Ordinance, Scheme and Syllabi for Master in Pharmacy

Jodhpur University, Jodhpur offers Master in Pharmacy (M.Pharm.) with effect from Academic Year (2008-2009) in the following specializations:
1) Pharmaceutics
2) Pharmaceutical Chemistry
3) Pharmacology
4) Pharmacognosy
5) Quality Assurance
6) Clinical Pharmacy
7) Industrial Pharmacy

Course Title : Master in Pharmacy
Abbreviation : M. Pharm.
Type of Course : A Two years degree course
Pattern : Semester

Nomenclature of Semesters : Semester-I & Semester-II, First Year M. Pharm.
Semester-III & Semester-IV, Second Year M. Pharm. (Dissertation)

Award of the Degree : Degree will be awarded for those passing in all the four semesters as per the rules and regulations given subsequently.

O-M.Ph.1.Duration of Course: A two year course divided into four Semesters. Each Semester will be normally of 15 weeks duration for class room teaching/ lecture and examination for that semester will be held during or after the 16th week from the commencement of the semester.

O-M.Ph.2.Eligibility for admission
The minimum qualification for admission to first semester of Master of pharmacy two years (four semesters) course shall be:-
(i) A candidate must secure 55% aggregate marks in B. Pharm. And GATE valid score card students are preferred. Any other qualification laid down by AICTE are also eligible.
(ii) 55% in B.Pharm marks with minimum 2 years experience from the date of passing B.Pharm for Sponsored Candidates.
(iii) 55% in B.Pharm marks for NRI/NRI Sponsored candidates.
O-M.Ph.3. Eligibility for appearing in the examination

O-M.Ph.3.1 No candidate shall be allowed to appear in any examination unless he / she has attended 75% of the classes held in each theory and practical separately in each subject.

O-M.Ph.3.2 A candidate can have a relaxation of 10% attendance on medical ground by producing a certificate from medical officer of government hospital and a 5% relaxation by the vice chancellor on the recommendation of dean faculty.

O-M.Ph.4 Scheme of Study

O-M.Ph.4.1 Candidates for the M. Pharm course shall be instructed and examined as per the Teaching and Examination Scheme and Course Content of respective semester.

Plan and scheme of Examination for M. Pharm. Semester - I

<table>
<thead>
<tr>
<th>Subject Code</th>
<th>Subject</th>
<th>L</th>
<th>P</th>
<th>Semester Exam.</th>
<th>Sessional Exam.</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Theory</td>
<td>Practical</td>
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<tr>
<td>0011</td>
<td>Advance Analytical Tech. - I (Compulsory)</td>
<td>3</td>
<td>6</td>
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<td>0012</td>
<td>Biostat Analysis &amp; Computer (Compulsory)</td>
<td>3</td>
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<td>0013</td>
<td>Professional practice (Compulsory)</td>
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<tr>
<td>0111</td>
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<td>3</td>
<td>6</td>
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<td>0112</td>
<td>Advances in drug delivery system</td>
<td>3</td>
<td>6</td>
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<td>0121</td>
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<tr>
<td>0131</td>
<td>Pharmacology – I (Basic principles of drug therapy and clinical pharmacology)</td>
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<tr>
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<td>Pharmacology – II (Biopharmaceutics and Pharmacokinetics)</td>
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<td>0141</td>
<td>Biogenesis &amp; Chemistry of Natural Product</td>
<td>3</td>
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<tr>
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<td>Advance Pharmacology &amp; Toxicology</td>
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<td>Cosmeticology</td>
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<td>Advances in drug delivery system</td>
<td>3</td>
<td>6</td>
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# Plan and scheme of Examination for M. Pharm. Semester - II

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<thead>
<tr>
<th>Subject Code</th>
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<th>Semester Exam.</th>
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<tbody>
<tr>
<td>0021</td>
<td>Intellectual Property Rights &amp; Drug Regulatory Affairs (Compulsory)</td>
<td>3</td>
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<td>Advance Analytical Tech.- II (Compulsory)</td>
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<td>0023</td>
<td>Professional practice (Compulsory)</td>
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**Branch:- Pharmaceutics (Branch Code:- 01)**

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<th>Sessional Exam.</th>
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<td>0211</td>
<td>Novel Drug Delivery System</td>
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<tr>
<td>0212</td>
<td>Product Development &amp; Packaging Technology</td>
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**Branch:- Pharmaceutical Chemistry (Branch Code:- 02)**

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<td>0221</td>
<td>Advance Medicinal Chemistry - II</td>
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<td>0222</td>
<td>Natural Chemistry (Chem. Of Natural Product)</td>
<td>3</td>
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**Branch:- Pharmacology (Branch Code:- 03)**

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<th>Semester Exam.</th>
<th>Sessional Exam.</th>
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<tr>
<td>0231</td>
<td>Pharmacology – III (Recent advances and emerging trends in pharmacology science)</td>
<td>3</td>
<td>6</td>
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<td>0232</td>
<td>Pharmacology IV (Pharmacological methods and toxicology)</td>
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**Branch:- Pharmacognosy (Branch Code:- 04)**

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<th>Sessional Exam.</th>
<th>Total</th>
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<tr>
<td>0241</td>
<td>Phytochemistry &amp; Biotechnology</td>
<td>3</td>
<td>6</td>
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<td>0242</td>
<td>Industrial Pharmacognosy</td>
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**Branch:- Quality Assurance(Branch Code:- 05)**

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<th>Sessional Exam.</th>
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<td>0251</td>
<td>Quality Assurance - II</td>
<td>3</td>
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**Branch:- Clinical Pharmacy (Branch Code:- 06)**

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<th>Sessional Exam.</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>0261</td>
<td>Clinical Pharmacology &amp; Therapeutic Drug monitoring</td>
<td>3</td>
<td>6</td>
<td>80</td>
<td>80</td>
<td>200</td>
</tr>
<tr>
<td>0262</td>
<td>Advances in novel Pharmacological Drug Target</td>
<td>3</td>
<td>6</td>
<td>80</td>
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</table>

**Branch:- Industrial Pharmacy (Branch Code:- 07)**

<table>
<thead>
<tr>
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<th>Semester Exam.</th>
<th>Sessional Exam.</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0271</td>
<td>Novel Drug Delivery System</td>
<td>3</td>
<td>6</td>
<td>80</td>
<td>80</td>
<td>200</td>
</tr>
<tr>
<td>0272</td>
<td>Industrial pharmacy and production management</td>
<td>3</td>
<td>6</td>
<td>80</td>
<td>80</td>
<td>200</td>
</tr>
</tbody>
</table>

O-M.Ph.5 EXAMINATIONS:  
There shall be one university examination at the end of each semester. These examinations will be designated as follows:

**O-M.Ph.5.1** During first year: M.Pharm. I semester, M.Pharm. II semester. (Including Professional Practice)

**O-M.Ph.5.2** During second year: M.Pharm.III semester, M.Pharm.IV semester. (Dissertation)
PROFESSIONAL PRACTICE: A student shall undergo professional training to assist in practical classes and in theory lectures to diploma and degree classes assign to him/her under the supervision of subject incharge. He/She has to submit a report on the work assign to him/her. His/Her evaluation will be on the basis of performance and report submitted by him/her.

DISSERTATION/RESEARCH PROJECT

• Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized faculty. The results of such a work shall be submitted in the form of a dissertation report/midterm report

• The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions.

• The dissertation should be written under the following headings.

  1. Introduction
  2. Aims or Objectives of study
  3. Review of Literature
  4. Material and Methods
  5. Results (Tables & Figures)
  6. Discussion
  7. Conclusion
  8. Summary
  9. References
  10. Annexures

• The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexures. It should be neatly typed with double line spacing on one side of the bond paper (A4 size, 8.27” x 11.69”) and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, and forwarded by the head of the Department and Head of the Institution. The dissertation shall be submitted at least two month before the end of M. Pharm. Part II term.

• A guide shall be a full time faculty of an institution affiliated to Jodhpur university and recognized by Jodhpur university as a guide for supervision of dissertation work. However a Co – guide can be opted wherever required. The Co – guide shall also be a faculty/industry personal recognized by Jodhpur University as guide.

• Synopsis: A candidate shall submit synopsis to the Registrar, Jodhpur University through the guide, HOD and head of the institution, not later than one month from the date of admission to M. Pharm III semester on or before the date specified by Jodhpur university.
SUBMISSION OF DISSERTATION

Three copies of the dissertation duly certified by the Guide, Head of the Department and the Principal, shall be submitted to the Registrar, Evaluation, Jodhpur university, through the Principal two months before the final examination notified by Jodhpur university.

Viva – voce examination
The Viva – voce examination shall aim at assessing the depth of knowledge, logical reasoning, confidence and oral communication skills.

The Viva – voce examination shall be held after the submission of dissertation. If any candidate fails, submit the dissertation on or before the date prescribed, his/her Viva – Voce shall be conducted during subsequent examination which shall not be earlier then six months from the date fixed in the first instance.

Examiners: there shall be at least two examiners in each branch/specialization, out of them one shall be external examiner and the other one shall be the internal examiner. The internal examiner ordinarily be the guide.

Distribution of marks for M. Pharm. Part – II examination

Total – 200 marks,
Sessional marks- 50
University Examination marks- 150  (dissertation thesis – 100 marks, viva voce – 50 marks.)

The dissertation and viva – voce shall be valued, by the examiners together appointed by the university.

O-M.Ph.6 STANDARD OF PASSING:

O-M.Ph.6.1 Each theory paper and practical will be treated as separate subject. In each subject Minimum 50% in sessional and semester examination taken together.

O-M.Ph.6.2 Candidate who has been admitted in M. Pharm. 1st semester will be promoted to the higher class in accordance with the following sub-rules:

O-M.Ph.6.2.1 No candidate will be awarded degree of Master in Pharmacy unless he/she has passed all the four semester

O-M.Ph.6.2.2 Promotion from odd semester to even semester in the same academic year

a) A Candidate who appeared in Semester - I examination of First Year M.Pharm. will be allowed to keep term for his/her Semester –II Examination, of First Year M.Pharm.

b) A Candidate who appeared in Semester – III examination of Second Year M.Pharm. will be allowed to keep term for his/ her Semester – IV Examination of Second Year M.Pharm.

