- 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 | <p>Prevention of Cruelty to animals Act-1960.</p> <p>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</p> | 03 |
| 10 | <p>Patents & design Act-1970.</p> <p>- 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.</p> <p>- Registration of designs, copyright, prohibition of certain designs, cancellation of designs, Offences and penalties.</p> | 03 |
| 11 | <p>Brief study of prescription and Non-prescription Products.</p> | 01 |

Assignments:

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.

22PD35T: MEDICINAL CHEMISTRY (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|--------|--|
| CO1 | Explain various Modern techniques of design and development which include CADD Studies ; |
| CO2 | Describe the detailed Prodrug concept combinatorial Chemistry aspects. |
| CO3 | Outline the Chemistry and explain physicochemical properties of the drugs |
| CO4 | Describe the brief SAR of the drugs with respect to their biological activity |
| CO5 | Explain the Mechanism of action, metabolism, adverse effects and uses of anti-infectives, antibiotics, Chemotherapeutic Agents, Cardiovascular Drugs, hypoglycemic agents, antithyroid agents, diuretics, steroids |
| CO6 | Explain various synthetic routes of some important drugs. |
| CO7 | Describe the Medicinal Compounds and their Importance in diagnostics purpose |
| CO8 | Describe various drugs belong to the Class of steroids and steroidal hormones |

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, 12th 2015, Wolter Kluwer
- b. Principles of Medicinal chemistry- William O. Foye, 7th ed. 2012, wolterkluwer,

Reference books

- a. A I Vogel Text book of Practical Organic Chemistry, 5th ed, Pearson
- b. Text Book of organic chemistry by I. L. Finar, 6th 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 |
|---|---|---------------------|
| 1 | <p>I. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.</p> <p>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.</p> <p>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, cetylpyridinium bromide Nitrofurans: nitrofurazone, furazolidone.</p> | <p>06</p> <p>15</p> |

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, idoxuridine, trifluridine, zidovudine, stavudine
 - f. Antiprotozoal agents: Introduction to protozoal diseases and causative organisms. Metronidazole*, diloxanide furoate*, dehydroemetine, nifurtimox
 - g. Anthelmintics: Benzimidazoles: mebendazole, albendazole
Piperazine, diethylcarbamazine*, ivermectin
- 2 **Sulfonamides and sulfones** 04
History and development of sulfonamides, SAR and mechanism of action of Sulfonamides, pKa of Sulfas and Crystalluria. Sulfamethoxazole*, sulfisoxazole, sulfacetamide*, sulfasalazine Folate reductase inhibitors: trimethoprim*, synergistic action of cotrimoxazole. Sulfones: dapsone*
- 3 **Antimalarials:** 05
Etiology of malaria, SAR and mechanism of action of quinolone Antimalarials Quinine sulphate, Chloroquine phosphate, amodiaquine, pamaquine*, primaquine, Quinacrine
Chloroguanide, cycloguanil, pyrimethamine*

| | | |
|----|--|----|
| | Calcium channel blockers: nifedipine, amlodipine | |
| | 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: | 03 |
| | History, development and SAR of sulfonylureas: tolbutamide*, chlorpropamide*, glipizide | |
| | Metaglinides: repaglinide | |
| | Thiazolidiones: rosiglitazone, pioglitazone | |
| | Biguanides: metformin, phenformin | |
| | Miscellaneous: acarabose, miglitol | |
| 8 | Thyroid and Antithyroid agents | 01 |
| | L-thyroxine, L-threonine | |
| | Propyl thiouracil, methimazole | |
| 9 | Diuretics: | 05 |
| | Carbonic anhydrase inhibitors: acetazolamide* | |
| | Thiazide diuretics: SAR of thiazide diuretics, chlorthiazide, benzthiazide, xipamide, chlorthalidone | |
| | Loop diuretics: frusemide*, ethacrynic acid* | |
| | Potassium sparing diuretics: spiranolactone, amiloride | |
| | Miscellaneous: mannitol | |
| 10 | Diagnostic agents | 01 |
| | Iodipamide, diatrizoate sodium | |
| | Amino hippurate, sulfobromphthalein, fluorescein sodium | |
| 11 | Steroidal Hormones and Adrenocorticoids | 05 |
| | Estrogens: estradiol, DES | |
| | Progestines: progesterone, norethindrone | |
| | Testosterone, nandralone | |
| | Betamethasone, prednisolone, beclomethasone | |

