SYLLABUS

M.Pharma

FACULTY OF PHARMACEUTICAL SCIENCES

JODHPUR NATIONAL UNIVERSITY

JODHPUR

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

Subject Code	Subject	L	P	Semester Exam.		Sessional Exam.		Total
				Theory	Practical	Theory	Practical	
0011	Advance Analytical Tech. - I (Compulsory)	3	6	80	80	20	20	200
0012	Biostat Analysis & Computer (Compulsory)	3	6	80	80	20	20	200
0013	Professional practice (Compulsory)	3	6					50
Branch:- Pharmaceutiecs (Branch Code:- 01)								
0111	Biopharmaceutiecs & Pharmacokinetic	3	6	80	80	20	20	200
0112	Advances in drug delivery system	3	6	80	80	20	20	200
Branch:- Pharmaceutical Chemistry (Branch Code:- 02)								
0121	Advance Organic Chemistry	3	6	80	80	20	20	200
0122	Advance Medicinal Chemistry - I	3	6	80	80	20	20	200
Branch:- Pharmacology (Branch Code:- 03)								
0131	Pharmacology – I (Basic principles of drug therapy and clinical pharmacology)	3	6	80	80	20	20	200
0132	Pharmacology – II (Biopharmaceutics and Pharmacokinetics)	3	6	80	80	20	20	200
Branch:- Pharmacognosy (Branch Code:- 04)								
0141	Biogenesis & Chemistry of Natural Product	3	6	80	80	20	20	200
0142	Advance Pharmacognosy	3	6	80	80	20	20	200
Branch:- Quality Assurance(Branch Code:- 05)								
0151	Quality Assurance - I	3	6	80	80	20	20	200
0152	Total Quality Management - I	3	6	80	80	20	20	200
Branch:- Clinical Pharmacy (Branch Code:- 06)								
0161	Biopharmaceutiecs & Pharmacokinetic	3	6	80	80	20	20	200
0162	Advance Pharmacology & Toxicology	3	6	80	80	20	20	200
Branch:- Industrial Pharmacy (Branch Code:- 07)								
0171	Cosmeticology	3	6	80	80	20	20	200
0172	Advances in drug delivery system	3	6	80	80	20	20	200

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

Subject Code	Subject	L	P	Semester Exam.		Sessional Exam.		Total
				Theory	Practical	Theory	Practical	
0021	Intellectual Property Rights & Drug Regulatory Affairs (Compulsory)	3	-	80	-	20	-	100
0022	Advance Analytical Tech.- II (Compulsory)	3	6	80	80	20	20	200
0023	Professional practice (Compulsory)							50
Branch:- Pharmaceutics (Branch Code:- 01)								
0211	Novel Drug Delivery System	3	6	80	80	20	20	200
0212	Product Development & Packaging Technology	3	6	80	80	20	20	200
Branch:- Pharmaceutical Chemistry (Branch Code:- 02)								
0221	Advance Medicinal Chemistry - II	3	6	80	80	20	20	200
0222	Natural Chemistry (Chem. Of Natural Product)	3	6	80	80	20	20	200
Branch:- Pharmacology (Branch Code:- 03)								
0231	Pharmacology – III (Recent advances and emerging trends in pharmacology science)	3	6	80	80	20	20	200
0232	Pharmacology IV (Pharmacological methods and toxicology)	3	6	80	80	20	20	200
Branch:- Pharmacognosy (Branch Code:- 04)								
0241	Phytochemistry & Biotechnology	3	6	80	80	20	20	200
0242	Industrial Pharmacognosy	3	6	80	80	20	20	200
Branch:- Quality Assurance(Branch Code:- 05)								
0251	Quality Assurance - II	3	6	80	80	20	20	200
0252	Total Quality Management - II	3	6	80	80	20	20	200
Branch:- Clinical Pharmacy (Branch Code:- 06)								
0261	Clinical Pharmacology & Therapeutic Drug monitoring	3	6	80	80	20	20	200
0262	Advances in novel Pharmacological Drug Target	3	6	80	80	20	20	200
Branch:- Industrial Pharmacy (Branch Code:- 07)								
0271	Novel Drug Delivery System	3	6	80	80	20	20	200
0272	Industrial pharmacy and production management	3	6	80	80	20	20	200

