Schemes of Examination for M. Pharm. Courses
w.e.f. Session 2017-18

Table 1: Scheme for internal assessments and end semester examinations (Industrial Pharmacy)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP101T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Customized drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Drug Regulations and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP104P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Table-2 Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC101T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC104P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Table-3 Schemes for internal assessments and end semester examinations (Pharmacognosy)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous Mode	Sessional Exams		Total	Marks	Duration	Marks
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG101T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Industrial Herbal drug technology	10	15	1 Hr	25	75	3 Hrs	100
MPG104P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPG201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG202T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Table-4 Schemes for internal assessments and end semester examinations (Pharmacology)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL101T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL104P	Pharmacology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical Research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Table-5 Schemes for internal assessments and end semester examinations (Drug Regulatory Affairs)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER I								
DRA101T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
DRA102T	Pharmaceutical Regulations in India	10	15	1 Hr	25	75	3 Hrs	100
DRA103T	International Pharmaceutical Regulations I	10	15	1 Hr	25	75	3 Hrs	100
DRA104T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
DRA105P	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
DRA201T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
DRA202T	Biologicals Regulations	10	15	1 Hr	25	75	3 Hrs	100
DRA203T	International Pharmaceutical Regulations II	10	15	1 Hr	25	75	3 Hrs	100
DRA204T	Medical Device Regulations	10	15	1 Hr	25	75	3 Hrs	100
DRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Table-6 Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER III								
MRM101T	Research Methodology and Biostatistics	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work	-	-	-	-	350	1 Hr	350
							Total	**525**
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
							Total	**500**

SYLLABUS - M. PHARM COURSES w.e.f. Session 2017-18

M. PHARM. PHARMACEUTICAL CHEMISTRY (MPC)

SEMESTER-1

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

1 UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

12 Hrs

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

12 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

12 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

12 Hrs

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY-1 (MPC101T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

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

- The principles and applications of retero-synthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY **60 Hrs**

1. Basic Aspects of Organic Chemistry

a. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.

b. Types of reaction mechanisms and methods of determining them,

c. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

i. Aliphatic and aromatic compounds,

ii. Nucleophilic uni- and bimolecular reactions (SN1 and SN2)

iii. Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)

iv. Rearrangement reaction

12Hrs

2. Study of mechanism synthetic applications of following named Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

12 Hrs

3. Synthetic Reagents & Applications

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

a. Role of protection in organic synthesis

b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals

c. Protection for the Carbonyl Group: Acetals and Ketals

d. Protection for the Carboxyl Group: amides and hydrazides, esters

e. Protection for the Amino Group and Amino acids: carbamates and amides

12Hrs

4. Heterocyclic Chemistry

General methods of synthesis and applications of drugs of five, six membered and fused heterocylces such as imidazole, pyrazole, triazole, pyrimidine, quinoline, acridine, phenothiazine and purine. Synthesis of few representative drugs containing these heterocyclic nucleus

12Hrs

5. Synthon approach and retrosynthesis applications

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA)

ii. C- X disconnections; C- C disconnections – alcohols and carbonyl compounds; 1,2- , 1,3- ,1,4- , 1,5- , 1,6- difunctionalized compounds

iii. Strategies for synthesis of three, four, five and six- membered ring

12Hrs

REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.

2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, NewYork.

3. “Organic Chemistry” Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.

4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.

5. A guide to mechanisms in Organic Chemistry – Peter Skyes (Orient Longman, New Delhi).

6. Reactive intermediates in organic chemistry – Tandom and Gowel. 60

7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik.

8. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)

9. Organic synthesis-The disconnection approach, S. Warren, Wily India

10. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns

11. Organic synthesis- Special techniques VK Ahluwalia and R Agarwal, Narosa Publishers

12. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

ADVANCED MEDICINAL CHEMISTRY (MPC102T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

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

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY **60 Hrs**

1. Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Chemistry of prostaglandins, leukotrienes and thromboxones.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

12 Hrs

2. Prodrug Design and Analog design:

- **Prodrug design**: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
- **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
- **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

12Hrs

3 Chemistry of Synthetic drugs: Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

12 Hrs

4. Rational Design of Enzyme Inhibitors: Enzyme kinetics & Principles of Enzyme inhibitors**,**Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

12 Hrs

5. Peptidomimetics: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally.

Combinatorial chemistry and High throughput screening: Different techniques, Solid phase synthesis, Solution phase synthesis, Parallel synthesis, applications of combinatorial chemistry. High Throughput Screening- general outline, importance and application.

12 Hrs

REFERENCES:

1. Medicinal Chemistry by Burger.

2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.

3. Comprehensive Medicinal Chemistry – Corwin and Hansch.

4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

5. Introduction to Quantitative Drug Design by Y.C. Martin.

6. Principles of Medicinal Chemistry by William Foye.

7. Drug Design Volumes by Arienes.

8. Principles of Drug Design by Smith.

9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman.

10. An Introduction to Medicinal Chemistry –Graham L.Patrick, (III Edition.)

11. Biopharmaceutics and pharmacokinetics by DM.Brahmankar, Sunil B .Jaiswal.

12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC103T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

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

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY **60 Hrs**

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs:

a. Drugs Affecting the Central Nervous System: Morphine Alkaloids

b. Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide

c. Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol

d. Neuromuscular Blocking Drugs: Curare alkaloids

e. Chemistry of macrolid antibiotics: Erythromycine, Azithromycine, Cephalosporins(New generation)

12Hrs

2. Alkaloids- General introduction, classification, isolation, purification, stereochemistry, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation of ephedrine, morphine, ergot, emetine and reserpine.

Flavonoids. Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

12Hrs

3. Steroids- General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, Structure elucidation of male & female sex hormones(testosterone, Estradial, progesterone), Adrenocortcoids (carsisone) and contraceptive agents.

Terpenoids – Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono, di and tri terpenoids, carotinoids.

12Hrs

4. Recombinant DNA technology and drug discovery:

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

Active constituent of certain crude drugs used in Indigenous system.

Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulate*, *Pterocarpus marsupiam*, *Swertia chirata*, *Trigonella foenum graccum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.

12Hrs

5. Structural Characterization of natural Products

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy

12Hrs

REFERENCES

1. Modern methods of plant analysis – Peech and M.V.Tracey.

2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.

3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles.