O-M.Ph.6.2.3 Promotion to subsequent academic year-
A candidate who fails in more than one third of total number of subjects taken together at Semester I and Semester II examination will not be permitted to keep terms in the higher class viz. Semester III (3 subjects in Theory and 2 subjects in practical)

**O-M.Ph.6.3** A Candidate who does not pass all subjects of Semester - I examination of First Year M.Pharm. will not be allowed to keep term for his/her Semester –IV Examination, of M.Pharm.

**O-M.Ph.7 Marks, Criteria for passing and other conditions.**

**O-M.Ph.7.1 Passing of the semester.**
Candidate will be considered as passed the semester only when the candidate passes in all the subjects with ATKT. Candidate will be given maximum seven years to complete his / her M. Pharmacy neither his enrollment stand cancel. If candidate fail to appear in examination, than also his attempt will be counted.

**O-M.Ph.9.Award of Degree, Division and Rank**

**O-M.Ph.9.1** Degree will be awarded to the candidates who have passed in all the subjects of all four semesters

**O-M.Ph.9.2** The division to a successful candidate shall be awarded on the basis of aggregate of marks obtained by him / her in M.Pharm first year, M.Pharm second year;

<table>
<thead>
<tr>
<th>Percentage of marks</th>
<th>Division</th>
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<tbody>
<tr>
<td>75% or above</td>
<td>Honors</td>
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<tr>
<td>60% or above</td>
<td>First Division</td>
</tr>
<tr>
<td>50% or above</td>
<td>Second Division</td>
</tr>
</tbody>
</table>

**O-M.Ph.9.3** Rank (I, II & III) and university gold medal shall be conferred on the basis of aggregate percentage of marks obtained in all the four semesters to those candidates who have passed the whole examination in first attempt. The candidate who found indulges in any misconduct / in disciplinary activity will not be eligible for University medals / awards.

**O-M.Ph.11. CONDONATION OF DEFICIENCY IN MARKS**

**O-M.Ph.11.1** with a view to moderate hard line cases in the examination the following rules shall be observe:

**O-M.Ph.11.2** Deficiency up to 5 marks be condoned to the best advantage of the candidate for passing the examination, provided the candidate fails in maximum of two theory, or one theory and one practical or two practicals. This facility shall be available only to those candidates who appear at the semester examination in full (i.e. in all theory, practicals and sessionals in first attempt.)

**O-M.Ph.11.3** While declaring result of the candidate no marks shall be added to or subtracted from the aggregate for the deficiency condoned as above. However, he/she will pass the subjects cleared through clause 11.2 after condoning the deficiency the candidate’s result shall be declared in the division, which the aggregate entitled him/her.
O-M.Ph.11.4 One grace mark will be given to the candidate who is failing/missing distinction/missing first division by one mark, by the Vice-Chancellor in the M. Pharm. examination. This benefit will not, however, be available to a candidate getting advantage under clause 11.2
M.PHARM. SEMESTER-I

ADVANCE ANALYTICAL TECHNIQUE-I

THEORY(Compulsory)
Subject code -0011T Hours – (--/week)


2. INFRARED SPECTROPHOTOMETRY: Introduction, basic principles, vibrational frequency and factors influencing vibrational frequency, instrumentation and sampling techniques, interpretation of spectra and applications in Pharmacy. FT-IR-theory and applications, Attenuated Total Reflectance (ATR).

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY: Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, FT-NMR, 2D -NMR, NMDR, NOE, NOESY, COSY and applications in Pharmacy, interpretation of spectra, C\textsuperscript{13} NMR-Introduction, Natural abundance, C\textsuperscript{13} NMR Spectra and its structural applications.

4. MASS SPECTROSCOPY: Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), GC-MS, interpretation of spectra and applications in Pharmacy.

5. THERMAL METHODS OF ANALYSIS: Theory, principles, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).


7. OPTICAL ROTARY DISPERSION: Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.


PRACTICALS
1. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
2. Quantitative Colorimetric determination of suitable drugs using following reagents:
a) Paradimethyl Amino Cinnamaldehyde b) MBTH 
c) FC reagent d) 2, 6 dichloro quinine chlorimide e) Ninhydrin
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. I.R. of certain compound possessing following functional groups………………
a) –OH b) carbonyl c)Amine d) Aromatic nucleus
6. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (at least for 4 compounds each).
7. Assay of following official formulations:
a) Frusemide tablet IP b) Metformine tablet IP c) Chloramphenicol Capsule IP
d) Digoxin Tablet IP

REFERENCES
16. IP/ BP/ USP.

BIO-STATISTICS AND COMPUTER APPLICATIONS

THEORY(Compulsory)
Subject code -0012T Hours – (--/week)

1. Samples Introduction, random sampling, sampling procedures – stratified, systematic and cluster sampling, sampling in quality control measurement of spread of data coding, precision, accuracy.
2. Statistical Inference Statistical estimation (confidence of intervals), statistical hypothesis testing composition of variances in independent samples, test of equality, population mean, variance in case of two population, large sample tests.
3. Linear regression and correlation. Introduction, analysis of standard curves in Drug analysis-application of linear regression, assumption of tests in hypothesis in linear regression, variance of sample estimates of the parameters, a Drug stability study – an example of the application of linear regression, confidence intervals in regression coefficients, nonlinear regression.

4. Analysis of variance Linear models One-way analysis of variance, planned versus a Posteriori (Unplanned) comparisons in ANOVA, example of one-way analysis of variance-unequal sample size and fixed and random models, two-way analysis of variance (Randomized blocks). Analysis of covariance, ANOVA for pooling regression lines as related to stability data.

5. Quality control Introduction, control charts, acceptance sampling and operating characteristic curves, statistical procedures in Assay. Department establishing in-house limits, some statistical aspects of quality and the “Barr Decision”.

6. Research Methodology and literature sources, thesis writing and presentation of the work, citation of references. Computer fundamentals, MS-Excel, SPSS/SYSTAT

**PRACTICALS**

1. Computer basics like MS-Office  
2. Chem-Sketch, ISIS draw  
3. Statistical software SPSS/Instat/Systat  
4. Data handling  
5. Some software of Medicinal Chemistry

**Text Books**

1. Pharmaceutical Statistics Marcel Dekker  
2. Practical and clinical applications 3rd Edn by Sanford Bolton, 1997 Marcel, Dekker.  
4. Biostatistics- Sadaker  
5. Statistics- Gofeti Radhakrishnan  
6. Biostatistics - Zar wiley Publication  
7. Statistical methods in clinical trial by Woolsan

**PROFESSIONAL PRACTICE**

**THEORY (Compulsory)**  
Subject code -0013  
Hours – (--)/week

**Professional Practice:**  
A student shall undergo professional training to assist in practical classes and in theory lectures to diploma and degree classes assign to him/her under the supervision of subject incharge. He/She has to submit a report on the work assign to him/her. His/Her evaluation will be on the basis of performance and report submitted by him/her.
M.Pharm. Branch:- Pharmaceutics (Branch Code:- 01)

(BIOPHARMACEUTICS AND PHARMACOKINETICS)

Theory
Subject code - 0111 Hours – (--/week)

1. ABSORPTION OF DRUGS:
Definition, Structure of cell membrane and composition, Gastrointestinal absorption –
Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical
and Pharmaceutical dosage form factors; Methods of determining absorption: Invitro and
Invivo methods; Absorption of drugs from non-oral route.

2. DISTRIBUTION OF DRUGS:
Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to
CNS, placental transfer of drugs and blood flow; Volume of distribution, Plasma protein
binding: Drug distribution and drug effects, Drug binding in tissues.

3. BIOTRANSFORMATION OF DRUGS:
Definition, Phase I and Phase II reactions and Factors affecting biotransformation.

4. EXCRETION OF DRUGS:
Definition, Renal and non- renal excretion.

5. PHARMACOKINETICS:
a) Definitions, Basic considerations - zero order and first order kinetics.
b) A detailed study of open one compartment model and open two compartment model.
c) Non-compartmental methods-Area under first movement curve (AUMC),
drug clearance, apparent volume of distribution, mean residence time (MRT) and its
significance.
d) Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal
c clearance.
e) Non- linear Pharmacokinetics: Cause of non-linearity, Michaelis-menten equation,
Estimation of Km and Vmax.

6. PHARMACODYNAMICS :
a. General aspects of receptor pharmacology.
b. Structural and functional aspects of receptors.
c. Regulation of receptors.
d. Classification of receptors.

7. BIOAVAILABILITY:
Definition, Estimating absorption rate of drugs; Preabsorptive hydrolysis and metabolism;
Presystemic metabolism:Hepatic metabolism and Gut wall metabolism; Bioavailability of
some specific drugs namely Acetazolamide, Ampicillin, Carbamazepine, Diazepam,
Furosemide, Nitrofurantoin, Tolbutamide; Measurement of bioavailability- Pharmacokinetic
methods and Pharmacodynamic methods. Methods of Enhancing Bioavailability of Drugs:
Solubilisation, Prodrugs, Enhancement of dissolution characteristics, Inclusion of
bioavailability enhancers.
8. DOSAGE REGIMEN:
Multiple dosing with respect to IV and oral route, concept of loading dose, maintenance dose and accumulation index.

9. BIOEQUIVALENCE STUDIES:
Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.

10. PHARMACOKINETIC VARIABILITY:
Body weight, Age, Sex, Genetic factors, Pharmacokinetic variability’s in disease, states of Renal, Liver, Cardiovascular, Thyroid and Dosage adjustment in the above conditions.