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.IVsemester. (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. Ist 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,:

Percentage of marks	Division
75% or above	Honors
60% or above	First Division
50% or above	Second Division

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)

1. **UV-VISIBLE SPECTROSCOPY:** Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects, modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (qualitative and quantitative analysis), Woodward –Fischer rules for calculating absorption maximum, Photometric titrations and its applications.
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^{13} NMR-Introduction, Natural abundance, C^{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).
6. **X-RAY DIFFRACTION METHODS:** Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray crystallography, X-ray powder diffraction, Miller indices, interpretation of diffraction patterns and applications.
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.
8. Application of Instrumental methods in the development of medicines, concept of Analytical methods development.

PRACTICALS

1. Use of Spectro photometer for analysis for Pharmacopoeial compounds and their formulations.
2. Quanitative 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

3. Simultaneous estimation of combination formulations (Ibuprofen and Paracetamol tablet, Paracetamol and Nimesulide tablet, Ciprofloxacin and Tinidazole tablet.).
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

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al, 7th Edition, 1981.
2. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
3. Text book of Biopharmaceutic Analysis- Robert Smith and James Stewart.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.
5. Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition, 2004.
6. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.
7. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
8. Instrumental Methods of Analysis – Hobert H. Willard, 7th Edition.
9. Spectroscopy of Organic Compounds by P. S. Kalsi.
10. Text book of pharmaceutical analysis-K.A. Conners.
11. Pharmaceutical analysis-Hiquchi, Bechmann, Hassan.
12. Methods of Drug analysis- Gearian, Graboski.
13. Quantitative analysis of Drugs- Garrot.
14. Quantitative analysis of Drugs in Pharmaceutical formulations- P.D. Sethi.
15. Instrumental Methods of Chemical Analysis – Y.R. Sharma.
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.
3. Fundamental of Applied Statistics: S.C. Gupta and C.K. Kapoor
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 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, opthalamichs, 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. Destablilization kinetics.
4) **Parentarl dosage forms**: Processing of small and large volume parenterl raw materials, principle and technique. Stability evaluation environment, personnel and management factors in control and quality assurance.
5) **Stability studies and kinetics**: stability and stabilization of Pharmaceuticals, Stability calculation, rate equation, activation energy calculation, interpretation of kinetic data, stability data in product development. Accelerated stability testing. Factors to responsible for destabilization of pharmaceutical product and techniques and means to improve stability. Mathematical treatment of stability test data. Calculation shelf life, Calculation of Q. 10 value and application Q. 10 value in stability testing.
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:

1. Remington's Pharmaceutical application of polymers, properties of polymers. Thermodynamics of polymer solution, phase separation, coacervation and Micro-encapsulation. Polymer in solid state.
2. Theory and practice of Industrial Pharmacy Leon Lachman, Herbert A Lieberman and Joseph L. kaning. Varghese Publishing House, Bombay
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
5. S. Copper Academic Press, New York and academic Press London.
6. Good Manufacturing Practices for pharmaceuticals – A plan for total Quality Control. S. H. Willing, M. M. Tuckerman, S. Hitchings, Marcel Dekker, Inc. New York.
7. Pharmaceutical Preformulation by J. I. Wells, John wiley & sons, N.Y.
8. Chemical Stability of Pharmaceutics – A Handbook for Pharmacists –Kenneth A Connors, Gordon L. Amidon. Voluation J. Stelle, John Wiley & Sons, New York.
9. Pharmaceutical Dosage Forms: Parenteral Medications Volumes 1, 2 and 3. Kenneth E. Vavis, Loan Lachman and Herbert A. Lichman. Marcel Dokker New York.
10. Pharmaceutical Dosage Forms: Dispersed System Vol. 1 & 2 Edited by as 13.
11. Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.
12. Sterile Dosage Forms, Salvatore Turbo and Rebest E. King Lea and Febiger, Philadelphia.
13. Pharmaceutics – The Sciences of Dosage Form Design Michael E. Aulton, Churchill Livingstone, New York.
14. Advances in Pharmaceutical Sciences, Edited by Bean, Bockett and Carless, Academic Press, New York.Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
15. Physical Pharmacy: A. N. Martine, James Swarbrick and Commarate (Lea & Febiger, Philadelphia.