22PD35P: MEDICINAL CHEMISTRY (PRACTICAL)**Practical: 3 Hrs./Week****75Hours****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 quinoxaline from OPDA
 10. Preparation of benzotriazole 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 | 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)

22PD36T: PHARMACEUTICAL FORMULATIONS (THEORY)**Theory: 2 Hrs. /Week****50 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|---|
| CO1 | Know the types of tablets & granulation techniques. |
| CO2 | Learn the quality control test and evaluation of uncoated as well as coated tablets. |
| CO3 | Learn production and filling of hard & soft gelatine capsules. Quality control test for Same |
| CO4 | Explain the formulation and evaluation of semisolid preparation such as ointment, gel etc. |
| CO5 | Learn the formulation concepts of pharmaceutical suspensions and emulsions and their stability problems |
| CO6 | Acquire working knowledge and understanding the production facilities of Parenterals |
| CO7 | Understand pharmacopoeial quality control tests, as well as Container-closure systems for injections |
| CO8 | Know the various controlled and novel drug delivery systems and its importance |

- 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 material

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.WolterKluwer 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. ofIndia, Ministry of Health

3. Lecture wise programme:

| | Topics | Hrs |
|---|---|------------|
| 1 | Tablets: Formulation of different types of tablets, tablet excipients, granulation techniques, Tablet coating, Type of coating, quality control tests and evaluation for uncoated andcoated tablets. | 10 |
| 2 | Capsules: Production and filling of hard gelatin capsules, Raw materials for shell, finishing. Production and filling of soft gelatin capsules, Importance of base adsorption, quality controltests for hard and soft gelatin capsules. | 07 |
| 3 | Liquid orals: Formulation, Manufacturing and evaluation of suspensions, emulsions and solutions. Instability problems in suspensions and emulsions. | 06 |
| 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 pertinentto sterile preparations and Pharmacopoeial quality control tests, Sterilization and evaluation. | 13 |

- 5 **Semi – Solids:** Introduction and classification Factors affecting absorption, Packaging, storage and labeling. Ointments: Types of Ointment Base Preparation of ointment. Gels: Types and formulation of Gels 06
- 6 **Definition and concept of Controlled and novel Drug delivery systems** with available examples, viz. transdermal, buccal, vaginal, nasal, implantable, ocular drug delivery systems 08

22PD36P: 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. Salicylic 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 | 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).

22PD41T: PHARMACOTHERAPEUTICS – III (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|--------|--|
| CO1 | Describe the Etiopathogenesis of selected disease states |
| CO2 | Discuss the various methods involved in the diagnosis of selected disease state |
| CO3 | Interpret and analyze the selected laboratory results of specific disease states |
| CO4 | Describe the therapeutic approach to manage the selected diseases |
| CO5 | Discuss the rationale for drug therapy of the selected disease |
| CO6 | Identify the controversies in drug therapy |
| CO7 | Develop the individualized therapeutic plans based on diagnosis |
| CO8 | Identify the patient-specific parameters relevant in initiating the drug therapy |
| CO9 | Describe evidence based medicine |

- 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 drugtherapy
2. The therapeutic approach to management of these diseases
3. The importance of preparation of individualised therapeutic plansbased 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; 5th.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 Elsevier India Pvt Ltd, New Delhi, 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 Lippincott Williams & Wilkins, New York
- 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

| | Topics | Hrs |
|---|---|------------|
| 1 | Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders – Alcoholic liver disease, Viral hepatitis including jaundice, and Druginduced liver disorders. | 20 |
| 2 | Haematological system: Anaemias, Venous thromboembolism, Drug induced blood disorders. | 12 |
| 3 | Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease | 16 |
| 4 | Psychiatry disorders: Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders | 14 |
| 5 | Pain management including Pain pathways, neuralgias, headaches | 08 |
| 6 | Evidence Based Medicine | 05 |

22PD41P: 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).