4. Chemistry of natural products Vol I onwards IWPAC.

5. Natural Product Chemistry Nakanishi Gggolo.

6. Natural Product Chemistry "A laboratory guide" – Rapheal Khan.

7. The Alkaloid Chemistry and Physiology by THF Manske.

8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.

9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall.

10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal.

11. Organic Chemistry Vol I and II by I.L. Finar

12. Elements of Biotechnology by P.K. Gupta.

13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit.

14. Biotechnology by Purohit and Mathoor.

15. Phytochemical methods of Harborne.

16. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL-I (MPC104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation

2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC

4. Experiments based on Gas Chromatography

5. Estimation of riboflavin/quinine sulphate by fluorimetry

6. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

7. Purification of organic solvents, column chromatography

8. Claisen-schimidt reaction.

9. Benzyllic acid rearrangement.

10. Beckmann rearrangement.

11. Hoffmann rearrangement

12. Mannich reaction

13. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)

14. Estimation of elements and functional groups in organic natural compounds

15. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.

16. Some typical degradation reactions to be carried on selected plant constituents

SEMESTER-II

ADVANCED SPECTRAL ANALYSIS (MPC201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

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

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments

 Identification of organic compounds

THEORY **60Hrs**

1. **UV and IR spectroscopy**: Wood ward – Fiesure rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

12Hrs

2. **NMR spectroscopy**: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

12Hrs

3. **Mass Spectroscopy**: Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

12Hrs

4. **Chromatography**: Principle, Instrumentation and Applications of the following:

a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography.

12Hrs

5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA.

Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.

Radio immuno assay: Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin

12Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY–II (MPC202T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall able to understand

 The principles and applications of Green chemistry

- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY **60 Hrs**

1. Green Chemistry

a. Introduction, principles of green chemistry

b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis

c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications

d. Continuous flow reactors: Working principle, advantages and synthetic applications.

12Hrs

2. Chemistry of peptides

a. Coupling reactions in peptide synthesis

b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies

d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

12Hrs

3. Photochemical Reactions

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, elctrocyclic reaction and sigmatrophic rearrangement reactions with examples

12Hrs

4. Catalysis

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages

b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.

c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler- Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs

d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions

e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

f. Phase transfer catalysis - theory and applications

12Hrs

5. Stereochemistry & Asymmetric Synthesis

a. Basic concepts in stereochemistry – optical activity, specific rotation racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.

b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

12Hrs

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.

2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, NewYork.

3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.

4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.

5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)

6. Organic synthesis-the disconnection approach, S. Warren, Wily India

7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns

8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers

9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

COMPUTER AIDED DRUG DESIGN (MPC203T)

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

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

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The *in silico* virtual screening protocols

Theory **60 Hrs**

1. Introduction to Computer Aided Drug Design (CADD): History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

12 Hrs

2. Quantitative Structure Activity Relationships: Applications

Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance of statistical parameters.

12 Hrs

3. Molecular Modeling and Docking

a. Molecular and Quantum Mechanics in drug design

b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

12 Hrs

4. Molecular Properties and Drug Design

a. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b. *De novo* drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c. Homology modeling and generation of 3D-structure of protein.

12 Hrs

5. Pharmacophore Mapping and Virtual Screening Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. *In Silico* Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based *in silico* virtual screening protocols.

12 Hrs

REFERENCES:

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

2. Introduction to Quantitative Drug Design by Y.C. Martin.

3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975.

4. Principles of Drug Design by Smith and Williams.

5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman.

6. Medicinal Chemistry by Burger.

7. An Introduction to Medicinal Chemistry –Graham L. Patrick, (III Edition.)

8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.

9. Comprehensive Medicinal Chemistry – Corwin and Hansch.

10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY (MPC204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

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

 The strategies of scale up process of apis and intermediates

 The various unit operations and various reactions in process chemistry

THEORY **60 Hrs**

1. Process chemistry

a. Introduction, Synthetic strategy

b. Stages of scale up process: Bench, pilot and large scale process.

c. In-process control and validation of large scale process.

d. Case studies of some scale up process of APIs.

e. Impurities in API, types and their sources including genotoxic impurities

12 Hrs

2. Unit operations

a. *Extraction:* Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

b. *Filtration*: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

c. *Distillation*: azeotropic and steam distillation

d. *Evaporation*: Types of evaporators, factors affecting evaporation.

e. *Crystallization*: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

12 Hrs

3. Unit Processes

a. **Nitration:** Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

b. **Halogenation:** Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c. **Oxidation**: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

12 Hrs

4. Unit Processes

a. **Reduction:** Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

b. **Fermentation**: Aerobic and anaerobic fermentation. Production of

i. Antibiotics; Penicillin and Streptomycin,

ii. Vitamins: B2 and B12

iii. Statins: lovastatin, simvastatin

Reaction progress kinetic analysis

a. Streamlining reaction steps, route selection,

b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

12 Hrs

5. Industrial Safety

a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

b. Fire hazards, types of fire & fire extinguishers

c. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

12 Hrs

REFERENCES:

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti

2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.

3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.

4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill

5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)

6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis

7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up

8. P.H.Groggins: Unit processes in organic synthesis (MGH)

9. F.A.Henglein: Chemical Technology (Pergamon)

10. M.Gopal: Dryden's Outlines of Chemical Technology

11. Clausen,Mattson: Principle of Industrial Chemistry

12. Lowenheim & M.K. Moran: Industrial Chemicals

13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II

14. J.K. Stille: Industrial Organic Chemistry (PH)

15. Srreve: Chemical Procress

16. B.K.Sharma: Industrial Chemistry

17. ICH Guidelines

18. United States Food and Drug Administration official website www.fda.gov

PHARMACEUTICAL CHEMISTRY PRACTICAL-II (MPC205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)

a. Oxidation

b. Reduction/hydrogenation

c. Nitration

2. Comparative study of synthesis of APIs/intermediates by different synthetic routes

(2 experiments)

3. Assignments on regulatory requirements in API (2 experiments)

4. Comparison of absorption spectra by UV and Wood ward – Fiesure rule

5. Interpretation of organic compounds by FT-IR

6. Interpretation of organic compounds by NMR

7. Interpretation of organic compounds by MS

8. Determination of purity by DSC in pharmaceuticals

9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra

10. To carry out the preparation of following organic compounds

11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).