Recommended books:
1. Biopharmaceutics and Clinical pharmacokinetics-M. Gibaldi
2. Biopharmaceutics and Clinical pharmacokinetics-Notari
3. Biopharmaceutics and relevant pharmacokinetics-T. G. Wagner
4. Biopharmaceutics and Drug interactions-Cadwallader
5. Pharmacokinetics-M. Gibaldi and D. Perrier

ADVANCES IN DRUG DELIVERY SYSTEM

Theory
Subject code - 0112     Hours – (~/week)

1) Preformulation Studies: on various dosage forms such as tablets, capsules, suspension, creams, emulsion, injectables, ophthalmics, and aerosols etc.
2) Advances in Solid dosages forms: Physics of tables compression, direct compression, recent advances in tablet coating, micro-encapsulation and uses of newer encapsulating agents and techniques. Particle size enlargement – various methods and application.
4) Parenteral dosage forms: Processing of small and large volume parenteral raw materials, principle and technique. Stability evaluation environment, personnel and management factors in control and quality assurance.
6) Production management: Organization structure, objectives and polices, good manufacturing practices, layout of buildings, service, equipments and maintenance – detail discussion. Material management handling and transportation, production planning
and control, industrial relations. Safety laws related to production and licensing factories act.

7) Packaging Technology: Role of packaging in protecting product. Packaging materials such as glass, plastics, metals, and paper based material, ancillary materials -use in packaging materials, economics of packaging methods and packages. Safety consideration and law relating to packaging.


Books Recommended:
3. Essential of Physical Chemistry and pharmacy Arnikar, Kadam, Gujar, Orient Longman.
4. Quality Control in The pharmaceutical Industry: Volumes 1,2 and 3, Murrany
7. Pharmaceutical Preformulation by J. I. Wells, John wiley & sons, N.Y.
11. Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.

Branch:- Pharmaceutical Chemistry (Branch Code:- 02)

ADVANCE ORGANIC CHEMISTRY

Theory
Subject code - 0121

Hours – (--/week)
1. **Structure of organic molecules:**
   a) Atomic and molecular structure, use of resonance.
   b) Localized chemical bonding, delocalized chemical bonding, bonding weaker than covalent, bond energy, bond length.
   c) Electro negativity, hyper conjugation, dipole moment.
   d) Acids and bases, electrophiles, nucleophiles.
   e) Effect of structure, kinetics, inductive, resonance and steric upon reactivity.
   f) Carbocation, carbanion, free radical, carbenes and nitrenes.

2. **Stereo chemistry**
   a) Stereo isomerism, Geometrical Isomers and optical isomers, basic concept of optical activity and chirality structural features necessary for optical activity.
   b) Configuration and a specification, correlation of configuration, absolute configuration, methods of determining configurations, racemic modification, resolution and optical purity.
   c) Stereo chemistry of olefins- cis-trans, stereo chemistry of ring systems-including fused ring and bridge rings.
   d) Confirmation and reactivity in a cyclic compounds- conformational analysis.
   e) Confirmation in open chain. Six membered rings and other rings having heteroatoms.

3. Aliphatic nucleophilic substitution (SN$_1$ & SN$_2$) and aliphatic electrophilic substitution with special emphasis on mechanism and reactivity.

4. Aromaticity, electrophilic and nucleophilic substitution in aromatic systems, E1, E2 mechanisms, Hofmann and Saytzeff elimination, competition between elimination and substitution, intermolecular elimination, addition reaction, Markownikoves rule, nucleophilic addition hydride transfer reactions, Cram’s rule, participation of neighboring groups in transannular rearrangements.

5. Reactions of carboxylic acids and esters, claisen condensation, enolization, keto-eno equilibrium, organometallic compounds.

6. **Pericyclic reactions:** Mechanism, Types of pericyclic reactions – cyclo addition, electrocyclic reaction, Sigmatrophic rearrangement.

7. **Photochemistry:** Basic theory, orbital symmetry rules and photoreactions.

8. Mechanism consideration in detail for the following organic reactions:-
    Hofmann rearrangements, free radicals displacement, addition and rearrangement of free radicals, Beckmann rearrangements, transannular rearrangements and Pinacol rearrangements. Curtius rearrangement, Schmidt rearrangement, Fries rearrangement, Benzidine rearrangement, Benzilic rearrangement, Allylic rearrangement, Dimoth rearrangement, Wittig reaction, Reimer-Tiemann’s reaction, Buchner method of ring enlargement, Carrol reaction, Diels-Alder reaction, Pinner reaction, Reformatsky reaction, Robinson reaction, Annelation reaction, Arndt Eistert synthesis, Cannizzarro’s reaction, Michael’s condensation, Oppenauer oxidation, Birch’s reduction, Clemmensen’s reduction, use of diazonium salt, diazomethane, and peracids in synthesis.

**Practicals:**
Following unit processes as applied to drugs and drug intermediates are to be performed:
Sulphonation, halogenation, hydrogenation, nitration, amination by catalytic and chemical reduction, diazotization oxidation, esterification, hydrolysis, polymerization and other name reactions.
Reference Books

2. Stereochemistry of Carbon Compounds by Eliel.
3. Conformational analysis by E.L. Eliel.
11. Unit Processes in Organic Synthesis by Groggins.

ADVANCE MEDICINAL CHEMISTRY-I

Theory

Subject code - 0122

Hours – (--)/week

Following classes of drugs with special references to brief chemistry, mechanism of action, synthesis of marketed drugs, SAR, clinical importance and recent advances:

1. Antibacterial.
2. Antineoplasics.
3. Antiviral.
4. Antimalarial.
5. Drugs for aids, amoebiasis, leishmania, tuberculosis and leprosy
6. CVS- antihypertensive, antiarrythmics, antianginals, cardiotonics.
7. CNS- anesthetics, sedative-hypnotics, anticonvulsants, antipsychotics and CNS stimulants.
8. Immunosuppressant and Immunostimulants.
9. Radio protectives and drugs against ageing.
10. Antifertility agents.
11. Analgesics.

Practicals:

Synthesis; determination of Rf value and purity by thin layer chromatography; spectral analysis and M.P. determination of following drugs/ drug intermediates and other drugs related to theory syllabus:
Phenytoin, Mefanemic acid, Para amino phenol, caprolactam from cyclohexanone, isatin from phthalalimide, antipyrin, dibenzal acetone from benzaldehyde, coumarins from resorcinol, pinacol from acetone, sulphanilamide from acetanilide, phenobarbitone, diketopiperazine, nifidipine and propranolol.

Reference Books

1. Progress in Medicinal Chemistry, Series by Ellis & Wert.
3. Medicinal Chemistry by Burger.
Branch: Pharmacology (Branch Code:- 03)

PHARMACOLOGY – I

(BASIC PRINCIPLES OF DRUG THERAPY AND CLINICAL PHARMACOLOGY)

Theory

Subject code - 0131                                                                 Hours – (--/week)


2. Drugs acting on the autonomic nervous system
   i) Neurotransmission Autonomic and somatic motor nervous system.
   ii) Muscarinic receptor agonists and antagonists.
   iii) Anticholinestrase agents
   iv) Agents acting at the neuromuscular junction and automatic ganglia
   v) Catecholamines, sympathomimetic drugs and adrenergic receptor antagonists, ocular pharmacology.
   vi) 5-Hydroxy tryptamine (Serotonin )

3. Drugs acting on the Central Nervous System
   i) Neurotransmission and the Central Nervous System (CNS)
   ii) History and principles of anaesthesiology
   iii) General anaesthetics
   iv) Local anaesthetics.
   v) Hypnotics, sedatives and ethanol
   vi) Drugs nd the treatment of psychiatric disorder. Psychosis, anxiety, depression and mania
   vii) Drugs effective in the therapy of epilepsy
   viii) Drugs effective in the therapy of migraine
   ix) Treatment of central nervous system degenerative disorders
   x) Opioid analgesics and antagonists
   xi) Drugs addiction and drugs abuse

4. Autocoids: Drug Therapy of Inflammation
   i) Introduction
   ii) Histamine, bradykinin and their antagonists
   iii) Lipid-derived autocoids: Eicosanoids and platelets activating factor
   iv) Analgesic, antipyretic and anti-inflammatory agents and drugs employed in the treatment of gout
   v) Drugs used in the treatment of asthma.
5. Drugs effecting renal, blood and cardiovascular function
   i) Diuretic
   ii) Drugs used in the treatment of Myocardial Ischemia (MI)
   iii) Antihypertensive agents and the drug therapy of hypertension
   iv) Pharmacological treatment of heart failure
   v) Anti-arhythmic drugs
   vi) Drugs used in the treatments of hyperlipoproteinemias
   vii) Heamatopoietic Agent: Growth factors, minerals and vitamins
   viii) Anti coagulant, thrombolytic and anti-platelets drugs.

PHARMACOLOGY – II
(BIOPHARMACEUTICS AND PHARMACOKINETICS)

Theory
Subject code - 0132 Hours – (----/week)

1. ABSORPTION OF DRUGS:
Definition, Structure of cell membrane and composition, Gastrointestinal absorption –
Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical
and Pharmaceutical dosage form factors; Methods of determining absorption: Invitro and
Invivo methods; Absorption of drugs from non-oral route.

2. DISTRIBUTION OF DRUGS:
Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to
CNS, placental transfer of drugs and blood flow; Volume of distribution, Plasma protein
binding: Drug distribution and drug effects, Drug binding in tissues.

3. BIOTRANSFORMATION OF DRUGS:
Definition, Phase I and Phase II reactions and Factors affecting biotransformation.

4. EXCRETION OF DRUGS:
Definition, Renal and non- renal excretion.

5. PHARMACOKINETICS:
a) Definitions, Basic considerations - zero order and first order kinetics.
b) A detailed study of open one compartment model and open two compartment model.
c) Non-compartmental methods-Area under first movement curve (AUMC),
drug clearance, apparent volume of distribution, mean residence time (MRT) and its
significance.
d) Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal
clearance.
e) Non- linear Pharmacokinetics: Cause of non-linearity, Michaelis-menten equation,
Estimation of Km and Vmax.

6. PHARMACODYNAMICS:
a. General aspects of receptor pharmacology.
b. Structural and functional aspects of receptors.
c. Regulation of receptors.
d. Classification of receptors.