22PD42T: HOSPITAL PHARMACY (THEORY)**Theory: 2 Hrs. /Week****50 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|---|
| CO1 | Describe the organizational structure of hospital & hospital pharmacy |
| CO2 | Explain different drug policies & committees in the hospital |
| CO3 | Operate various drug distribution methods in the hospital |
| CO4 | Describe the management of inventory control in the hospital pharmacy |
| CO5 | Explain the continuing professional development programs in hospitals |
| CO6 | Understand the manufacturing practices of various formulations in hospital set up |
| CO7 | Explain the professional relations and practices of hospital pharmacist |
| CO8 | Describe the procedure for procuring & warehousing of drugs & pharmaceuticals |

- 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:

| | Topics | Hrs |
|---|--|------------|
| 1 | Hospital - its Organisation and functions | 01 |
| 2 | Hospital pharmacy-Organisation and management | 04 |
| | a) Organizational structure-Staff, Infrastructure & workload statistics | |
| | b) Management of materials and finance | |
| | c) Roles & responsibilities of hospital pharmacist | |
| 3 | The Budget – Preparation and implementation | 01 |
| 4 | Hospital drug policy | 10 |
| | a) Pharmacy and Therapeutic Committee (PTC) | |
| | b) Hospital formulary | |
| | c) Hospital committees | |
| | - Infection committee | |
| | - 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 volumeparenterals | |
| | b) Manufacture of Ointments, Liquids, and creams | |
| | c) Manufacturing of Tablets, granules, capsules, and powders | |
| | d) Total parenteral nutrition | |
| 7 | Continuing professional development programs | 03 |
| | Education and training | |
| 8 | Radio Pharmaceuticals – Handling and packaging | 02 |
| 9 | Professional Relations and practices of hospital pharmacist | 02 |

22PD42P: 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:

| | Sessional | 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).

22PD43T: CLINICAL PHARMACY (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|--------|---|
| CO1 | Describe development and scope of clinical pharmacy |
| CO2 | Discuss various services provided by clinical pharmacist in a hospital |
| CO3 | Assess the drug therapy of patient through medication chart review and clinical review |
| CO4 | Interpret and analyze clinical laboratory test results of specific diseases |
| CO5 | Discuss the Organization and functions of Drug & Poison information and centers |
| CO6 | Discuss the importance of drug safety monitoring and the development of pharmacovigilance program |
| CO7 | Identification and management of Adverse Drug Reactions |
| CO8 | Discuss critical evaluation of biomedical literature |
| CO9 | Explain communication skills required for clinical pharmacy services provision |

1. **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, 2nd. Ed. 1996, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics, Leon Shargel, 6th ed.2013, Prentice Hall Publication
- d. Textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarathi, Karin Nyfort-Hansen, Milap Nahata, 2nd ed. 2015, Orient Longman Pvt. Ltd.

Reference Books

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

3. Lecture wise programme

| | Topics | Hrs |
|---|---|------------|
| 1 | Definitions, development and scope of clinical pharmacy | 03 |
| 2 | Introduction to daily activities of a clinical pharmacist | 13 |
| | <ol style="list-style-type: none"> a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) b. Ward round participation c. Adverse drug reaction management d. Drug information and poisons information e. Medication history e. Patient counselling f. Drug utilisation evaluation (DUE) and review (DUR) g. Quality assurance of clinical pharmacy services | |
| 3 | Patient data analysis | 03 |
| | <ul style="list-style-type: none"> • The patient's case history, its structure and use in evaluation of drug therapy & understanding common medical abbreviations and terminologies used in clinical practices | |