12. Preparation of 4-iodotolene from p-toluidine.

13. NaBH4 reduction of vanillin to vanillyl alcohol

14. Preparation of umbelliferone by Pechhman reaction

15. Preparation of triphenyl imidazole

16. To perform the Microwave irradiated reactions of synthetic importance (Any two)

17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares

18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling

19. 2D-QSAR based experiments

20. 3D-QSAR based experiments

21. Docking study

22. Virtual screening based experiment

M. PHARM. PHARMACOGNOSY (MPG)

SEMESTER-I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

1 UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

12 Hrs

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

12 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

12 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

12 Hrs

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED PHARMACOGNOSY-1 (MPG101T)

SCOPE:

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES:

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

1. Know the advances in the cultivation and production of drugs

2. Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.

3. Know the various nutraceuticals/herbs and their health benefits

Course Description

THEORY **60 Hours**

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current good agricultural practices, Current good cultivation practices, Current good collection practices, Conservation of medicinal plants- *Ex-situ* and *In-situ* conservation of medicinal plants.

12 Hrs

2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

12 Hrs

3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks from natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

12 Hrs

4. Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein) b) Limonoids – i) d-Limonene ii) α – Terpineol c) Saponins – i) Shatavarins d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin e) Phenolic acids- Ellagic acid f) Tocotrienols and Tocopherols g) Andrographolide, glycolipids, gugulipids, withanolides, vascine, taxol

12 Hrs

5. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

12 Hrs

REFERENCES:

1) Cultivation of medicinal and aromatic crops, 1st edition, by AA Farooqui and B.S. Sreeramu. University Press, 2001.

2) Medicinal natural products (a biosynthetic approach), 1st edition, by Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.

3) Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998

4) Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.

5) Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.

6) Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.

7) Pharmacognosy-Tyler, Brady, Robbers

8) Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II

9) Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.

10) Chemistry of Marine Natural Products- Paul J. Schewer 1973.

11) Marine Natural Products-Vol.I to IV.

12) Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.

13) Cultivation and Utilization of Aromatic Plants By C.K. Atal & B.M. Kapoor

14) Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.

15) Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.

16) Pharmacognosy and Pharmacobiotechnology by Ashutoshkar, New Age Publications, New Delhi.

17) Text Book of Pharmacognosy by T.E. Wallis

PHYTOCHEMISTRY (MPG102T)

Scope:

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify the extract and phyto-constituents

Objectives:

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

1. know the different classes of phytoconstituents and their properties and general process of natural product drug discovery

2. know the process isolation, purification and identification of phytoconstituents

THEORY **60 Hrs**

1. Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:

a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vincaalkoloids.

b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Ginsenosides, Quercitin, Rutin.

c) Steroids: Hecogenin, guggulosterone and withanolides

d) Coumarin: Umbelliferone.

e) Terpenoids: Cucurbitacins

f) Carotenoids: Lycopene, β-carotene.

g) Camphor, Menthol, Eugenol.

12 Hrs

2. Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from anticancer, CNS cardiovascular drugs, antitubercular drugs and immunomodulators, Clinical studies emphasis on phase of clinical trials, protocol design for lead molecules.

12 Hrs

3. Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, and method of fractionation. Detection of different classes of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography, AAS.

12 Hrs

4. Phytochemical finger printing: HPTLC and LCMS/GCMS characterization of extracts containing alkaloids, saponins, glycosides and flavanoids.

12 Hrs

5. Pharmacological screening: In vitro, In vivo screening techniques with reference to antiglycomerate, analgesics, antidiabetic, antilipidemic, anticancer, antiulcer, antiviral, antipsychotic, antilithiatic, Toxicity studies as per OECD guidelines, acute, chronic and clinical toxicity.

12 Hrs

REFERENCES:

1) Organic chemistry by I.L. Finar Vol.II

2) Pharmacognosy by Trease and Evans, ELBS.

3) Pharmacognosy by Tylor and Brady.

4) Text book of Pharmacognosy by Wallis.

5) Clark's isolation and Identification of drugs by A.C. Mottal.

6) Plant Drug Analysis by Wagner & Bladt.

7) Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.

8) The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International

Edn. 1994.

9) Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui

10) Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.

11) Chemistry of Natural Products- Vol. 1 onwards IWPAC.

12) Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II

INDUSTRIAL HERBAL DRUG TECHNOLOGY (MPG103T)

Scope:

To understand the Industrial and commercial potential of herbal drugs and drugs of natural origin, integrate traditional medicines and systems of India with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

Objective:

By the end of the course the student shall be able to:-

1. Know the requirements for setting up the herbal/natural drug industry.

2. To know and understand the guidelines for quality of herbal/natural medicines and regulatory issues.

3. To know patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY **60Hrs**

1. Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation production management.

12 Hrs

2. Regulatory requirements for setting herbal drug industry: Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export – import (EXIM) policy, TRIPS, IPR. Quality assurance in herbal/natural drug products. Concepts of TDM, GMP, GLP, ISO-9000.

12Hrs

3. Monographs of herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

12 Hrs

4. Testing of natural products and drugs: Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Stability testing of natural products, protocols.

12 Hrs

5. Patents: Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

12 Hrs

REFERENCES:

1. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.

2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.

3. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.

4. The complete technology book on herbal perfumes and cosmetics, by H.Pande, National Institute of Industrial Research, Delhi.

5. Quality control of herbal drugs by Pulok K Mukarjee (2002), Ist Edition, Business Horizons Pharmaceutical Publisher, New Delhi.

6. PDR for Herbal Medicines (2000), 2nd Edition, Medicinal Economic Company, New Jersey.

7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.

8. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), 4th Edition, Nirali Prakashan, New Delhi.

9. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.

10. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.

11. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.

12. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.

13. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,

14. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), II Edition, Eastern Publisher, New Delhi.

PHARMACOGNOSY PRACTICAL-I (MPGI04P)

1. Analysis of pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer

2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Analysis of recorded spectra of simple phytoconstituents

4. Experiments based on Gas Chromatography

5. Estimation of sodium/potassium by flame photometry

6. Developmernt of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawronia by HPTLC method

7. Method of extraction

8. Phytochemical screening

9. Thin layer chromatography

10. Demonstration of HPLC- estimation of glycyeizin

11. Monograph analysis of clove oil

12. Monograph analysis of castor oil.

13. Identification of bioactive constituents from plant extracts

14. Formulation using qualitative and quantitative methods.

SEMESTER-II

MEDICINAL PLANT BIOTECHNOLOGY (MPG201T)

Scope

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

Objectives

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

 Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.

 Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY 60Hrs

1. Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

12 Hrs

2. **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.

12 Hrs

3. **Immobilisation techniques & Secondary Metabolite Production:**

Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.

12 Hrs

4. **Biotransformation and Transgenesis:**

Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

12 Hrs

5. Fermentation technology:

Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.

12 Hrs

REFERENCES:

1. Plant tissue culture – Bhagwani, Vol 5. (Elsevier)
2. Plant cell and Tissue Culture (Lab. Manual) – J.R.M.M. Yeoman.
3. Elements in biotechnology by P. K. Gupta.
4. An introduction to plant tissue culture by M. K. Razdan.
5. Experiments in plant tissue culture by John H. D and Lorin W. R.
6. Pharmaceutical biotechnology by S. P. Vyas and V. K. Dixit.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker.
8. Plant tissue culture by Dixon, Oxford Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and W. C. Evans.
11. Biotechnology by Purohit and Mathur.
12. Biotechnological applications to tissue culture by Shargool.
13. Pharmacognosy by Virroo E. Tyler, Lynn R. Brady and James E. Robberrt.

ADVANCED PHARMACOGNOSY-II (MPG202T)

Scope:

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

Objectives

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

 Know the validation of herbal remedies

 Know the methods of detection of adulteration and evaluation techniques for the herbal drugs

 To know the methods of screening of herbals for various biological properties

THEORY **60Hrs**

1. **Herbal remedies – Toxicity and Regulations:**

Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

12 Hrs

2. **Adulteration and Deterioration:** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs fruital formulation.

12 Hrs

3. **Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bioprospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

12 Hrs

4. **Analytical Profiles of herbal drugs:** *Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia.*

12 Hrs

5. **Biological screening of herbal drugs:** Introduction and Need for Phyto- Pharmacological Screening, New Strategies for evaluating Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility.

12 Hrs

REFERENCES:

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V. George Tropical Botanic Garden & Research Institute, 1995.

2. Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press1991.

3. Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.

4. Pharmacognosy-Tyler, Brady, Robbers

5. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II

6. Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.

7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.

8. Text Book of Pharmacognosy by T.E. Wallis

9. Quality control of herbal drugs by Pulok K Mukarjee (2002), Ist Edition, Business Horizons Pharmaceutical Publisher, New Delhi.

10. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.

11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.

12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.

13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.

14. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition.

INDIAN SYSTEMS OF MEDICINE (MPG203T)

Scope

To make the students understand thoroughly on principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

Objective

After completion of the course, student is able to

 To understand the basic principles of various Indian systems of medicine

 To now the clinical research of traditional medicines, Current Good Manufacturing

Practice of Indian systems of medicine and formulation.

THEORY

60Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine:

Different dosage forms of the ISM **Ayurveda:** Chronological development of Charak Samhita, Sushrut Samhita and Kashyapa Samhita. Ayurvedic Pharmacopoeia Analysis of Ayurvedic Formulations and crude drugs with references to: Identity, purity and quality of crude drugs.

Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in siddha system of medicine, Purification process (Suddhi).

12Hrs

2. Naturopathy, Yoga and Aromatherapy practices:

a) Naturopathy - Introduction, basic principles and treatment modalities.

b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

12 Hrs

3.**Formulation development of various systems of medicine:** Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations.

12 Hrs

4. Schedule T – Good Manufacturing Practice of Indian systems of medicine:

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. Quality assurance in herbal drug industry of GAP, GMP and GLP in traditional system of medicine. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/regional pharmacopoeias.

12 Hrs

5. TKDL, Geographical indication skill, Government skills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.

12 Hrs

REFERENCES:

1. Ayurvedic Pharmacopoeia (2004), The Controller of Publications, Civil Lines, Govt. of

India, New Delhi.

2. Hand Book on Ayurvedic Medicines by H.Panda National Institute of Industrial Research,

New Delhi.

3. Ayurvedic System of Medicine by Kaviraj Nagendranath Sengupata (1998), 2nd Revised Edition, Sri Satguru Publications, New Delhi.

4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines (2000), IMCOPS, Chennai.

5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines (2004), IMCOPS, Chennai.

6. Homeopathic Pharmacy An introduction & Hand book by Steven B. Kayne (1997), Churchill Livingstone, New York.

7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.

8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.

9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), First edition, Business Horizons, New Delhi.

10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt.of India, New Delhi.

11. Essential of Food and Nutrition by Swaminathan (1999), Bappco, Bangalore.

12. Clinical Dietitics and Nutrition by F.P. Antia (1997), 4th Edi, Oxford Universith Press, Delhi.

13. Yoga- The Science of Holistic Living by V.K.Yoga (2005), Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG204T)

Scope

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding Drug and cosmetic act.

Objective

After completion of the course, student is able to

 Understand the basic principles of various herbal/natural cosmetic preparations

 Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

THEORY

60Hrs

1. **Introduction:** Herbal/natural cosmetics, Classification& Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics**.**

12 Hrs

2. **Herbal Cosmetics for the skin:** Physiology and chemistry of skin and pigmentation, hairs, scalp, oral and nail, Cleansing cream, Lotions, Vanishing and Foundation creams, Anti- sun burn preparations, Moisturizing cream , deodorants, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : Shampoos, Conditioners, Tonic, Bleaches, Colorants, Depilatories and Hair oils, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails**.** **12 Hrs**

3. **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Fairness formulations. **12 Hrs**

4. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colours, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

12 Hrs

5. **Analysis of Cosmetics, Toxicity screening and test methods:** Quality control and toxicity studies as per Drug and Cosmetics acts**.**

12 Hrs

REFERENCES:

 Panda H. 2007. Herbal Cosmetics (Hand book), Edition I, Asia Pacific Business Press Inc, New Delhi.

 Thomson EG. 2006. Modern Cosmetics, Edition I, Universal Publishing Corporation, Mumbai.

 P.P.Sharma. 2008. Cosmetics- Formulation, Manufacturing & Quality Control, Edition 4, Vandana Publications, New Delhi.

 Supriya K B. 2005. Handbook of Aromatic Plants, Edition II(Revised and Enlarged), Pointer Publishers, Jaipur.