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, elctrocyclic 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, Michaels condensation, Oppeneaur 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

1. Advanced Organic Chemistry, Reaction Mechanism and Structure by J. March.
2. Stereochemistry of Carbon Compounds by Eliel.
3. Conformational analysis by E.L.Eliel.
4. A Guidebook to Mechanism in Organic Chemistry by Sykes.
5. Mechanism and Structure in Organic Chemistry by Gould.
6. Principles of Ionic Organic Reactions by Alexander.
7. Reactions in Organic Chemistry by Surrey.
8. Reaction Organic Chemistry by Hendrickson.
9. Organic Chemistry, Vol.-I by Finar.
10. Organic Chemistry, Vol.-II., The Fundamentals and Principles by Finar.
11. Unit Processes in Organic Synthesis by Groggins.
12. Mechanism and theory of Organic Chemistry, Lowry and Richardson, Harper
13. Stuart Warren: Organic Synthesis – The Disconnection Approach (John Wiley & Sons)

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. Antineoplastics.
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.
12. Antidiabetics.

Practicals:

Synthesis; determination of R_f 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 phthalimide, 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.
2. Wilson & Gisvolds – Text book of organic medicinal and pharmaceutical chemistry, 10th Edition, 1998.
3. Medicinal Chemistry by Burger.

4. Principles of Medicinal Chemistry by Foye.
5. Organic Drug Synthesis, Vol. 1, 2, 3& 4 by Ledinicer.
6. Annual Reports in Medicinal Chemistry by Hans, Jurgen Hess.
7. Medicinal Chemistry Series by Ariens.
8. Progress in Medicinal Chemistry Series by Ellis and West.
9. Comprehensive Medicinal Chemistry – Series – I-VI (Academic Press)

Branch:- Pharmacology (Branch Code:- 03)

PHARMACOLOGY – I

(BASIC PRINCIPLES OF DRUG THERAPY AND CLINICAL PHARMACOLOGY)
Theory
Subject code - 0131 **Hours – (--/week)**

1. Definition, scope, organization and growth of clinical pharmacology, Cellular transduction mechanisms. Clinic pharmacokinetic, monitoring of drug therapy. Adverse drug reactions, patient compliance. Pharmacogenetic, paediatric and geriatric pharmacology. Drug interaction, drug therapy during pregnancy and lactation.
2. Drugs acting on the autonomic nervous system
    i) Neurotransmission Autonomic and somatic motor nervous system.
    ii) Muscarinic receptor agonists and antagonists.
    iii) Anticholinestrage 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)
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-arrhythmic 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 **Hours – (--/week)**

- 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, qunoline, imidazole, isoquonoline, indole, etc.
  - Glycosides: anthraquinone, saponin, sterol etc.
  - Isoprenoides compopunds.
  - 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 **90 hours (6 hrs. / Week)**

- 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.
- Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
- Herbal cosmetics Hand book – H.Panda.
- Homoeopathic pharmacy – Steven B.Kayne.
- Dictionary of Indian Folk medicine and Ethnobotony – Dr.S.K.Jain.
- Thin Layer Chromatography – E/ Stahl, 2nd Edition 1969
- Ayurvedic Pharmacopoeia of India: Govt. of India.
- Spectroscopic Identification of Organic compounds, Silverstein R. M. Bassler G.
- C. and Morril T. C. 5th Ed. John Wiley and Sons Inc. 1991.
- 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 Pharmacuetical Chemistry by A.N.Knevell.
- 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.
- Practical Pharmacognosy, Khandelwal, K. R. 7th Ed., Nirali Prakashan, Pune 2000
- 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, Sidhha, 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, terpens, 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 -
- Anti-inflammatory, Anti-malarial, Diuretics, Antidiabetic, Hepatoprotective, Anti-fertility, Immunomodulators, Analgesic, Antipyretic, Anti oxidants, Anti obesity, Anticancer, Anti viral, Anti bacterial.
- 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.
- Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
- Introduction to flavonoids: Bruce A. Bohm, harwood academic publishers, 1998.
- Herbal Drug Industry: R. D. Chudhary, Eastern Publishers, New Delhi 1996.
- Wealth of India, CSIR, New Delhi (Related Volumes)
- Cultivation & Utilization of medicinal plants: Atal & Kapoor, PRL, Jammu.
- Cultivation & Utilization of aromatic plants: Atal & Kapoor, PRL, Jammu.
- Various journals related to medicinal plants.
- Pharmacognosy: Trease W.C. Evans G. E. Bailliere & Tindall, London, 14th edn.
- 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.