| | | |
|----|---|----|
| 4 | Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results | 15 |
| | <ul style="list-style-type: none"> • Haematological, Liver function, Renal function, thyroidfunction tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Microbiological culture sensitivity tests • Pulmonary Function Tests | |
| 5 | Drug & Poison information | 08 |
| | <ul style="list-style-type: none"> • Introduction to drug information resources available • Systematic approach in answering DI queries • Critical evaluation of drug information and literature • Preparation of written and verbal reports • Establishing a Drug Information Centre • Poisons information- organization & information resources | |
| 6 | Pharmacovigilance | 10 |
| | Scope, definition and aims of pharmacovigilance <ul style="list-style-type: none"> • Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scalesused], • Reporting, evaluation, monitoring, preventing &management of ADRs • Role of pharmacist in management of ADR. | |
| 7 | Communication skills, including patient counseling techniques, medication history interview, presentation of cases. | 10 |
| 8 | Pharmaceutical care concepts | 04 |
| 9 | Critical evaluation of biomedical literature | 06 |
| 10 | Medication errors | 03 |

22PD43P: 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 history interview, 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.
- 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
- Time allocated for presentation at the end of the academic year may be 8+2min

22PD44T: 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, Biostatistics, 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. 4th 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 a) Types of clinical study designs: Case studies, observational studies, interventional studies, b) Designing the methodology c) Sample size determination and Power of a study, Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study d) Report writing and presentation of data | 10 |
| 2 | 2.1 Biostatistics a) Introduction b) Types of data distribution c) Measures describing the central tendency distributions- average, median, mode d) Measurement of the spread of data-range, mean deviation, standard deviation, variance, coefficient of variation, standard error of mean. 2.2 Data graphics : Construction and labeling of graphs, histogram, Pie charts, scatter plots, semi-logarithmic graphs 2.3 Basics of testing hypothesis : | 10 |
| | a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals. b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way) c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA) d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient. e) Introduction to statistical software: SPSS, Epi Info, SAS. | 02 |
| | 2.4 Statistical methods in epidemiology Incidence and prevalence, relative risk, attributable risk | 15 |
| | | 05 |

- 3 **Computer applications in pharmacy** 08
- Computer System in Hospital Pharmacy:**
 Patterns of Computer use in Hospital Pharmacy –
 Patient record database management, Medication orderentry – 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 ledgersystem
- Drug Information Retrieval & Storage :**
 Introduction – Advantages of Computerized LiteratureRetrieval, Use of Computerized Retrieval

22PD45T: BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

75 Hours

Course Outcome

At the end of the course students will be able to...

| CO No. | Outcome statement |
|--------|--|
| CO1 | Define the basic concepts in biopharmaceutics and pharmacokinetics |
| CO2 | Select the correct pharmacokinetic model based on plasma level or urinary excretion data that best describes the process of drug absorption, distribution, metabolism and elimination (ADME) |
| CO3 | Determine the effect of Pharmacokinetic (ADME) parameters on the biological effects of the drug |
| CO4 | Carry out biopharmaceutical studies and use data so obtained in the development of new drugs or dosage forms |
| CO5 | Calculate various pharmacokinetic parameters from plasma and urinary excretion data applying compartment modeling and model independent methods |
| CO6 | Design dosage regimens for patients based on calculated pharmacokinetic parameters |
| CO7 | Design Bioavailability and Bioequivalence studies of new drugs or dosage forms |
| CO8 | Evaluate drug-protein binding as a tool to predict pharmacokinetics of drugs |

- 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 productequivalency
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

Material Text books

- a) Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi. 4th 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 International edition. USA
- d) Bio pharmaceutics and Pharmacokinetics-A Treatise, D. M. Brahmankar and Sunil B.Jaiswal, 3rd. ed. 2015, Vallabh Prakashan Pitampura, Delhi