 Skaria P. 2007. Aromatic Plants (Horticulture Science Series Vol. 1) , Edition I, New India Publishing Agency, New Delhi.

 Kathi Keville and Mindy Green.1995. Aromatheraphy (A Complete Guide to the Healing Art), Edition I, Sri Satguru Publications, New Delhi.

 Chattopadhyay PK. 2000. Herbal Cosmetics & Ayurvedic Medicines (EOU), Edition I, National Institute of Industrial Research, Delhi.

 Balsam MS & Edward Sagarin. 2008. Cosmetics Science and Technology, Edition II (Vol-II), Wiley Interscience, New York.

PHARMACOGNOSY PRACTICAL-II (MPG205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization of whole cell
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde
8. Estimation of phenolic content in herbal raw materials
9. Estimation of alkaloid content in herbal raw materials
10. Estimation of flavonoid content in herbal raw materials

11. Preparation and standardization of various simple dosage forms from Ayurvedic, siddha, homoeopathy and Unani formulary

12. Preparation of certain Aromatherapy formulations

13. Herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products

14. Evaluation of herbal tablets and capsules

15. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction

16. Formulation of cough syrup

M. PHARM. PHARMACOLOGY (MPC)

SEMESTER-1

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills

THEORY **60 HOURS**

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

12 Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

12 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

12 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

12 Hrs

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

X ray Crystallography: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED PHARMACOLOGY-I (MPL101T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

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

 Discuss the pathophysiology and pharmacotherapy of certain diseases

 Explain the mechanism of drug actions at cellular and molecular level

 Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY **60HOURS**

UNIT-I

General Pharmacology

12 Hrs

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

UNIT-II

12 Hrs

Neurotransmission

06 Hrs

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

06 Hrs

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

a. Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT-III

12 Hrs

Central nervous system Pharmacology

General and local anesthetics 02 hrs

Sedatives and hypnotics, drugs used to treat anxiety. 02 hrs

Depression, psychosis, mania, epilepsy, neurodegenerative diseases. 05 hrs

Narcotic and non-narcotic analgesics. 03 hrs

UNIT-IV

Cardiovascular Pharmacology

12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure

and hyperlipidemia. 07 hrs

Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs 05 hrs

UNIT- V

Autocoid Pharmacology

12 Hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins

Opioid autocoids. 08 hrs

Pharmacology of antihistamines, 5HT antagonists. 04 hrs

REFEERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man‘s

2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan et al.

3. Basic and Clinical Pharmacology by B.G -Katzung

4. Pharmacology by H.P. Rang and M.M. Dale.

6. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.

7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I (MPL102T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

Objectives

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

 Appraise the regulations and ethical requirement for the usage of experimental animals.

 Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals

 Describe the various newer screening methods involved in the drug discovery process

 Appreciate and correlate the preclinical data to humans

THEORY **60 HOURS**

Unit-I

12 Hrs

Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals. 02 hrs

Transgenic animals: Production, maintenance and applications 02 hrs

Anaesthesia and euthanasia of experimental animals. 03 hrs

Maintenance and breeding of laboratory animals. 02 hrs

CPCSEA guidelines to conduct experiments on animals 02 hrs

Good laboratory practice. 01 hrs

Unit-II

12 Hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple

sclerosis. Drugs acting on Autonomic Nervous System.

Unit-III

12 Hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro,* and other possible animal alternative models.

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.

Unit-IV

12 hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro,* and other possible animal alternative models.

Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and agents. Anti cancer agents

Unit V

12 hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo, in vitro,* and other possible animal alternative models.

Immunosuppressants and immunomodulators 02 hrs

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin 08 hrs

Limitations of animal experimentation and alternate animal experiments. 01 hr

Extrapolation of *in vitro* data to preclinical and preclinical to humans. 01 hr

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin

2. Indian Pharmacopeia and other Pharmacopeias

3. Screening methods in Pharmacology by Robert Turner. A

4. Evaluation of drugs activities by Laurence and Bachrach

5. Methods in Pharmacology by Arnold Schwartz.

6. Fundamentals of experimental Pharmacology by M.N.Ghosh

7. Pharmacological experiment on intact preparations by Churchill Livingstone

8. Drug discovery and Evaluation by Vogel H.G.

9. Experimental Pharmacology by R.K.Goyal.

10. Preclinical evaluation of new drugs by S.K. Gupta

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process

Objectives:

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

 Explain the receptor signal transduction processes.

 Explain the molecular pathways affected by drugs.

 Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.

 Demonstrate molecular biology techniques as applicable for pharmacology

Unit I

12 Hrs

Cell biology

Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

Unit II

12Hrs

Cell signaling

Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; Gprotein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5- trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

Unit III

12Hrs

Principles and applications of genomic and proteomic tools 06 hrs

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

Recombinant DNA technology and gene therapy 06 hrs

Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV

12Hrs

Pharmacogenomics 08 hrs

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics **04 hrs**

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V

12Hrs

Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays

Principles and applications of flow cytometry

Unit VI

Biosimilars

References:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.

2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong

Immunotherapeutics

3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al

4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al

5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller

6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)

7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

PHARMACOLOGY PRACTICAL-I (MPL104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer

2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC

4. Experiments based on Gas Chromatography

5. Estimation of riboflavin/quinine sulphate by fluorimetry

6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.

2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.

3. Functional observation battery tests (modified Irwin test)

4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.

5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.

6. Evaluation of diuretic activity.

7. Evaluation of antiulcer activity by pylorus ligation method.

8. Oral glucose tolerance test.

9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).

10. Isolation of RNA from yeast

11. Estimation of proteins by Braford/Lowry's in biological samples.

12. Estimation of RNA/DNA by UV Spectroscopy

13. Gene amplification by PCR.

14. Protein quantification Western Blotting.

15. Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).