- ❖ Modern Toxicology vol.II by P.K.Gupta, D.k. Salunkhe
- ❖ Clinical applications of the Ayurvedic remedies.
- ❖ Baidyanth Book of Ayurvedic Knowledge.

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, immunoflorescence, 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. Theoritical 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
3. Michael E. Swartz, Analytical method development & validation.

Total Quality Management-I

THEORY

Subject code -0152T Hours – (--/week)

1. Concepts and philosophy of TQM, GLP, GMP (orange guide).
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.
5. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP).
6. Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.
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.
9. Standard test procedures.
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)

6. Definition, scope, organization and growth of clinical pharmacology, Cellular transduction mechanisms. Clinic pharmacokinetic, monitoring of drug therapy. Adverse drug reactions, patient compliance. Pharmacogenetic, paediatric and geriatric pharmacology. Drug interaction, drug therapy during pregnancy and lactation.
7. Drugs acting on the autonomic nervous system
    i) Neurotransmission Autonomic and somatic motor nervous system.
    ii) Muscarinic receptor agonists and antagonists.
    iii) Anticholinestrage 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) Heamatopoietic Agent: Growth factors, minerals and vitamins
   viii) Anti coagulant, thrombolytic and anti-platelets drugs.

(BIOPHARMACEUTICS AND PHARMACOKINETICS)

Theory
Subject code - 0162 **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:- Industrial Pharmacy (Branch Code:- 07)

COSMETICOLOGY

Theory
Subject code - 0171 **Hours – (--/week)**

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.
4) **Evaluation of cosmetics:** Performance, physicochemical, microbiological and Psychometric evaluation of cosmetics. Design and assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen', anti-aging products. and other 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

Subject code - 0172 **Hours – (--/week)**

1) **Preformulation Studies**: on various dosage forms such as tablets, capsules, suspension, creams, emulsion, injectables, opthalamichs, 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. Destablilization kinetics.
4) **Parentarl dosage forms**: Processing of small and large volume parenterl raw materials, principle and technique. Stability evaluation environment, personnel and management factors in control and quality assurance.
5) **Stability studies and kinetics**: stability and stabilization of Pharmaceuticals, Stability calculation, rate equation, activation energy calculation, interpretation of kinetic data, stability data in product development. Accelerated stability testing. Factors to responsible for destabilization of pharmaceutical product and techniques and means to improve stability. Mathematical treatment of stability test data. Calculation shelf life, Calculation of Q. 10 value and application Q. 10 value in stability testing.
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:

1. Remington's Pharmaceutical application of polymers, properties of polymers. Thermodynamics of polymer solution, phase separation, coacervation and Micro-encapsulation. Polymer in solid state.
2. Theory and practice of Industrial Pharmacy Leon Lachman, Herbert A Lieberman and Joseph L. kaning. Varghese Publishing House, Bombay
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
5. S. Copper Academic Press, New York and academic Press London.
6. Good Manufacturing Practices for pharmaceuticals – A plan for total Quality Control. S. H. Willing, M. M. Tuckerman, S. Hitchings, Marcel Dekker, Inc. New York.
7. Pharmaceutical Preformulation by J. I. Wells, John wiley & sons, N.Y.
8. Chemical Stability of Pharmaceutics – A Handbook for Pharmacists –Kenneth A Connors, Gordon L. Amidon. Voluation J. Stelle, John Wiley & Sons, New York.

9. Pharmaceutical Dosage Forms: Parenteral Medications Volumes 1, 2 and 3. Kenneth E. Vavis, Loan Lachman and Herbert A. Lichman. Marcel Dokker New York.
10. Pharmaceutical Dosage Forms: Dispersed System Vol. 1 & 2 Edited by as 13.
11. Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3.
12. Sterile Dosage Forms, Salvatore Turbo and Rebest E. King Lea and Febiger, Philadelphia.
13. Pharmaceutics – The Sciences of Dosage Form Design Michael E. Aulton, Churchill Livingstone, New York.
14. Advances in Pharmaceutical Sciences, Edited by Bean, Bockett and Carless, Academic Press, New York.Dermatological Formulation – Percutaneous Absorption. Srian W. Berry, Marcel Dekker Inc. New York.
15. Physical Pharmacy: A. N. Martine, James Swarbrick and Commarate (Lea & Febiger, Philadelphia.