Reference Books

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

3. Lecture wise programme

| | Topics | Hrs |
|---|--|-----|
| | I Biopharmaceutics | |
| 1 | Introduction to biopharmaceutics | 01 |
| 2 | Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non <i>per OS</i> extra-vascular routes | 08 |
| 3 | Distribution of drugs 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 binding | 08 |
| 4 | Drug Elimination. 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 | Bioavailability and Bioequivalence: 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 K_a , K_E from plasma and urinary excretion data | 15 |
| 8 | Multicompartment models: Two compartment open model. IV bolus, IV infusion and oral administration | 08 |
| 9 | Multiple – Dosage Regimens: a). Repetitive Intravenous injections – One Compartment Open Model b). Repetitive Extravascular dosing – One Compartment Open model | 05 |

| | | |
|----|---|----|
| | c). Multiple Dose Regimen – Two Compartment Open Model | |
| 10 | Nonlinear Pharmacokinetics. | 05 |
| | a. Introduction, | |
| | b. Factors causing Non-linearity. | |
| | c. Michaelis-menton method of estimating parameters | |
| 11 | Noncompartmental Pharmacokinetics. Statistical Moment Theory,. MRT for various compartment models. Physiological Pharmacokinetic Model | 04 |

**22PD45P: BIOPHARMACEUTICS AND PHARMACOKINETICS
(PRACTICAL)**

Practical: 3 Hrs./Week

75 Hours

List of experiments

1. Improvement of dissolution characteristics of slightly soluble drugs by co-solvency
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 K_a , K_e , $t_{1/2}$, C_{max} , 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

22PD46T: CLINICAL TOXICOLOGY (THEORY)**Theory: 2 Hrs. /Week****50 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|--------|--|
| CO1 | Describe general principles involved in the management of poisoning |
| CO2 | Differentiate the clinical symptoms of various acute poisonings |
| CO3 | Manage the clinical symptoms of different acute poisonings |
| CO4 | Distinguish the clinical symptoms of chronic poisoning by heavy metals |
| CO5 | Manage the various clinical symptoms of different chronic poisoning by heavy metals |
| CO6 | Recognize the clinical symptoms and management of envenomation, food poisoning and poisoning by various plants |
| CO7 | Devise public and health care professionals in the management of emergency cases |
| CO8 | Evaluate, minimize and prevent the substance abuse cases in local population |

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, 4th 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

| Topics | Hrs |
|---|------------|
| 1. General principles involved in the management of poisoning | 02 |
| 2. Antidotes and the clinical applications | 01 |
| 3. Supportive care in clinical Toxicology | 02 |
| 4. Gut Decontamination | 02 |
| 5. Elimination Enhancement | 01 |
| 6. Toxicokinetics | 02 |
| 7. Clinical symptoms and management of acute poisoning with the following agents | 21 |
| a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids | |
| b) Opiates overdose. | |
| c) Antidepressants | |
| d) Barbiturates and benzodiazepines | |
| e) Alcohol: ethanol, methanol | |
| f) Paracetamol and salicylates | |
| g) Non-steroidal anti-inflammatory drugs | |
| h) Hydrocarbons: Petroleum products and PEG. | |
| i) Caustics: inorganic acids and alkali | |
| j) Radiation poisoning | |
| 8. Clinical symptoms and management of chronic poisoning with the following agents - Heavy metals: Arsenic, lead, mercury, iron, copper | 05 |
| 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 |
| 12. Envenomations – Arthropod bites and stings | 01 |
| 13. Substance abuse: | 08 |
| 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 | |

22PD47T: PHARMACOTHERAPEUTICS I & II (THEORY)**Theory: 3 Hrs. /Week****75 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|--|
| CO1 | Describe the etiopathogenesis of selected disease states |
| CO2 | Discuss the various methods involved in the diagnosis of selected disease states |
| CO3 | Interpret and analyze the selected laboratory results of specific disease states |
| CO4 | Describe the therapeutic approach to manage the selected diseases |
| CO5 | Discuss the rationale for drug therapy of the selected diseases |
| CO6 | Identify the controversies in drug therapy |
| CO7 | Develop the individualized therapeutic plans based on diagnosis |
| CO8 | Describe the general prescribing guidelines for special population |
| CO9 | Explain role of pharmacist in promoting rational drug use and essential drug concept |