16. Cell viability assays (MTT/Trypan blue/SRB).

17. DNA fragmentation assay by agarose gel electrophoresis.

18. DNA damage study by Comet assay.

19. Apoptosis determination by fluorescent imaging studies.

20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares

21. Enzyme inhibition and induction activity

22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)

23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

References

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,

2. Fundamentals of experimental Pharmacology by M.N.Ghosh

3. Handbook of Experimental Pharmacology by S.K. Kulkarni.

4. Drug discovery and Evaluation by Vogel H.G.

5. Spectrometric Identification of Organic compounds - Robert M Silverstein,

6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,

7. Vogel‘s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,

8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille

9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)

10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

SEMESTER-II

ADVANCED PHARMACOLOGY-II (MPL201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

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

 Explain the mechanism of drug actions at cellular and molecular level

 Discuss the Pathophysiology and pharmacotherapy of certain diseases

 Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

UNIT-I

Endocrine Pharmacology 12 Hrs

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

UNIT-II

Chemotherapy 12 Hrs

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT-III 12 Hrs

Chemotherapy 06 Hrs

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology 06 Hrs

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

UNIT-IV

GIT Pharmacology 08 Hrs

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology 04 Hrs

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V

Free radicals Pharmacology 04 Hrs

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment: 08 Hrs

Alzheimer ’s disease, Parkinson’s disease , Cancer, Diabetes mellitus

References

1. The Pharmacological basis of therapeutics- Goodman and Gill man‘s

2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.

3. Basic and Clinical Pharmacology by B.G -Katzung

4. Pharmacology by H.P. Rang and M.M. Dale.

5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.

6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.

7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL202T)

Scope:

The subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

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

 Explain the various types of toxicity studies.

 Appreciate the importance of ethical and regulatory requirements for toxicity studies.

 Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Unit I

12 Hrs

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)

Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP)

History, concept and its importance in drug development

Unit II

12 Hrs

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.

Test item characterization- importance and methods in regulatory toxicology studies

Unit III

12 Hrs

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II)

Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies)

In vivo carcinogenicity studies

Unit IV

12 Hrs

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

Unit V

12 Hrs

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics

Importance and applications of toxicokinetic studies.

Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).

2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi

3. Drugs from discovery to approval by Rick NG.

4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan

5. OECD test guidelines.

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.

7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

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

 Explain the various stages of drug discovery.

 Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery

 Explain various targets for drug discovery.

 Explain various lead seeking method and lead optimization

 Appreciate the importance of the role of computer aided drug design in drug discovery

Unit-I

12 Hrs

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit-II

12 Hrs

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

Unit-III

12 Hrs

Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Unit-IV

12 Hrs

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit-V

12 Hrs

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

References

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.

2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.

3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.

4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH

6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.

7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., Hoboken, New Jeney.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

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

 Explain the regulatory requirements for conducting clinical trial

 Demonstrate the types of clinical trial designs

 Explain the responsibilities of key players involved in clinical trials

 Execute safety monitoring, reporting and close-out activities

 Explain the principles of Pharmacovigilance

 Detect new adverse drug reactions and their assessment

 Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

UNIT-I

12 hours

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee- Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR

Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT- II

12 hours

Clinical Trials: Types and Design

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

UNIT- III

12 hours

Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

UNIT-IV

12 hours

Basic aspects, terminologies and establishment of pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring

programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

UNIT-V

12 hours

Methods, ADR reporting and tools used in Pharmacovigilance

International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

UNIT-VI

Pharmacoepi Dermatology , pharmacoeconomics , safety pharmacology

References:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.

2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.

7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGY PRACTICAL-II (MPL205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.

2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.

3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.

4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation

5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation

6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.

7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.

8. To study the effects of various drugs on isolated heart preparations

9. Recording of rat BP, heart rate and ECG.

10. Recording of rat ECG

11. Drug absorption studies by averted rat ileum preparation.

12. Acute oral toxicity studies as per OECD guidelines.

13. Acute dermal toxicity studies as per OECD guidelines.

14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.

15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.

16. Protocol design for clinical trial.

17. Protocol design for clinical trial.

18. Protocol design for clinical trial.

19. Design of ADR monitoring protocol.

20. In silico docking studies.

21. In silico pharmacophore based screening.

22. In silico QSAR studies.

23. ADR reporting

24. In silico docking studies.

References

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh

2. Hand book of Experimental Pharmacology-S.K.Kulakarni

3. Text book of *in-vitro* practical Pharmacology by Ian Kitchen

4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen

5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.

6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

M.PHARM. DRUG REGULATORY AFFAIRS (DRA)

SEMESTER-1

GOOD PHARMACEUTICAL PRACTICES (DRA 101T)

Scope

This course is designed to impart fundamental knowledge biological and medical devices on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP pharmaceutical industries and understand the rationale behind these requirements and will propose ways and means of complying them.

Objectives

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

 The key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices

 The check lists for various Good Regulatory Practices and

 Prepare SOPs for Good Pharmaceutical Practices

 Implement Good Regulatory Practices in the Health care Industries and

 Prepare for the Audit of the Pharmaceutical Industries.

 Prepare for the rediness and conduct of the audit/inspections

THEORY **60Hrs**

1. **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical devices, GHTF guidance docts

12Hrs

2. **Good Laboratory Practices:** Introduction,USFDA GLP Regulations (Subpart A to Subpart K),Controlling the GLP inspection process,GLP Documentation,Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, ISO

12Hrs

3. **Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP

Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11,General check list of 21CFR Part 11, Software Evaluation checklist, ISO.

12Hrs

4. **Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP(Supply chain integrity), GHTF guidance/IMDRF/CDSCO

12Hrs

5. **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Schedule M III

12Hrs

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition,Drugs and the Pharmaceutical Sciences, Vol.168

2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press

3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.

4. How to practice GLP by PP Sharma, Vandana Publications.

5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

PHARMACEUTICAL REGULATIONS IN INDIA (DRA 102T)

Scope:

This course is designed to impart fundamental knowledge on regulations and legislations in India with respect to PMBC. It prepares the students for basic regulatory requirements in India of PMB for manufacture, import, registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives:

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

 Know different Acts and guidelines that regulate PMBC industry in India.