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 teratoginicity. 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.
4. Regulatory aspects of pharmaceutical and bulk drug purchasing, manufacture, regulatory drug analysis. Controlled test on the finished products, stability data, Bioequivalence study, study of polymorphism, Analytical method validation, Bio-pharmaceutics.
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.
7. Introduction to patent, Indian Patent Law: Comparison with EP Patent Law and US. Introduction to Indian & U.S. Patents Office. Provisional application. PCT route to filling of patents. Examination & oppositions of patent application. Fee structure of patent, renewal fee requirement in the United States, Europe and India. Introduction to Patent infringement – literal infringement and doctrine of equivalents. Patent search engines, keywords and databases.

Practical

1. Written Analysis of Case studies related to Drug regulatory affairs.
2. Patent searching for U.S., U.K. & ROW (with special emphasis of Indian patents).
3. Searching of Innovator's patent for pharmaceutical products.

Books Recommended:

1. Willing, S. H. "Good Manufacturing Practices for Pharmaceuticals" Marcel Dekker, Inc. New York
2. Drugs and Cosmetics Acts and Rules.
3. Bharathi, Drugs and Pharmacy Laws in India.
4. Nash R. A. and Wachter, A. H. "Pharmaceutical Process Validation" Marcel Dekker, Inc, New York.
5. Banker, G. S. and Rhodes, C. T. "Modern Pharmaceutics", Marcel Dekker, ince, New York
6. OPPI, Quality Assurance
7. Garfield, Quality Assurance Principles of Analytical Laboratories.

ADVANCE ANALYTICAL TECH.- II (COMPULSORY)

Theory
Subject code - 0022 **Hours – (--/week)**

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 Chemiluminiscence.
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.**
11. Reference standards: Source, preparation, characterization, usage, storage and records.

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 Pharmacopoieal 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

1. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
2. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
3. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
4. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
5. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
6. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd edition.

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:** 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.
B) Nasal: Anatomy and physiology of nasal mucosa, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation.
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.
11) H.S. Bean, A.H. Beckett, and J.E. Carless; Advances in Pharmaceutical Sciences; Vol. 5, Academic Press.
12) R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivry; Marcel Dekker
13) T.J. Roseman and S.Z. Mansdorf; Contolled 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.

9. Specific requirements, contents and format of N D A, NDA Review guide.

10. Brief introduction to Abbreviated and Supplemental New Drug Applications

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

DRUG DISCOVERY & DEVELOPMENT

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

1. **Drug Design**- Definition, Historical development approach to drug discovery, Parameters involved in drug design- Importance of physicochemical & steric properties (including isosteric modifications) in new drug discovery, H-bonding, Chelation, S. A. agents, Redox potential, Tailor-made drugs, Specific and non-specific protein binding, Tissue depots, Influence of formulations on bioavailability.
   Various approaches used in drug design, electronic aspects of design, molecular size, shape, molecular orbital approach & quantitative drug design.
2. **Metabolism**- Definition, general introduction, different phases, metabolic pathways, importance in drug design.
3. **Quantitative Structure Activity Relationship(QSAR)**- Introduction, methods of QSAR, aims, object, limitations, applications, Hansch's LFER model, various physicochemical parameters used in drug design and their practical determination, free Wilson mathematical model
   Molecular Modeling- structure based drug design-3 D-QSAR, Computer aided drug design
4. Molecular connectivity, Electro topological state atom indices (ETSAI), combinatorial chemistry & libraries and High throughput screening concepts & bioinformatics to new drug discovery.
5. **Pharmacokinetic Studies in New Drug Discovery**- Introduction, relation of drug metabolism to drug design structure, absorption-distribution relationship-significance for 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.
2. Drug Design, Vol. VII by Ariens.
3. Progress in Pharmaceutical Research by Woodridge.
4. Annual Reports in Medicinal Chemistry, Academic Press Inc.
5. Comprehensive Medicinal Chemistry, Vol. 4.
6. Burger's Medicinal Chemistry, Vol. 1
7. Manfred E. Wolff and Burger's, Medicinal Chemistry and Drug Discovery- Vol. I-VI, Principles and Practice, Vth Ed., John Wiely & Sons.