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 drugtherapy.
2. The therapeutic approach to management of these diseases.
3. The controversies in drug therapy.
4. The importance of preparation of individualized therapeutic plans basedon 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

Material Text

Books

- a) Clinical Pharmacy and Therapeutics; 5th.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 Elsevier 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 Lippincott 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

Etio pathogenesis and pharmacotherapy of diseases associated with followingsystems/ diseases

| Topics | Hrs |
|---|------------|
| 1. Cardiovascular system Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidemia, Electrophysiology of heart and Arrhythmias | |
| 2. Respiratory system Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases. | 06 |
| 3. Endocrine system Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis | 08 |
| 4. General prescribing guidelines for 4.1 Paediatric patients 4.2 Geriatric patients 4.3 Pregnancy and breast feeding | 04 |
| 5. Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial. | 03 |
| 6. Introduction to rational drug use Definition, Role of pharmacist Essential drug concept Rational drug formulations. | 02 |
| 7. Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis. | 18 |
| 8. Musculoskeletal disorders Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus. | 06 |
| 9. Renal system Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders. | 05 |

- | | | |
|-----|--|----|
| 10. | Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis. | 06 |
| 11. | Dermatology: Psoriasis, Scabies, Eczema, Impetigo. | 04 |

22PD47P: 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.
- Name and signature of the student
- Assignment can be a combined presentation
- Time allocated for presentation at the end of the academic year may be 8+2Min

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)

22PD51T: CLINICAL RESEARCH (THEORY)**Theory: 2 Hrs. /Week****50 Hours****Course Outcome***At the end of the course students will be able to...*

| CO No. | Outcome statement |
|---------------|--|
| CO1 | Describe the concept of new drug development process |
| CO2 | Describe the various phases of clinical trials |
| CO3 | Recognize the regulatory and ethical requirements in clinical trials |
| CO4 | Describe the regulatory environment in USA, Europe and India |
| CO5 | Recognize the roles and responsibilities of clinical trial study team |
| CO6 | Develop the various clinical trial documents |
| CO7 | Discuss various procedures and activities involved in the conduct of clinical trials |
| CO8 | Interpret the various aspects of clinical trial data management |

- 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, Andrew.J.Fletcher 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 CCA2000 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 CCA2000 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.

| 2. Lecture wise programme Topics | Hrs |
|--|------------|
| 1. Drug development process: | 10 |
| Introduction | |
| 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. | 03 |
| 5. Good Clinical Practice – ICH, GCP, Central drug standard control organization (CDSCO) guidelines. | 08 03 |
| 6. Challenges in the implementation of guidelines. | 02 |

| | | |
|--|----|----|
| 7. Ethical guidelines in Clinical Research. | 02 | |
| 8. Composition, responsibilities, procedures of IRB / IEC. | 10 | |
| 9. Overview of regulatory environment in USA, Europe and India. | 07 | |
| 10. Role and responsibilities of clinical trial personnel as per ICH GCP | | |
| a. Sponsor | | |
| b. Investigators | | |
| c. Clinical research associate | | |
| d. Auditors | | |
| e. Contract research coordinators | 06 | |
| f. Regulatory authority | 02 | |
| 11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment). | 05 | 04 |
| 12. Informed consent Process. | | |
| 13. Data management and its components. | | |
| 14. Safety monitoring in clinical trials. | | |

22PD52T: PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs./Week

75 Hours

Course Outcome

At the end of the course students will be able to...

| CO No. | Outcome statement |
|--------|--|
| CO1 | Identify the applications of pharmacoepidemiology and pharmacoconomics in clinical settings |
| CO2 | Discuss the various pharmacoepidemiological outcome measures |
| CO3 | Describe the concept of risk in pharmacoepidemiology and different methods of measuring risk |
| CO4 | Explain the various pharmacoepidemiological methods |
| CO5 | Explain the sources of data for pharmacoepidemiological studies |
| CO6 | Explain the various systems for studying drug effects in populations |
| CO7 | Discuss the methods to measure outcomes in pharmacoecomic studies |
| CO8 | Describe the current pharmacoecomic evaluation methods |