 Understand the approval process and regulatory requirements for drugs and medical devices

THEORY 60 HOURS

UNIT I

 Study of Relevant provisions of FPMBC

 Acts and Rules (with latest amendments):

 Drugs and Cosmetics Act 1940 and other Relevant provisions (Rules, Schedules and Guidelines) for approval of FPMBC , Rules 1945: DPCO and NPPA

 Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs& Packing of drugs & other related Acts-Narcotic etc Central Drug Standard Control Organization and State Licensing Authority:

1. Rules, Regulations, Guidelines For Regulatory filling of FPMB to Relevant Regulations

2. Fomat and contents of Regulatory dossier filling

3. Clinical trials /Investigations

 Clinical Trials

 New Drugs

 Medical Devices

 Fixed Dose Combinations

12 Hrs

UNIT II

Regulatory requirements FNPCMB and approval procedures for:

12 Hrs

UNIT III

Indian Pharmacopoeial standards

 BIS Standards & ISO and other relevant standards

UNIT IV

BA/ BE: Bioavailability and Bioequivalence data, BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study

Stability requirements: ICH and WHO

Guidelines for drug testing in animals/Preclinical studies

 Animal testing: Rationale for conducting studies, CPCSEA Guidelines

 ethical guidelines for human participants

 ICMR-DBT Guidelines for Stem Cell Research

12 Hrs

UNIT V

Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

12 Hrs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India

2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer

3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee

4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.

5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)

6. ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite

7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)

8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO

9. Guidelines for Import and Manufacture of Medical Devices by CDSCO

10. Guidelines from official website of CDSCO

INTERNATIONAL PHARMACEUTICAL REGULATIONS-I (DRA103T)

Scope:

This course is designed to impart the fundamental knowledge on the drug development general regulatory requirements for approval of FNPCMB Japan. It prepares the students to have elimentary knowledge on the regulatory requirements, documentation requirements, and registration procedures for marketing the products in above countries.

Objectives: Upon completion of the course, the student shall be able to understand the Regulatory registration and landscape

THEORY **60 Hours**

Unit-I

12 Hours

USA and CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA

Unit-II

12 Hours

EUROPEAN UNION and AUSTRALIA: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU

Unit-III

12 Hours

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan

UNIT IV

BRAZIL and CHINA

UNIT V

ASEAN and SOUTH ASIA

REFERENCES:

Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer,

Marcel Dekker series, Vol.143Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel

Dekker Series,Vol.144

1. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.

Martin, Drugs and the Pharmaceutical Sciences,Vol.185 Informa Health care Publishers.

2. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5^{th} edition, Drugs and the Pharmaceutical Sciences, Vol.190.

3. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

4. Drugs: From Discovery to Approval, Second Edition By Rick Ng

5. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu

6. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko

7. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema

8. Country Specific Guidelines from official websites.

CLINICAL RESEARCH REGULATIONS (DRA 104T)

Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of FNPCMB, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in INDIA. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical trials and investigations

Objectives: Upon completion of the course, the student shall be able to (know, do and appreciate)

- Clinical drug development process and different phases of clinical trials, investigations
- History, origin and ethics of clinical research
- regulatory requirements for conducting clinical trials investigations and research
- regulations and guidance governing the conduct of clinical research,

THEORY **60 Hours**

Unit-I

12 Hours

Basics for Clinical trials for drug development process

- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices)
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form

 The informed consent process and documentation

Unit-II

12 Hours

Basic CT for MD Ethics in Clinical Research:

 Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis

Study, The Belmont Report, The declaration of Helsinki

 Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

 The ethics of randomized clinical trials

 The role of placebo in clinical trials

 Ethics of clinical research in special population

 Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data

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 Data safety monitoring boards.

 Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

Unit-III

12 Hours

Regulations governing Clinical Trials

USA: Regulations to conduct drug studies in USA (FDA)

 NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)

 NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)

 ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)

 FDA Guidance for Industry - Acceptance of Foreign Clinical Studies

 FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

India: Clinical Research regulations in India – Schedule Y

Unit-IV

Clinical Research Related Guidelines **12 Hours**

 Good Clinical Practice Guidelines (ICH GCP E6)

 Indian GCP Guidelines

 ICMR Ethical Guidelines for Biomedical Research

 CDSCO guidelines

Regulatory Guidance on Efficacy and Safety

ICH Guidance's

 E4 – Dose Response Information to support Drug Registration

 E7 – Studies in support of General Population: Geriatrics

 E8 – General Considerations of Clinical Trials

 E10 – Choice of Control Groups and Related Issues in Clinical Trials,

 E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

Unit-V 12 Hours

USA & EU Guidance

USA: FDA Guidance

 CFR 21Part 50: Protection of Human Subjects

 CFR 21Part 54: Financial Disclosure by Clinical Investigators

 CFR 21Part 312: IND Application

 CFR 21Part 314: Application for FDA Approval to Market a New Drug

 CFR 21Part 320: Bioavailability and bioequivalence requirements

 CFR 21Part 812: Investigational Device Exemptions 213

 CFR 21Part 822: Post-market surveillance

 FDA Safety Reporting Requirements for INDs and BA/BE Studies

 FDA Med Watch

 Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

 EU Directives 2001

 EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use

 EU Annual Safety Report (ASR)

 Volume 9A – Pharmacovigilance for Medicinal Products for Human Use

REFERENCES:

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams

2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD

3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and

Frederick P. Ognibene

4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.

5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy;

Anthony C. Cartwright; Taylor & Francis Inc., USA.

6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc.,

NY.

7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA

8. Country Specific Guidelines from official websites.

RECOMMENDED WEBSITES:

1. 1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf

2. Code of Federal Regulations FDA:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

3. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html

4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm

5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm

6. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk 214

7. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCOGuidanceForIndustry. pdf

8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

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PHARMACEUTICAL REGULATORY AFFAIRS PRACTICAL-I (MRA105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.

2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.

3. Preparation of SOPs, Analytical reports (Stability and validation)

4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)

5. Labeling comparison between brand & generics.

6. Preparation of clinical trial protocol for registering trial in India

7. Registration for conducting BA/ BE studies in India

8. Import of drugs for research and developmental activities

9. Preparation of regulatory dossier as per Indian CTD format

10. Registering for different Intellectual Property Rights in India

11. GMP Audit Requirements as per CDSCO

12. Preparation and documentation for Indian Patent application.

13. Preparation of checklist for registration of IND as per ICH CTD format.

14. Preparation of checklist for registration of NDA as per ICH CTD format.

15. Preparation of checklist for registration of ANDA as per ICH CTD format.

16. Case studies on response with scientific rationale to USFDA Warning Letter

17. Preparation of submission checklist of IMPD for EU submission.

18. Comparison study of marketing authorization procedures in EU.

19. Comparative study of DMF system in US, EU and Japan

20. Preparation of regulatory submission using eCTD software

21. Preparation of Clinical Trial Application (CTA) for US submission

22. Preparation of Clinical Trial Application (CTA) for EU submission

23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.