8. Receptor based drug design, by P. Leff, Marcel Dakker, New York, 1998. 6. Paul's charifron – Practical application of computer Aided drug design – Marcel Dakker – 1997.
9. The Organic Chemistry of Drug design and Drug Action - R.B.Silverman – Academic Press –1992.
10. Exploring QSAR – Fundamental and applications in Chemistry and Biology by Carowari Hansch and Albert Leo, ACS, Washington DC – 1995.
11. Advanced in drug discovery techniques by Alan L. Harney.

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 structure studies 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
4. **Amino acids, Peptides & Proteins**- Introduction, Classification, Synthesis of amino acids, polypeptides. Synthesis of naturally occurring proteins, structure of polypeptides, amino and carboxyl terminal determination, Proteins; Introduction, classification, composition, structure and chemistry of oxytocin, insulin, angiotensin and peptides of medicinal importance. Purines and nucleic acid.
5. **Steroids**- General introduction, Stereochemistry**,** nomenclature and structural elucidation of sterols (cholesterol), sapogenin (diosgenin).
6. **Cardiac glycosides**- Cardiac, saponins, anthraquinones, etc.
7. **Alkaloids**- General introduction and Classification, General methods of isolation & structure determination, structural elucidation of morphine, ergotamine, atropine, reserpine, colchicines, Vinca, podophyllum and quinine.
8. **Flavonoids -** Detailed chemical account of rutin and quercetin.
9. **Triterpenoids –** A general chemical treatment and structural elucidation of terpenoids.
10. **Coumarins –** General methods of isolation and purification and structural determination of xanthotoxin and psoralene.
11. Selected Synthesis: Stereochemical aspects of vitamin A, ascorbic acid, cholesterol, cortisone, progesterone-dihydroabietic acid, coenzyme A, β-carotene, estrone, prostaglandins $F_{2\alpha}$ and E_2.

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

Books Recommended:

1. Manfred E. Wolff and Burger's, Medicinal Chemistry and Drug Discovery- Vol.I-VI, Principles and Practice, Vth Ed, John Wiely & Sons.
2. E.J. Ariens; Drug Design, Academic Press, New York.
3. Progress in Medicinal Chemistry, Series by Ellis & Wert.
4. Wilson & Gisvolds – Text book of organic medicinal and pharmaceutical chemistry, 10th Edition, 1998.
5. Receptor based drug design, by P. Leff, Marcel Dakker, New York, 1998. 6. Paul's charifron – Practical application of computer Aided drug design – Marcel Dakker – 1997.
6. The Organic Chemistry of Drug design and Drug Action - R.B.Silverman – Academic Press –1992.
7. Exploring QSAR – Fundamental and applications in Chemistry and Biology by Carowari Hansch and Albert Leo, ACS, Washington DC – 1995.
8. Alan L. Harney - Advanced in drug discovery techniques.
9. Alfred Burger – Text Book of medicinal chemistry Vol. 1 & Vol. 2.
10. William O. Foye – Principles of Medicinal Chemistry Varghese Publishing House, Bombay – 3rd Edition, 1989.
11. Wilson and Gisvolds – Textbook of organic medicinal and Pharmaceutical Chemistry, 10th Edition, 1998.
12. Ellis & Wert – Progress in Medicinal Chemistry – Academic Press, New York.
13. Chemistry of Alkaloids by S.W.Pelletier
14. Alkaloids by Manske.
15. Plant Physiology by Dieter Hess.
16. Alkaloidsoids by Fieser and Fieser.
17. Organic Chemistry by I.L.Finar Vol.II.
18. History of Natural Products by K.W.Bentley.
19. Synthesis of Aromatic Compounds by Ulrich Weiss & J.Michael Edwards.
20. Jerry March, Advanced organic Chemistry – Reaction Mechanism and Structure – John Willey & Sons, New York.
21. E.L Eliel – Stereo chemistry of carbon compounds – Mc Graw – Hll Book Company – Inc. New York.
22. E.S. Gould – Mechanism and Structure in organic chemistry.
23. E.L.Eliel - Conformational analysis.
24. Organic Functional Group Analysis by Cheronis.