7. BIOAVAILABILITY:
Definition, Estimating absorption rate of drugs; Preabsorptive hydrolysis and metabolism; Presystemic metabolism: Hepatic metabolism and Gut wall metabolism; Bioavailability of some specific drugs namely Acetazolamide, Ampicillin, Carbamazepine, Diazepam, Furosemide, Nitrofurantoin, Tolbutamide; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Methods of Enhancing Bioavailability of Drugs: Solubilisation, Prodrugs, Enhancement of dissolution characteristics, Inclusion of bioavailability enhancers.

8. DOSAGE REGIMEN:
Multiple dosing with respect to IV and oral route, concept of loading dose, maintenance dose and accumulation index.

9. BIOEQUIVALENCE STUDIES:
Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.

10. PHARMACOKINETIC VARIABILITY:
Body weight, Age, Sex, Genetic factors, Pharmacokinetic variability’s in disease, states of Renal, Liver, Cardiovascular, Thyroid and Dosage adjustment in the above conditions.

Recommended books:
1. Biopharmaceutics and Clinical pharmacokinetics-M. Gibaldi
2. Biopharmaceutics and Clinical pharmacokinetics-Notari
3. Biopharmaceutics and relevant pharmacokinetics-T. G. Wagner
4. Biopharmaceutics and Drug interactions-Cadwallader
5. Pharmacokinetics-M. Gibaldi andD. Perrier

Branch:- Pharmacognosy (Branch Code:- 04)

BIOGENESIS AND CHEMISTRY OF NATURAL PRODUCTS

Theory
Subject code - 0141

- Biomolecules of natural origin used as medicine. Natural substances as raw material in drug synthesis.
- Study of basic metabolic pathway. Techniques employed in the elucidation of basic metabolic pathway.
- Study of heterocyclic present in active principle of Biomolecules including their chemistry.
- Study of various factors influencing production or biogenesis of biomedicinals.
Biogenesis and structure elucidation of compounds belonging to following categories – (at least one from each category)
- Alkaloids: tropane, quinoline, imidazole, isoquonoline, indole, etc.
- Glycosides: anthraquinone, saponin, sterol etc.
- Isoprenoides compounds.
- Lignan and flavonoids, coumarin.
- Plant growth regulators
- Antibiotics: Penicillin, semi synthetic penicillin, tetracycline, macrolids, aminoglycosides, betalectin.
- Protein (insulin vasopressin, and oxytocin etc.) and vitamin (A, B-12, C etc.).
- Carbohydrates.
- Tannins and resins.
- Steroids: Cholesterol and plant sterols.
- Fats, oils.
- Terpenoids.

**Experiments**

- Estimation of elements and functional groups present in natural drugs, extracts, formulations.
- Qualitative and quantitative analysis of natural products as prescribed in syllabus.
- Comparative study and analysis of extracts obtained through conventional and modern methods.

**Recommended Books:**

- Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
- Pharmacognosy by Varro E.Tyler, Lynn. R.Brady, James E.Robbers.
- Homoeopathic pharmacy – Steven B.Kayne.
- Dictionary of Indian Folk medicine and Ethnobotony – Dr.S.K.Jain.
- Ayurvedic Pharmacopoeia of India: Govt. of India.
- Spectroscopic Identification of Organic compounds, Silverstein R. M. Bassler G.
- Chromatography of Alkaloids by Vapoorte, Swendson.
- Elements of chromatography by P.K.Lala.
- Introduction to chromatography theory & Practicals by V.K. Srivastava, K.Kishore.
- Principles of Biotechnology by Leininger.
- Jenkins Quantitative Pharmaceutical Chemistry by A.N.Knevall.
- Handbook of vitamins by L.J.Machlein.
- Clerk’s Isolation & Identification of drugs by A.C.Mottal.
- Phytochemical methods of chemical analysis by Harbone.
- Organic chemistry vol.II by I.L.Finar.
- The Essential oil by Gunther.E.
- The use of Pharmacological techniques for the evaluation of natural products by B.N.DhavanR.C.Srimal. CDRI, Lucknow.
- Pharmacopoeia of India, Ministry of health, Govt of India 1996
- Practical Pharmacognosy, Kokate C. K. Vallabh Prakashan, New Delhi
ADVANCED PHARMACOGNOSY

Theory
Subject code - 0142                  Hours – (--/week)

- Classification of herbal drugs with special reference to chemotaxonomy.
- Biomedicinals of recent discovery. Current status of plants in alternative system of medicine
- Basic principal of treatment in different system of medicine (Ayurvedic, Unani, Siddha, Chinese, Kempo).
- Recent advances in Pharmacognosy. Modern method of extraction, isolation, drying & purification of phytoconstituents with their merits and demerits
- Review on plant bitters, sweeteners, dyes, pigments & preservatives, endangered medicinal plants including classification.
- Extraction, Isolation, purification & analytical interpretation of phytoconstituents-alkaloids, terpenes, glycosides, tannin, resin, flavonoids, volatile oils, carbohydrates, coumarine & other phenolics compounds, fats & fixed oils etc.
- A review of marine drugs including collection, storage & therapeutic activities
- General method of screening of natural products for the following biological activities -
- A review on herbs as insecticides, pesticides, cosmetics, functional food and neutraceutical.
- Use of microtome in the preparation of histological slides.

Recommended Books:
- Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
- Pharmacognosy by Varro E.Tyler, Lynn. R.Brady, James E.Robbers.
- Introduction to flavonoids: Bruce A. Bohm, harwood academic publishers, 1998.
- Wealth of India, CSIR, New Delhi (Related Volumes)
- Various journals related to medicinal plants.
- Pharmacognosy: Kokate, Purohit, Gokhale, 15th edition, Nirali Prakashan, Pune
- British Herbal Pharmacopoeia, (vol. I, II, & III) Her Majesty’s Services, U. K.
- Phytochemical methods: J. B. Harborne
- Various Research Journals on Medicinal natural products.
Branch:- Quality Assurance (Branch Code:- 05)

Quality Assurance -I

Theory
Subject code -0151T		Hours – (--/week)

1. Microbiological assay of antibiotics and vitamins. Immunological assays: - ELISA, immunoblotting, immunoflurescence, immunoaffility including Radio immuno assay.
2. In process quality control testing of pharmaceuticals like tablets, capsules and liquid dosage forms, parenteral preparations, transdermal products, suppositories and controlled release products.
3. Containers, closures and packaging materials for pharmaceuticals: Types, performance, quality control tests; assuring quality of glass; types of plastics used, permeation, leaching, sorption, chemical reaction, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment.
4. A critical review of pharmacopoeias and advanced methods used for qualitative and quantitative estimation of drugs and their formulations.
5. An approach to the development of analytical methods including recovery studies for drugs in bulk and in formulations,
6. Theoretical aspect of analysis of drugs in biological fluids like urine, blood etc.
7. Clinical trials including preclinical studies.
8. Stability studies of various formulations as per ICH guidelines.
9. Sterility testing including Pyrogen testing.
10. Extraction of important biochemicals like alkaloids, glycosides, tannins, resins etc. from plant sources.
11. Quality control testing of Herbals and screening of plant extracts as per WHO guidelines.
12. Quality control testing of Cosmetics as per BIS.

PRACTICAL
Practical based on theory.

BOOKS RECOMMENDED:
1. IP, BP & USP
2. Enzymes – Biochemistry, Biotechnology, Clinical Chemistry

Total Quality Management-I

THEORY
2. Good manufacturing practices.
3. Organization and personnel, responsibilities, training, hygiene.
4. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination.
7. Warehousing design, construction, maintenance and sanitation, good warehousing practice, materials management.
8. Standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.
10. Quality control laboratory: Responsibilities, good laboratory practices, routine control instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house.

Branch:- Clinical Pharmacy (Branch Code:- 06)

BASIC PRINCIPLES OF DRUG THERAPY AND CLINICAL PHARMACOLOGY

Theory

Subject code - 0161

Hours – (--/week)

7. Drugs acting on the autonomic nervous system
   i) Neurotransmission Autonomic and somatic motor nervous system.
   ii) Muscarinic receptor agonists and antagonists.
   iii) Anticholinestrase agents
   iv) Agents acting at the neuromuscular junction and automatic ganglia
   v) Catecholamines, sympathomimetic drugs and adrenergic receptor antagonists, ocular pharmacology.
   vi) 5-Hydroxy tryptamine (Serotonon )
8. Drugs acting on the Central Nervous System
   i) Neurotransmission and the Central Nervous System (CNS)
   ii) History and principles of anaesthesiology
   iii) General anaesthetics
   iv) Local anaesthetics.
   v) Hypnotics, sedatives and ethanol
   vi) Drugs nd the treatment of psychiatric disorder. Psychosis, anxiety, depression and mania
   vii) Drugs effective in the therapy of epilepsy
   viii) Drugs effective in the therapy of migraine
ix) Treatment of central nervous system degenerative disorders
x) Opioid analgesics and antagonists
xi) Drugs addiction and drugs abuse

9. Autocoids: Drug Therapy of Inflammation
   i) Introduction
   vi) Histamine, bradykinin and their antagonists
   vii) Lipid-derived autocoids: Eicosanoids and platelets activating factor
   viii) Analgesic, antipyretic and anti-inflammatory agents and drugs employed in the treatment of gout
   ix) Drugs used in the treatment of asthma.

10. Drugs effecting renal, blood and cardiovascular function
   i) Diuretic
   ii) Drugs used in the treatment of Myocardial Ischemia (MI)
   iii) Antihypertensive agents and the drug therapy of hypertension
   iv) Pharmacological treatment of heart failure
   v) Anti-arrhythmic drugs
   vi) Drugs used in the treatments of hyperlipoproteinemias
   vii) Haematopoietic Agent: Growth factors, minerals and vitamins
   viii) Anti coagulant, thrombolytic and anti-platelets drugs.

(BIOPHARMACEUTICS AND PHARMACOKINETICS)

Theory
Subject code - 0162

1. ABSORPTION OF DRUGS:
Definition, Structure of cell membrane and composition, Gastrointestinal absorption – Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical and Pharmaceutical dosage form factors; Methods of determining absorption: Invitro and Invivo methods; Absorption of drugs from non-oral route.