1. **Scope and Objectives:** This course is designed to impart knowledge regarding various methods and applications of pharmacoepidemiology and pharmacoconomics 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 pharmacoecomic studies and evaluate the cost-benefit ratio
2. **Course Materials:**

Reference Books

- a) Pharmacoconomics and outcomes: Applications for patient care, case studies, Graer DW, Lee J, Odom TD, 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 4th edition,
- d) Clinical epidemiology- How to do clinical Practice Research. 3rd edition, Brian Haynes, David L Sachett, Lippinkot

3. Lecture wise programme

| | Topics | Hrs |
|---|--|------------|
| 1 | <p>Pharmacoepidemiology : Definition and scope: Origin and evaluation of Pharmacoepidemiology, need for pharmacoepidemiology, aims and applications of Pharmacoepidemiology</p> | 06 |
| 2 | <p>Measurement of outcomes in pharmacoepidemiology Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement</p> | 06 |
| 3 | <p>Concept of risk in pharmacoepidemiology Measurement of risk, attributable risk, relative risk, time-risk relationship and odds ratio</p> | 06 |
| 4 | <p>Pharmacoepidemiological methods Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods; Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.</p> | 21 |
| 5 | <p>Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems.</p> | 04 |
| 6 | <p>Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth defects.</p> | 08 |

| | | |
|---|--|----|
| 7 | Pharmacoeconomics: | 24 |
| | 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) | |

22PD53T: CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs./Week

50 Hours

Course Outcome

At the end of the course students will be able to...

| CO No. | Outcome statement |
|--------|--|
| CO1 | Formulate and design a dosage regimen for individual patients |
| CO2 | Interpret and correlate the plasma drug concentration with patient's therapeutic outcomes |
| CO3 | Recommend dosage adjustment in renal and hepatic disease |
| CO4 | Recommend dosage adjustment for paediatrics, geriatrics and obese patients |
| CO5 | Analyze and resolve pharmacokinetic drug interactions |
| CO6 | Illustrate and apply pharmacokinetic parameters in clinical settings |
| CO7 | Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and pharmacodynamics of drugs |
| CO8 | Employ pharmacokinetic modeling for the given data using the principles of pharmacometrics |

- 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, 4th., 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) Clinical Pharmacokinetics, Concepts and Applications: By . Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 4th ed. 2010
- e) Biopharmaceutics and Applied Pharmacokinetics, Leon Shargel, 6th ed. 2013, Prentice Hall Publication

3. Lecture wise Programme:

| Topics | 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: | 03 |
| a. Pharmacokinetic drug interactions | |
| b. Inhibition and Induction of Drug metabolism | |
| c. Inhibition of Biliary Excretion. | |
| 4. Therapeutic Drug monitoring: | 20 |
| a) Introduction | |
| b) Individualization of drug dosage regimen (Variability – Genetic, age, 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. | |
| 5. Dosage adjustment in Renal and hepatic Disease. | 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.
- 6. Population Pharmacokinetics.** 05
- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with feedback.
- 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 considerations

**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. to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii. to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an 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 practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-

| | | |
|----|--|-----------|
| 1. | Proficiency of knowledge required for each case management | SCORE 0-5 |
| 2. | The competency in skills expected for providing Clinical Pharmacy Services | SCORE 0-5 |
| 3. | Responsibility, punctuality, work up of case, involvement in patient care | SCORE 0-5 |
| 4. | including medical doctors, nursing staff and | SCORE 0-5 |
| 5. | Initiative, participation in discussions, research | SCORE 0-5 |

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

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

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 outstudents.**

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 10th - 16th 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 |
|--|-------------------------------|
| <ul style="list-style-type: none"> • 10 + 2 Science academic stream Or • D.Pharm | 6 years |
| <ul style="list-style-type: none"> • 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

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

Dated: 30.9.2011

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 88th /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

faithfullySd/-

(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

Dated 21.11.2011

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: 16th February 2012

To

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

Sub: Pharm.D Course - Clarification regarding nomenclature of 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