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, constioation

ii)Agents affecting gastrointestinal water flux and motility: emesis and antiemetic, bile acids and pancreatic enzymes

2. Therapy of Infections 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 protozonal 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 antithyrioid 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 agement 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 neucleotides

iii) TNF, apoptosis

iv) Ion channel modulators

v) Neurosteroids and cannabiods

vi) Nitric Oxide

vii) ANF,anti oxidants: Melatonin

viii) Chiral pharmacology

ix) Gene therapy

x) Neuropeptide, Substance P, angeiotention 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

7. Indian Journal of Pharmacology

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, antiparkinsoniun agents, antipileptics, analgesic, anti-inflammatory agents, local anaesthetics.
b) Antihypertensives, antirrhythmics, antitherosclerotics, drugs for myocardial infarction.
c) Antiulcer 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) pD_2 Value
iii) pA_2 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, antipileptics, analgesic, anti-inflammatory, antihypertensive, anti MI. anti ulcer, antidiabetic and antioxidants.

Synopsis of Research Project
Seminar and viva voice on Research methodology and Research project

Branch: - Pharmacognosy (Branch Code: - 04)

PHYTOCHEMISTRY AND MEDICINAL PLANT BIOTECHNOLOGY

THEORY
Subject code-0241 Hours – (--/week)

- 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, polyploidy, 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 **60 hours (3 hrs. / Week)**

- 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:

- Text book of Pharmacognosy – Trease and Evans.
- Medicinal Natural Products IInd Edition (A biosynthetic approach) – Paul M. Dewier.
- Pharmacognosy, Phytochemistry, Medicinal Plants IInd Edition – Jean Bructon.
- Herbal Medicine – Manuchair Ebadi.
- Plant tissue Culture – Bhagwani Vol 5. (Elsevier)
- Plant Cell and Tissue Culture (Lab. Manual) – J.R.M.M. Yeoman.
- Medicinal Natural roducts IInd Edn. (A biosynthetic Approach) Paul M. Dewick.
- Pharmacognosy, Phytochemistry Medicinal Plants IInd Edn. Jean Bruneton.
- Elements of Biotechnology – P.K. Gupta. Kalyani Publication.
- 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.
- Biosynthesis of Aromatic Compounds by Ulrich Weiss & J.Michael Edwards.
- Essential oils and waxes: H.F.Linskens & J.F.Jackson.
- The Ayurveda Encyclopedia – 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
- Ayurvedic Medicines – H.Panda.
- 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.
- Stadardisation 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, charaterisation 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.
- Text Book of Pharmacognosy by T.E. Wallis, CBS Pub. Delhi.
- 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.
- Pharmacoepial standards for Ayurvedic formulations –CCRAS, Delhi.
- Practical Pharmacognosy by Dr.C.K.Kokate.
- Practical Pharmacognosy by Dr.P.K.Lala.
- Bibiliography on pharmacognosy of medicinal plants-Roma Mitra.
- British Herbal Pharmacopoeia.
- Essential oils and waxes: H.F.Linskens & J.F.Jackson.
- The Ayurveda Encyclopedia – 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
- Ayurvedic Medicines – H.Panda.

- Pharmacognosy and Pharmacobiotechnology – Ashutoshkar.
- Foundations of Ayurveda – K.H.Krishnamurthy.
- The complete Germancommision, E.Monographs-Blumenthal Buse, Gold bery, Gruenwald Hall.
- The Ayurvedic system of medicine – K.N.Sengupta.
- Herbal cosmetics Hand book – H.Panda.
- Homoeopathic pharmacy – Steven B.Kayne.
- Dictionary of Indian Folk medicine and Ethnobotony – Dr.S.K.Jain.
- Practical Pharmacognosy, Khandelwal, K. R. 7th Ed., Nirali Prakashan, Pune 2000
- 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
- Thin Layer Chromatography – E/ Stahl, 2nd Edition 1969
- Ayurvedic Pharmacopoeia of India: Govt. of India.
- Spectroscopic Identification of Organic compounds, Silverstein R. M. Bassler G.
- C. and Morril T. C. 5th Ed. John Wiley and Sons Inc. 1991.