2. DISTRIBUTION OF DRUGS:
Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to CNS, placental transfer of drugs and blood flow; Volume of distribution, Plasma protein binding: Drug distribution and drug effects, Drug binding in tissues.

3. BIOTRANSFORMATION OF DRUGS:
Definition, Phase I and Phase II reactions and Factors affecting biotransformation.

4. EXCRETION OF DRUGS:
Definition, Renal and non-renal excretion.

5. PHARMACOKINETICS:
a) Definitions, Basic considerations - zero order and first order kinetics.
b) A detailed study of open one compartment model and open two compartment model.
c) Non-compartmental methods-Area under first movement curve (AUMC),
drug clearance, apparent volume of distribution, mean residence time (MRT) and its significance.

d) Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal clearance.
e) Non-linear Pharmacokinetics: Cause of non-linearity, Michaelis-menten equation, Estimation of Km and Vmax.

6. PHARMACODYNAMICS :
a. General aspects of receptor pharmacology.
b. Structural and functional aspects of receptors.
c. Regulation of receptors.
d. Classification of receptors.

7. BIOAVAILABILITY:
Definition, Estimating absorption rate of drugs; Preabsorptive hydrolysis and metabolism; Presystemic metabolism: Hepatic metabolism and Gut wall metabolism; Bioavailability of some specific drugs namely Acetazolamide, Ampicillin, Carbamazepine, Diazepam, Furosemide, Nitrofurantoin, Tolbutamide; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Methods of Enhancing Bioavailability of Drugs : Solubilisation, Prodrugs, Enhancement of dissolution characteristics, Inclusion of bioavailability enhancers.

8. DOSAGE REGIMEN :
Multiple dosing with respect to IV and oral route, concept of loading dose, maintenance dose and accumulation index.

9. BIOEQUIVALENCE STUDIES:
Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.

10. PHARMACOKINETIC VARIABILITY:
Body weight, Age, Sex, Genetic factors, Pharmacokinetic variability’s in disease, states of Renal, Liver, Cardiovascular, Thyroid and Dosage adjustment in the above conditions.

Recommended books:
1. Biopharmaceutics and Clinical pharmacokinetics-M. Gibaldi
2. Biopharmaceutics and Clinical pharmacokinetics-Notari
3. Biopharmaceutics and relevant pharmacokinetics-T. G. Wagner
4. Biopharmaceutics and Drug interactions-Cadwallader
5. Pharmacokinetics-M. Gibaldi and D. Perrier

Branch:- Industrial Pharmacy (Branch Code:- 07)

COSMETICOLOGY
1) **Physiological consideration**: Skin, hair, nail and eye – in relation to cosmetic application.

2) **Rheology of cosmetic**: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

3) **Manufacturing techniques**: cosmetics cream, powders, compacts, sticks, liquids, foam and aerosol cosmetics.


5) **Clinical safety testing**: Clinical safety testing and protocols for Irritation, sensitization, photo-irritation, photo-allergy, and ocular irritation.

6) **Regulatory requirements**: Manufacturing and sale of cosmetics

7) **Herbal cosmetics**: Formulation development and their stability studies.

8) **Packaging**: Package development and design for cosmetics

9) **Advances in cosmetics**: Liposome, multiple and micro-emulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.

**Recommended Books:**

1) J. Knowlton and S. Rearece: Handbook of cosmetic sciences and technology; Elsevier science publisher.

2) J. B. Wilkinsin and R. J. Moore; Harry’s Cosmetology Longman Science and Technical

3) S. N. Katju’s: Law of Drugs; Law Publishers (I) Pvt. Ltd.

4) E. G. Thomssen; Modern cosmetics; Universal Publishing Cop.

5) M.S. Balsam and E. Sagarin; Cosmetics, sciences and technology; John Wiley and sons.

6) R. L. Elder; cosmetic ingredients; their safety assessment; Pathotox

7) H.R. Moskowitz; Cosmetic Product Testing; Marcel Dekker

8) W. C. Waggoner; Clinical safety and efficacy testing of cosmetic; Marcel Dekker.

9) C. G. Gebelein, T.C. Cheng and V. C. Yang; Cosmetic and pharmaceutical applications of polymers; Plenum

10) L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle press.

11) W. A. Poucher; Poucher’s Perfumes, cosmetics and soaps; vol. 3 chapman and Hall

12) Dr. Laba; ‘Rheological properties of cosmetics and toiletries; Marcel Dekker

**ADVANCES IN DRUG DELIVERY SYSTEM**

**Theory**
1) **Preformulation Studies**: on various dosage forms such as tablets, capsules, suspension, creams, emulsion, injectables, ophthalmics, and aerosols etc.

2) **Advances in Solid dosages forms**: Physics of tables compression, direct compression, recent advances in tablet coating, micro-encapsulation and uses of newer encapsulating agents and techniques. Particle size enlargement – various methods and application.

3) **Advances in liquid dosages forms**: Theoretical and particle aspects in the manufacture of liquid dosage forms such as suspension, emulsion. Solublization, formulation of parenteral suspension and emulsion. Techniques and principles involved in the formulation of multiphase and micro-emulsion. Mechanism of droplet stabilization. Stability of multiphase and micro-emulsion. Destabilization kinetics.

4) **Parenteral dosage forms**: Processing of small and large volume parenteral raw materials, principle and technique. Stability evaluation environment, personnel and management factors in control and quality assurance.


6) **Production management**: Organization structure, objectives and polices, good manufacturing practices, layout of buildings, service, equipments and maintenance – detail discussion. Material management handling and transportation, production planning and control, industrial relations. Safety laws related to production and licensing factories act.

7) **Packaging Technology**: Role of packaging in protecting product. Packaging materials such as glass, plastics, metals, and paper based material, ancillary materials -use in packaging materials, economics of packaging methods and packages. Safety consideration and law relating to packaging.

8) **Polymer Sciences**: Pharmaceutical applications of polymer, properties of polymers. Thermodynamics of polymer solution, phase separation, coacervation and micro-encapsulation. Polymer in solid state.

**Books Recommended:**
3. Essential of Physical Chemistry and pharmacy Arnikar, Kadam, Gujar, Orient Longman.
4. Quality Control in The pharmaceutical Industry: Volumes 1,2 and 3, Murrary
7. Pharmaceutical Preformulation by J. I. Wells, John wiley & sons, N.Y.
11. Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.

M.PHARM. SEMESTER-II

Intellectual Property Rights & Drug Regulatory Affairs (Compulsory)

Theory
Subject code - 0021
Hours – (--/week)

1. Introduction to Intellectual Property Rights; Copy Right Act, Trade Mark Act, Patent Act and Industrial design Act, WTO, TRIPS and TRIMS. Introduction to Drug regulatory and accrediting agencies of the world (USFDA, MHRA, TGA, ICH, WHO, ISO etc.).
2. Regulatory Considerations for Pre-clinical and Clinical Evaluation: Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratogenicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism.
3. Globalization of drug industry, present status and scope of pharmaceutical industry in India & U.S.
5. New Chemical Entity (NCE). Approval of New Drug: Investigational new drug (IND) submission, format and content of IND, content of investigator brochure, clinical research protocols, objective and protocol design. FDA guidelines for clinical trials, reviews and approval of a clinical study. General consideration, content, format and approval of NDA & Abbreviated New Drug Application (ANDA).
6. Procedure of exporting and importing Pharmaceutical drugs & products. Study of tax aspects, marketing aspects, labor aspects and economic integration. BOP analysis, foreign exchange control and governmental policies.
Practical

1. Written Analysis of Case studies related to Drug regulatory affairs.
3. Searching of Innovator’s patent for pharmaceutical products.

Books Recommended:
2. Drugs and Cosmetics Acts and Rules.
3. Bharathi, Drugs and Pharmacy Laws in India.
6. OPPI, Quality Assurance

ADVANCE ANALYTICAL TECH.- II (COMPULSORY)

Theory
Subject code - 0022

1. FLAME EMISSION SPECTROSCOPY AND ATOMIC ABSORPTION SPECTROSCOPY: Principle, instrumentation, interferences and applications in Pharmacy.
2. SPECTROFLUORIMETRY AND PHOSPHOMETRY: Theory, instrumentation, advantages, relationship of chemical structure to fluorescence spectra, solvent effect, effect of acids and bases on fluorescence spectra, concentration effects, factors affecting fluorescence intensity, comparison of fluorescence and UV-Visible absorption methods and applications. Principle, instrumentation and application of Chemiluminescence.
3. ELECTRON SPIN RESONANCE SPECTROSCOPY: Theory and Principle, Limitations of ESR, choice of solvent, g-values, hyperfine splitting, instrumentation, difference between ESR & NMR and applications.
4. CHROMATOGRAPHIC TECHNIQUES:
   a) Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange chromatography, size exclusion /gel permeation chromatography, column chromatography and affinity chromatography –techniques and applications.
   b) Gas Chromatography (GC): Theory and principle, column operation, instrumentation, derivatisation methods and applications in Pharmacy.
   c) High Performance Liquid Chromatography (HPLC): Principle, instrumentation, solvents used, elution techniques, NP-HPLC, RP-HPLC, LC-MS and applications in Pharmacy.
   d) HPTLC and Super Critical Fluid Chromatography (SFC): Theory and Principle, instrumentation, elution techniques and pharmaceutical applications.
5. **ELECTROPHORESIS**: Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

6. **Radio chemical assays**: Sodium iodide, Cynocobalamine and quality control of Radio Pharmaceuticals.

7. **AC pulse polarography and square wave chromatography**.

8. **Enzyme analysis**: Pepsin, papain, hyaluronidase.

9. **Analysis of drug obtained from genetic engineering**: Vaccines, sera and toxoids.

10. **Basic principles, classifications, instrumentation and application of LASER**.


**PRACTICALS**

1. Experiments on Electrophoresis:…..
   a) Separation of Indicators.  b) Separation of Amino acids.

2. Experiments of Chromatography.
   (a) Thin Layer Chromatography.
   (b) Paper Chromatography.
      1) Ascending Technique.
      2) Descending Technique.
      3) Circular Technique.

3. Two dimensional Paper Chromatography and TLC.

4. Experiments based on HPLC & GC.

5. Use of fluorimeter for analysis of Pharmacopoeical compounds.

6. Calibration and Validation of official compounds by Fluorimetry:
   a) Quinine b) Codeine c) Thiamine d) Riboflavin

7. Study of Quenching effect in fluorimetry: quenching of Quinine by potassium iodide.

8. Determination of Sodium in Sodium chloride injection by flame photometry.

9. Any other relevant exercises based on theory.

**REFERENCES**


**PROFESSIONAL PRACTICE**

**THEORY (Compulsory)**

Subject code -0023                      Hours – (--)/week
Professional Practice:
A student shall undergo professional training to assist in practical classes and in theory lectures to diploma and degree classes assign to him/her under the supervision of subject incharge. He/She has to submit a report on the work assign to him/her. His/Her evaluation will be on the basis of performance and report submitted by him/her.

Branch: - Pharmaceutics (Branch Code: - 01)

NOVEL DRUG DELIVERY SYSTEMS

THEORY
Subject code-0211 Hours – (--/week)

1) Basic considerations of novel drug delivery systems: Biopharmaceutiological aspects and technology transfer of controlled release dosage forms.
2) Oral drug delivery systems: Based on different control mechanism such as Osmotic pressure, membrane controlled pH, ion-exchange, gastrointestinal transit etc.
3) Mucosal drug delivery: Physiological, biopharmaceutical consideration, formation and models used.
   A) Buccal: Physiology and permeability of oral mucosa, penetration enhancement, drug delivery systems and in-vitro and in-vivo techniques.
   C) Pulmonary: Structure and function of pulmonary system, factors affecting deposition in lungs. Dosage forms: Nebulizers, pressurized inhalation aerosols, aerosol powder devices.
   D) Rectal: Physiology, advantages, dosage forms and evaluation models.
4) Intrauterine and intravaginal drug delivery devices.
5) Ocular delivery: Ocular delivery mechanism and development of ocular controlled release.
6) Transdermal drug delivery: Permeation through skin, permeation enhancers, technologies nanoparticles.
7) Micro-encapsulation: various techniques, parameters affecting microcapsules, microcapsule stability, mechanisms, manufacturing equipments.

Recommended Books:
1) P. Tyle; Drug Delivery Devices, fundamental and applications; Marcel Dekker.
2) Morton Rosoff; Controlled release of drugs; VCH Publishers.
3) Osborne, and Amann; Topical drug delivery formulations; Marcel Dekker.
4) P. Tyle; Drug delivery devices: Marcel Dekker.
5) Barry: Dermatological formulation; Marcel Dekker
6) Robinson; Novel Drug Delivery systems; Marcel Dekker
7) N.K. Jain; controlled and novel drug delivery; CBS Publication, New Delhi
8) P. Johnson and J. G. Lloyd – Jones; Drug delivery systems; VCH Publisher
9) P. Tyle and B. P. Ram; Targeted therapeutics systems; Marcel Dekker.
10) C.G. Wilson & N. Washington; Physiological Pharmaceutics; Ellis Horwood Limited.
12) R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivery; Marcel Dekker
13) T.J. Roseman and S.Z. Mansdorf; Controlled release delivery systems; Marcel Dekker
14) A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology; Marcel Dekker.
15) J. Kreuter; Controlled drug delivery system; Marcel Dekker
16) P.B. Deasy; Microencapsulation and related drug processes; Marcel Dekker.

PRODUCT DEVELOPMENT AND PACKAGING TECHNOLOGY

THEORY
Subject code-0212 Hours – (~/week)

PACKAGING TECHNOLOGY
1. Packaging - Introduction, components of packaging, brand consciousness and packaging, bioactive packaging for neutraceuticals.

2. Adhesives in packaging, types, evaluation in terms of viscosity adhesion strength, rheology hygroscopicity, stability, compatibility etc.

3 Containers and closures

4. Labeling, Package inserts,(Specific requirements, indications and usage, pregnancy category specifications, drug abuse dependence, over dosage ),dosage administrations.

5. G M P Guidelines for the Pharmaceutical Packaging Materials

6. Validation of Packaging Process and Future Trends in Packaging, Intelligent packaging (Oxygen scavenging, time temperature history, microbial growth indicators, physical shock indicator), learning packaging from Mother Nature

NEW DRUG APPROVAL PROCESS

7. Introduction, non clinical requirements of IND and NDA, waivers, principals of IND submission, format and contents of IND, Investigator’s Brochure and CFR’s descriptions.

8 N D A Definitions, general requirements, N D A regulations in U S, N D A –Day.


10. Brief introduction to Abbreviated and Supplemental New Drug Applications

Branch:- Pharmaceutical Chemistry (Branch Code:- 02)

2. **Metabolism** - Definition, general introduction, different phases, metabolic pathways, importance in drug design.


6. **Design and Application of Prodrugs** - Prodrug concept, Prodrugs of various functional groups like carbonyl, hydroxyl, amides, amines; Application of Prodrug approaches to- Improvement of bioavailability, Prevent first pass metabolism, Reduction of side effects, Prolong duration of action, Site specific delivery.

7. **Approaches to the rational design of enzyme inhibitors** - Enzyme inhibitors in medicines, Enzyme inhibitors in basic research, rational design of non-covalently & covalently binding enzyme inhibitors.

8. **Peptidomimetics in drug design** - Use of peptidomimetics in peptide design.

**Reference Books**
1. Introduction to the Principles of Drug Design by Smith & Williams.

CHEMISTRY OF NATURAL PRODUCTS

THEORY
Subject code-0221 Hours – (--)/week

1. Isolation, Identification and application of GLC, HPLC and counter current distribution to separation of plant constituents. Application of IR, NMR, MS, ORD and CD to study structures of natural products.
2. Carbohydrates- Introduction, Classification, Disaccharides; determination of structure, sucrose, maltose, lactose, Polysaccharides; cellulose, starch, introduction to lignin, pectin, pectic substances
3. Fats, oils, waxes, lipoproteins- Introduction, General classification and chemistry
5. Steroids- General introduction, Stereochemistry, nomenclature and structural elucidation of sterols (cholesterol), sapogenin (diosgenin).
6. Cardiac glycosides- Cardiac, saponins, anthraquinones, etc.
8. Flavonoids - Detailed chemical account of rutin and quercetin.
9. Triterpenoids – A general chemical treatment and structural elucidation of terpenoids.
11. Selected Synthesis: Stereochemical aspects of vitamin A, ascorbic acid, cholesterol, cortisone, progesterone-dihydroabietic acid, coenzyme A, β-carotene, estrone, prostaglandins F_2α and E_2.

Practicals: Related with Isolation and Characterization of Medicinally active Natural products

Books Recommended:
3. Progress in Medicinal Chemistry, Series by Ellis & Wert.
13. Chemistry of Alkaloids by S.W.Pelletier
16. Alkaloidsoids by Fieser and Fieser.
17. Organic Chemistry by I.L.Finar Vol.II.
18. History of Natural Products by K.W.Bentley.
23. E.L.Eliel - Conformational analysis.

Branch:- Pharmacology (Branch Code:- 03)

PHARMACOLOGY – III

(RECENT ADVANCES AND EMERGING TRENDS IN PHARMACOLOGY SCIENCE)

THEORY
Subject code-0231 Hours – (--/week)

1. Digestive system
i) Pharmacotherapy of peptic ulcer, diarrhea, constipation
ii) Agents affecting gastrointestinal water flux and motility: emesis and antiemetic, bile acids and pancreatic enzymes

2. Therapy of Infectious Diseases
   i) General principal, antibacterial drugs sulphonamides, quinolones, penicillins, cephalosporins, tetracyclines, chloramphenicol
   ii) Drugs used in the chemotherapy of protozoal infection: Malaria
   iii) Drugs used in the chemotherapy of protozoal infections: Trypanosomiasis, leishmaniasis, amebiasis, giardiasis, trichomoniasis, and other protozoal infection
   iv) Drugs used in the chemotherapy of helminthiasis
   v) Drugs used in the chemotherapy of leprosy, tuberculosis, fungal infections, viral infection
   vi) Drugs used in the chemotherapy of neoplastic diseases
   vii) Immunomodulators: Immunosuppressive agent and immunostimulants

3. Newer chemotherapeutic agents
   i) Hormones and Antagonists:
   ii) Adenohypophyseal hormones and their hypothalamic releasing factors.
   iii) Hormones of posterior pituitary
   iv) Thyroid and antithyroid drugs
   v) Estrogens and progestins, antifertility agents
   vi) Androgens
   vii) Adrenocorticotropic hormones; adrenocortical steroids and their synthetic analogs: inhibitors of the synthesis and actions of adrenocortical hormones.
   viii) Insulin, oral hypoglycemic agent and the pharmacology of pancreatic hormones.
   ix) Agent affecting calcification and bone turnover.
   x) Calcium phosphate, parathyroid hormones, vitamin D, calcitonin and other compounds.
   xi) Vasopressin and other agents affecting the renal conservation of water.
   x) Emerging Trends & Recent advances in:
      i) Receptor and G-protein
      ii) Cyclic nucleotides
      iii) TNF, apoptosis
      iv) Ion channel modulators
      v) Neurosteroids and cannabinoids
      vi) Nitric Oxide
      vii) ANF, anti oxidants: Melatonin
      viii) Chiral pharmacology
      ix) Gene therapy
      x) Neuropeptide, Substance P, angiogenesis II modulators.