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.
3. Validation of processes: Mixing, granulation, drying, compression, filtration, filling.
4. Validation of sterilization methods and equipments: Dry heat sterilization, autoclaving, membrane filtration, gaseous sterilization and sterilization by radiation.
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.
10. Finished products release, quality review, quality audits, batch release document.
11. Loan license (contract manufacture) auditing.
12. Recent amendments to Drugs and Cosmetic Act and other relevant rules.
13. Relevant provisions of Consumer Protection Act, Environmental Protection Act, Factories Act.

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 erythematosus

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:

1. Clinical Pharmacy & Therapeutics- Roger & Walker, Churchill Livingston publications.
2. Pharmacotherapy: A Pathophysiologic Approach- Joseph T. Dipiro et al, Appletone & Lange.
3. Pathologic Basis of Disease-Robinson SL, WB Saunders Publications.
4. Pathology and Therapeutics for Pharmacists: A Basis for Clinical
Pharmacy Practice- Green and Harris, Chapman and Hall Publications.

5. Clinical Pharmacy & Therapeutics- Eric T Hefindal. Williams & Wilkins Publications.
6. Applied Therapeutics: The Clinical Use of Drugs. Lloyed Young and Koda-Kimble MA (ISBN-0333-65881-7)
7. Avery's Drug Treatment, 4 th Edn 1997, Adis International Ltd
8. Basic skills in interpreting laboratory data- Scott L T. American Society of Health System Pharmacists.
9. Practice Standards and Definitions- The Society of Hospital Pharmacists-Australia. 1997
10. Clinical Pharmacokinetics- Rowland and Tozer, Williams and Wilkins Publications
11. Biopharmaceutics and Applied Pharmacokinetics- Leon Shargel, Printice and Hall publications
12. Relevant review articles from recent medical and Pharmaceutical Journals

Journals:

British Medical Journal
Annals of Pharmacotherapy
New England Journal of Medicine
Lancet
Pharmaceutical Journal Royal Pharmaceutical Society, London
Journal of Pharmacy and Research Society of Hospital Pharmacists of Australia
International Journal of Pharmacy practice UK
Hospital Pharmacist, UK
Indian Journal of Hospital Pharmacy

ADVANCEMENT IN NOVEL PHARMACOLOGY AND DRUG DESIGN

THEORY

Subject code-0262 Hours – (--/week)

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.

4. Endogenous bioactive molecules as TNF Interleukins, Process of apoptosis, arachidonic acid metabolites, COX-2 regulators and their role in inflammation.

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.

8. Concept of gene therapy and recent development in the treatment of various hereditary diseases. Human genome mapping and its potential in drug research.

9. Antisence genes as a research tool.

Books Recommended:

1. Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication,California
2. Barar F.S.K Essentials of pharmacotherapeutics (S.Chand & C. New Delhi)
3. Bow man W. C. and Rand M. J. Text book of Pharmacology (Blackwell, Oxford)
4. Melmon K. L. and Morelli. Clinical pharmacology Basic principles of Therapeutics (Macmillan New York)
5. Carig C. R. and Stizel B. E. Modern Pharmacology (Little Brown & Co. Boston)
6. Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York)
7. Grollman Pharmacology & Therapeutics (Lea and Tebiger Philadelphia)
8. Baeq Z. M. Capek. Fundamentals of Biochemical Pharmacology.
9. Avery G. S. Drug treatment (Adis Press, Sydney)
10. Goodman and Gilman Pharmacological Basis of Therapeutics (MacGraw Hill)
11. Rang H. P. and Dale M. M. Pharmacology (Churchill Livingston, U. K.)

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.

B) Nasal: Anatomy and physiology of nasal mucosa, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation.

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.
11) H.S. Bean, A.H. Beckett, and J.E. Carless; Advances in Pharmaceutical Sciences; Vol. 5, Academic Press.
12) R. O. Potts, and R.H. Guy; Mechanisms of transdermal drug delivry; Marcel Dekker
13) T.J. Roseman and S.Z. Mansdorf; Contolled 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.

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 ekker.
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.
13) J.M. Juran and A.B. Godfrey; Juran's Quality Handbook; McGraw Hill.
14) S. N. Katju's Law and drugs; Law Publishers (I) Pvt. Ltd.