Journals recommended
1. Annual Review Pharmacology and Toxicology
2. Drugs
3. Pharmacological Reviews
4. Trends in Pharmacological Sciences
5. Indian Journal of Physiology & Pharmacology
6. Indian Journal of Experimental Biology
PHARMACOLOGY IV

PHARMACOLOGICAL METHODS AND TOXICOLOGY

THEORY
Subject code-0232                                    Hours – (---/week)

1. Principles of pharmacological and clinical evaluation of drugs.
2. Pharmacological techniques to evaluate drugs belonging to following categories:
   a) Antipsychotics, antianxiety agents; nootropics; antidepressants, antiparkinsonian
      agents, antiepileptics, analgesic, anti-inflammatory agents, local anaesthetics.
   b) Antihypertensives, antirhythmic, antithrombotics, drugs for myocardial
      infarction.
   c) Antulcer drugs, antidiabetics, antitussives
   d) Evaluation of antioxidants
   e) Transgenic animals, genetically prone animal models
   f) Anticancer drugs
   g) In-vitro techniques
   h) Antifertility agents
3. Drugs toxicity, safety evaluation of new drugs
4. Regulation for laboratory anima care and ethical requirements.

Semester II
PRACTICALS

i) Study of agonist and antagonist
ii) pD2 Value
iii) pA2 Value
iv) 5HT bioassay (Graphical, four point)
v) Oxytocin bioassay (Graphical)
vi) Antagonist bioassay
vii) Ach bioassay (Rat funds)
viii) Histamine assay guinea pig ileum (Graphical and four point assay)
ix) Blind screening of drugs
x) Estimation of drugs in body fluids using modern analytical techniques.

Semester II
PRACTICALS
1. Screening methods in pharmacology
2. Screening of antipsychotics, antianxiety, nootropics, antidepressants, antiparkinsonian,
   antiepileptics, analgesic, anti-inflammatory, antihypertensive, anti MI, anti ulcer, antidiabetic
   and antioxidants.
Phytochemical studies of following classes of drugs including basic chemistry, chemical or phytochemical properties (excluding synthesis) of herbal medicine. Studies includes Carbohydrates, Glycosides, Alkaloids, Flavonoids, Tannins, Terpines, Coumarin and other Phenolic compounds, Essential or Volatile oil, Resin.

Review on chemistry, bioactivity and mechanism of action of insecticides and pesticides of natural and synthetic origin.

An over view on hallucinogenic, teratogenic, poisonous plants and mushroom.

Influence of mutation, polyplody, hybridization on phytoconstituents.

Historical perspectives and applications of plant biotechnology in pharmacy and allied fields.

Types, techniques, nutritional requirements and growth of plant tissue cultures. Organogenesis and embryogenesis. Protoplast fusion and cultures. Biotechnology of micro propagation of medicinal plants.

Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Procedures and elicitors on production of Biomolecules Immobilization techniques and its application on secondary metabolites production.

Biotransformation, bioreactors, for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture.

Hairy roots and multiple shoots culture and their application.

Experiments

Preliminary phytochemical screening and detection of various plant constituents such as Carbohydrates, Alkaloids, Anthraquinones, Flavonoids, Polyphenolic compounds, Lipids, Proteins and Amino acids.

Preparation of extracts enriched with active principles and studying their Stability.

Phytochemical analysis of isolated plant constituents by UV, HPLC and HPTLC.

UV analysis of some crude drugs and phytochemicals for identification and detection.

Fumigation of aseptic area and air sampling.

Methods of preservation of culture.

Qualitative analysis of potable water.

Estimation of microbial load in pharmaceutical excipients and raw materials as per official pharmacopoeia.

Preparation and maintenance of primary cell culture and cell lines.

Animal immunization – innoculation, bleeding and antigen- antibody reactions by haemaggulutination – inhibition, neutralization and precipitin reactions.
Standardization of inoculum and estimation of MIC by serial dilution and gradient plate technique.
Qualitative and quantitative analysis of anti-microbial agents by ditch – plate method and extinction methods (RWC test).
Microbial sensitivity of some human pathogenic isolates against various Antibiotics.

Recommended Books:
- Medicinal Natural Products IInd Edition (A biosynthetic approach) – Paul M. Dewier.
- Pharmacognosy, Phytochemistry, Medicinal Plants IInd Edition – Jean Bruneton.
- Herbal Medicine – Manuchair Ebadi.
- Plant tissue Culture – Bhagwani Vol 5. (Elsevier)
- Pharmacognosy, Phytochemistry Medicinal Plants IInd Edn. Jean Bruneton.
- Plant Tissue Culture an alternative for production of useful metabolites. Masanaru Misawa.
- Chemistry of Alkaloids by S.W.Pelletier
- A Hand Book of Common remedies in Siddha system of medicine- CCRIMH
- Alkaloids by Manske. 3. Plant Physiology by Dieter Hess.
- Steroids by Fieser and Fieser.
- Organic Chemistry by I.L.Finar Vol.II.
- Chemistry of Natural Products by K.W.Bentley.
- Encyclopedia of Natural medicine – Michael Murray & Joseph. Pizzorno
- Toxic plants and other Natural toxicants – Tom Garland & Catharine Barr.
- Alternate medicine – Dr. K.B.Nangia
- Pharmacognosy and Pharmacobiotechnology – Ashutoshkar.

INDUSTRIAL PHARMACOGNOSY

THEORY
Subject code-0242 Hours – (~/week)

- Presents status and future aspects of Pharmacognosy in the herbal industries.
- Guideline related to quality control of herbal drugs- GAP, WHO, ICH, CGMP, D & C for herbal and ayurvedic drugs.
- Problems encounters in discovering and processing of new drugs from plants. Pilot plant scale up technique for herbals.
- Standardisation of herbs, herbal formulation and extract by Pharmacognostical, Phytochemical, Pharmacological/ Biological (including toxicological parameter) & analytical approach.
Techniques for processing of medicinal for dosage form and technique transformation of ayurvedic formulation to newer dosage forms.

Information and application of herbs & herbal formulation available in Indian & international market

Isolation, analytical interpretation, caracterisation and uses of phytoconstituents: Caffeine, Atropine, Curcumin, Taxol, Ergometrine, Podophyllum, Diosogenin, Digoxin, Solasodine, Berberine, Quinine, Emetine, Withanoliods, Rutine, Artimisine.

Targeted drug delivery system of phytoconstituent.

Experiments 90 hours (6 hrs. / Week)

- Macroscopical and microscopical evaluation including Quantitative microscopy.
- Physical, Chemical and Biological evaluation in quality control of crude drugs.
- Preliminary phytochemical screening of medicinal plants, extracts and formulations.
- Isolation of different phyto constituents and estimation using spectroscopic and chromatographic techniques.
- Estimation of secondary metabolites like alkaloids, terpenoids and flavonoids by different methods.
- Estimation of plant phytoconstituents using modern methods like UV, HPLC and HPTLC etc.
- Extraction, isolation and charaterisation of plant phytoconstituents
- Formulation and evaluation of herbal cosmetics and other formulations.

Recommended Books:

- Pharmacognosy by G.E. Trease, W.C. Evans, ELBS.
- Pharmacognosy by Varro E.Tyler, Lynn. R.Brady, James E.Robbers.
- Plant Physiology of Frank B.Salisburry, Cleon. W.Ross, CBS Pub. Delhi
- Indian Medicinal Plants by Kirthikar, Basu.
- Indian Meteria Medica by K.M. Nalkarni
- The Essential Oils by Guenther. E.
- Modern Toxicology vol.II by P.K.Gupta, D.k. Salunkhe
- Proceeding of the seminar on scope of Aromatic plants & Processing Industries.
- Pharmacographia Indica by W.Dymock.
- A Hand Book of Common remedies in Siddha system of medicine- CCRIMH.
- Clinical applications of the Ayurvedic remedies.
- Baidyanth Book of Ayurvedic Knowledge.
- Perfumery technology by Wallis, Billot.M.
- Jenkin’s quantitative pharmaceutical Chemistry by A.M.Knevell.
- Phytochemical methods of chemical analysis by Harbone.
- Pharmacopelpia standards for Ayurvedic formulations –CCRAS, Delhi.
- Practical Pharmacognosy by Dr.C.K.Kokate.
- Practical Pharmacognosy by Dr.P.K.Lala.
- Bibliography on pharmacognosy of medicinal plants-Roma Mitra.
- British Herbal Pharmacopoeia.
- The Ayurveda Encyclopedi – Swami Sada Shiva Tirtha.
- Encyclopedia of Natural medicine – Michael Murray & Joseph. Pizzorno
- Toxic plants and other Natural toxicants – Tom Garland & Catharine Barr.
- Alternate medicine – Dr. K.B.Nangia
Pharmacognosy and Pharmacobiotechnology – Ashutoshkar.
The complete Germancommision, E.Monographs-Blumenthal Buse, Gold bery, Gruenwald Hall.
The Ayurvedic system of medicine – K.N.Sengupta.
Homoeopathic pharmacy – Steven B.Kayne.
Dictionary of Indian Folk medicine and Ethnobotony – Dr.S.K.Jain.
Pharmacopoeia of India, Ministry of health, Govt of India 1996
Practical Pharmacognosy, Kokate C. K. Vallabh Prakashan, New Delhi
Indian Herbal Pharmacopoeia, Vol. III IDMA, Mumbai
Ayurvedic Pharmacopoeia of India: Govt. of India.
Spectroscopic Identification of Organic compounds, Silverstein R. M. Bassler G.

Branch:- Quality Assurance(Branch Code:- 05)

Quality Assurance -II

THEORY
Subject code-0251 Hours – (--/week)

1. Validation and calibration of equipments and instruments.
2. Elements of validation, benefits, types of process validation, validation protocol, process characterization and optimization.
5. Validation of analytical procedures as per ICH.
6. Validation of air handling equipments and facilities in sterile and non-sterile areas, cleaning validation.
7. Validation of water purifying systems (de-mineralized water, distilled water and water for injection).
8. Validation and security measures for pharmaceutical data processing.
9. Validation of computer aided instruments.

PRACTICAL
Practicals based on theory.

Total Quality Management-II
THEORY:
Subject code- 0252T                Hours – (--/week)
1. Certification and licensing procedures, Quality, safety and legislation for cosmetic products, Quality, safety and legislation for herbal products.
2. Schedule U requirements.
3. Product development stage documentation.
4. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.
5. Waste disposal, scrap disposal procedures and records.
6. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.
7. Retention samples and records.
8. Quality control documentation.
9. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities.
11. Loan license (contract manufacture) auditing.
12. Recent amendments to Drugs and Cosmetic Act and other relevant rules.

BOOKS RECOMMENDED:

Branch:- Clinical Pharmacy (Branch Code:- 06)

CLINICAL PHARMACOLOGY AND THERAPEUTIC DRUG MONITORING

THEORY
Subject code-0261                Hours – (--/week)

1. Introduction to daily activities of a clinical pharmacist
Drug therapy monitoring (medication chart review, clinical review, pharmacist intervention), Ward round participation, Adverse drug reaction management, Drug information and poison information, Medication history, Patient counseling, Pharmaceutical care, Drug utilization evaluation (DUE) and review (DUR), Quality assurance of clinical pharmacy service.

2. Clinical pharmacokinetics
Clinical pharmacokinetics models, Physiological determination of drug clearance and volume of distribution, Renal and non-Renal clearance, Organ extraction and models of hepatic clearance, Estimation and determination of bioavailability, Multiple dosing Calculation of loading and maintenance dose, Dose adjustment in renal failure, Hepatic dysfunction, Gastric and paediatric patient, Therapeutic drug monitoring (general aspects)
3. **Cardiovascular System**: Hypertension, Congestive cardiac failure, Ischemic heart disease, Myocardial infarction, Arrhythmias, Hyperlipidemias
4. **Central Nervous System**: Ischemia, headache, epilepsy, Parkinsonism
5. **Respiratory System**: Asthma, Chronic obstructive airways diseases, Drug acting on pulmonary diseases
6. **Haematological diseases**: Anaemia’s, deep vein thrombosis, drug induced haematological diseases
7. **Gastrointestinal System**: Peptic ulcer diseases, reflux oesophagitis, inflammatory bowel diseases, hepatitis, jaundice & cirrhosis, diarrhoea & constipation, drug induced liver diseases.
8. **Renal System**: Acute/Chronic renal failure, Renal dialysis and transplantation, Drug induced renal diseases
9. **Endocrine system**: Thyroid disease, Oral contraceptives, Hormone replacement therapy, Osteoporosis
10. **Psychiatric diseases**: Schizophrenia, depression, anxiety, sleep disorders, drug induced psychosis
11. **Infectious diseases**: General guidelines for the rational use of antibiotics, meningitis, respiratory tract infections, gastroenteritis bacterial endocarditis septicaemia, Otitis media, urinary tract infection, tuberculosis, leprosy, malaria, helmenthiasis, HIV and opportunistic infections, Fungal infections, Rheumatic fever.
12. **Neoplasia**: General principle of cancer chemotherapy, commonly use cytotoxic drugs, chemotherapy of lung cancer, cytological malignancy, management of nausea and vomiting
13. **Pain management**
   Pain pathways, analgesics and NSAIDS, neuralgias including herpetic, trigeminal and glossopharyngeal neuralgia, Rheumatoid arthritis, osteoarthritis, gout, systemic lupus erythematous
14. **Immunology**
   Autoimmunity- Definition, classification, mechanism of autoimmune disease, pathogenesis of autoimmunity, immunoglobulins
15. **Prescribing guidelines for**
   Paediatric patients, Geriatric patients, Pregnancy and breast feeding
16. **Patient data analysis**
   Patient case history, its structure and use in evaluation of drug therapy and understanding common medical abbreviation and terminologies use in clinical pharmacy. Communication skill including patient counselling techniques, medication history. Interview presentation of cases, teaching skills. Clinical laboratory tests used in evaluation of disease state, and interpretation of test result like: Haematological, Liver function, Renal function, Thyroid function test. Tests associated to cardiac disorders. Fluid and electrolyte balance. Microbial culture sensitivity test. Pulmonary function test.

**References:**
4. Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice- Green and Harris, Chapman and Hall Publications.
1. A general treatment of the approaches to drug design: including the methods of variation, study of the use of biochemical and physiological information involving new drugs.

2. Guidelines for drug and analog drug design:
   a. Basic considerations of drug design, de-novo drug design, lead seeking methods, rational drug design.
   b. Structural factors in drug design.
   c. Prodrug concepts.

3. Molecular mechanisms of drug action: Receptor occupancy and cellular signaling system such as G-proteins, cyclic nucleotides, calcium and phosphatidylinositol. Ionic channels and their modulators.


5. Recent trends on different classes of receptors and drugs acting on them
   a. Cholinergic receptors
   b. Dopamine receptors
   c. Serotonin receptors
   d. Hormone receptors
   e. GABA receptors
   f. Opioid receptors
g. Purinergic receptors  
h. Glutamate receptors  

6. Endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.  

7. c-receptors on T and B lymphocytes, Antibody dependent and cellular cytotoxicity.  


9. Antisence genes as a research tool.  

Books Recommended:  
1. Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication, California  
7. Grollman Pharmacology & Therapeutics (Lea and Tebiger Philadelphia)  
10. Goodman and Gilman Pharmacological Basis of Therapeutics (MacGraw Hill)  

Branch:- Industrial Pharmacy (Branch Code:- 07)  

NOVEL DRUG DELIVERY SYSTEMS  

THEORY  
Subject code-0271 Hours – (-/-week)  

1) Basic considerations of novel drug delivery systems: Biopharmaceutical aspects and technology transfer of controlled release dosage forms.  
2) Oral drug delivery systems: Based on different control mechanism such as Osmotic pressure, membrane controlled pH, ion-exchange, gastrointestinal transit etc.  
3) Mucosal drug delivery: Physiological, biopharmaceutical consideration, formation and models used.  
   A) Buccal: Physiology and permeability of oral mucosa, penetration enhancement, drug delivery systems and in-vitro and in-vivo techniques.  
   C) Pulmonary: Structure and function of pulmonary system, factors affecting deposition in lungs. Dosage forms: Nebulizers, pressurized inhalation aerosols, aerosol powder devices.
D) Rectal: Physiology, advantages, dosage forms and evaluation models.
4) **Intrauterine and intravaginal drug delivery devices.**
5) **Ocular delivery:** Ocular delivery mechanism and development of ocular controlled release.
6) **Transdermal drug delivery:** Permeation through skin, permeation enhancers, technologies, nanoparticles.
7) **Micro-encapsulation:** various techniques, parameters affecting microcapsules, microcapsule stability, mechanisms, manufacturing equipments.
8) **Advances in drug delivery:** Pulsatile, colon specific, intra-arterial, noncorneal drug delivery and systemic delivery of ophthalmic diseases.

**Recommended Books:**
1) P. Tyle; Drug Delivery Devices, fundamental and applications; Marcel Dekker.
2) Morton Rosoff; Controlled release of drugs; VCH Publishers.
3) Osborne, and Amann; Topical drug delivery formulations; Marcel Dekker.
4) P. Tyle; Drug delivery devices: Marcel Dekker.
5) Barry: Dermatological formulation; Marcel Dekker
6) Robinson; Novel Drug Delivery systems; Marcel Dekker
7) N.K. Jain; controlled and novel drug delivery; CBS Publication, New Delhi
8) P. Johnson and J. G. Lloyd – Jones; Drug delivery systems; VCH Publisher
9) P. Tyle and B. P. Ram; Targeted therapeutics systems; Marcel Dekker.
10) C.G. Wilson & N. Washington; Physiological Pharmaceutics; Ellis Horwood Limited.
12) R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivery; Marcel Dekker
13) T.J. Roseman and S.Z. Mansdorf; Controlled release delivery systems; Marcel Dekker
14) A.J. Hickey; Pharmaceutical Inhalation Aerosol Technology; Marcel Dekker.
15) J. Kreuter; Controlled drug delivery system; Marcel Dekker
16) P.B. Deasy; Microencapsulation and related drug processes; Marcel Dekker.

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**INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT**

**THEORY**

Subject code-0272 Hours – (--/week)

1) **Pilot plant scale:** up, pilot plant design: tablets, capsules liquid orals, parenteral and semisolid preparations. Basis requirement for design of product, facility equipments selection, personnel, Pharmaceutical process validation for various products.
2) **Quality Assurance:** GMP consideration, quality assurance and process control. Total quality management and productivity. ISO 9000 series salient features.
3) **Optimization techniques:** Optimization parameter, classical optimization, statistical design and applied optimization methods.
4) **Production planning:** Plant site selection, layout and organization of pharmaceutical industries. Vedor development capacity (plant, machine human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix.
5) **Drug and Cosmetics Act:** Requirement related to manufacture and sale of drugs.
6) **Machinery Engineering:** Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handling for various pharmaceutical products.
7) **Safety:** Industrial hazards due to fire, accident, mechanical and electrical equipment chemical and pharmaceutical, monitoring and preventive system.
8) **Effluent testing and Treatment**: For pharmaceutical industry.

9) **Automation**: Flexible manufacturing system, computer control system: data acquisition, distributed control and centralized control system. Typical models for solid and liquid manufacturing.

Recommended Books:

1) P. R. Watt; Tablet machine instrument in pharmaceuticals: John Wiely and Sons.
2) B. Rothery; ISO 14000 and ISO 9000; Grower.
3) G. C. Cole; Pharmaceutical production facilities, Design and applications; Taylor and Francis
4) J.R. Berry and R. A. Nash; Pharmaceutical process validation; Marcel Dekker
5) S. Bolton; Pharmaceutical statistics; Marcel Dekker.
6) S.H. Will and J.R. Stoker; good manufacturing practices for pharmaceuticals; Marcel Dekker.
7) R. F. Brewe; Design of Experiments for process improvement and quality assurance; Narosa.
8) A. Jaiswal; Management of quality control and standardization: Kanishka Publisher, New Delhi
9) D.H. Stamatis: Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
10) P. Gilson, G. Green halgh and K. Kerr; Manufacturing management; Chapman and Hall.
11) S.S. Rao; Optimization theory and applications; Wiley Eastern Limited.
12) J. F. Despautz: Automation and validation of information in pharmaceutical processing; Marcel Dekker.
14) S. N. Katju's Law and drugs; Law Publishers (I) Pvt. Ltd.