24. Regulatory requirements checklist for conducting clinical trials in India.

25. Regulatory requirements checklist for conducting clinical trials in Europe.

26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER-II

DOCUMENTATION AND REGULATORY WRITING (DRA 201T)

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

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

1. Know the various documents pertaining to drugs in pharmaceutical industry

2. Understand the basics of regulatory compilation

3. Create and assemble the regulation submission as per the requirements of agencies

4. Follow up the submissions and post approval document requirements

1. ***Documentation in pharmaceutical industry***: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development

Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch

Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

2. ***Dossier preparation and submission:*** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions

Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission

3. ***Audits:*** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection

4. ***Inspections:*** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA)

5. ***Product life cycle management:*** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.

2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley- Interscience, A John Wiley and sons, Inc., Publications.

3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.

4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana

Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000

6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001

8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001

9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997

10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications

12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications

BIOLOGICALS REGULATIONS (DRA 202T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives

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

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Theory **60 Hrs**

Unit I

1.India : Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

12 Hrs

Unit II

2.USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labeling and packing of biologics

12 Hrs

Unit III

3. European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

12 Hrs

Unit IV

4. **Vaccine regulations in India, US and European Union**: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

12 Hrs

Unit V

5**. Blood and Blood Products Regulations in India, US and European Union**: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)

12 Hrs

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008

2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley, 2013

3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011

4. www.who.int/biologicals/en

5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/

6. www.ihn-org.com

7. www.isbtweb.org

8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India

9. www.cdsco.nic.in

10. www.ema.europa.eu › scientific guidelines › Biologicals

11. www.fda.gov/biologicsbloodVaccines/GuidanceCompliance Regulatory Information (Biologics)

INTERNATIONAL PHARMACEUTICAL REGULATIONS – II (DRA 203T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements for registration of drugs, medical devices and post approval requirements in WHO and emerging market (rest of world countries) like CIS,GCC, LATAM, ASIAN and African region.

Objectives

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

 Know the regulatory Requirements for drug and medical device registration in emerging market;

 Understand the registration requirements of emerging market by comparison; and

 Prepare dossiers for the registration of the products in emerging market.

THEORY **60 HOURS**

1. **Emerging Market:** Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

12Hrs

2. **WHO:** WHO GMP,Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

12Hrs

3. **ASIAN Countries:** Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in **China and South Korea** & **Association of Southeast Asian Nations (ASEAN) Region** i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

12Hrs

4. **CIS (Commonwealth Independent States):** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine

12Hrs

5. **GCC (Gulf Cooperation Council) for Arab states:** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

12Hrs

REFERENCES

1.http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf

2. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2

3. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7

4. Building a Future With Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer

5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,

6. The world Bank, Washington, DC, ISBN: 0-8212-5896-0

7. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139

8. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)

9. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9

10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

MEDICAL DEVICE REGULATIONS (DRA 204T)

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and *in vitro* diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and ASEAN countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices in regulated countries.

Objectives:

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

- basics of medical devices, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing medical devices

 regulatory approval process for medical devices in US, EU and Asia

 clinical aspects of medical devices

THEORY 60 Hours

Unit-I

12 Hours

Medical Devices: Introduction, differentiating medical devices from IVDs and Combination Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices, Classification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

Unit-II

12 Hours

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971**,** Validation and Verification of Medical device, Adverse Event Reporting of Medical device

Unit-III

12 Hours

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and *In vitro* Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of *In vitro* diagnostics, classification and approval process.

Unit-IV

12 Hours

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and *In vitro* Diagnostics (*In Vitro* Diagnostics Directive), CE certification process. Basics of *In vitro* diagnostics, classification and approval process.

Unit-V

12 Hours

Medical Device Regulations in World Health Organization (WHO): Registration Procedures,

Quality System requirements and Regulatory requirements **Asia:** Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

REFERENCES:

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.

2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan

3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh

4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina

5. Country Specific Guidelines from official websites.

PHARMACEUTICAL REGULATORY AFFAIRS PRACTICAL-II (DRA 205P)

Number of Practicals based on above mentioned Theory.

M. PHARM. INDUSTRIAL PHARMACY

SEMESTER-1

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

12 Hrs

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

12 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

12 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

12 Hrs

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP101T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D

Objectives

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

- The scheduled activities in a Pharmaceutical firm.

- The pre formulation studies of pilot batches of pharmaceutical industry.

- The significance of dissolution and product stability

THEORY **60Hrs**

12 Hrs

1. Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drugexcipient compatibility studies, methods of determination.

12 Hrs

2. Formulation Additives: Study of different formulation additivies, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

12 Hrs

3. **Solubility:** Importance, experimental determination, phase-solubility analysis, pHsolubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

12 Hrs

4. **Dissolution:** Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, *in-vitro* and *in-vivo* correlations, levels of correlations.

12 Hrs

5. Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

REFERENCES:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3 rd ed., Varghese Publishers, Mumbai 1991.

2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 th ed., B.I. Publications Pvt. Ltd, Noida, 2006.

3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.

4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.

5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., . New York, 1981

6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi,2005.

7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.

8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.

9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.

10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.

11. W. Grimm - Stability testing of drug products.

12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.

13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.

14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.

15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.

16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.

CUSTOMIZED DRUG DELIVERY SYSTEMS (MIP102T)

Scope

This course is designed to impart knowledge and skills necessary to train the students in the area of customized drug delivery systems.

Objective

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

 The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.

 To formulate and evaluate various customized/novel drug delivery systems

THEORY **60Hrs**

12 Hrs

1. Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for Drug Delivery: Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

12 Hrs

2. Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems.

12 Hrs

3. Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc and it's regulatory aspects.

12 Hrs

4. Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythorocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.

Biotechnology in Drug Delivery Systems: Brief review of major are as recombinant DNA technology, monoclonal antibodies, gene therapy.

12 Hrs

5. Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES:

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

DRUG REGULATIONS AND INTELECTUAL PROPERTY RIGHTS (MIP103T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

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

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY **60Hrs**

12 Hrs

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

12 Hrs

2. Role of GATT, TRIPS, and WIPO.

12 Hrs

3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector,

12 Hrs

4. Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

12 Hrs

5. Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition

2. Applied Production and Operation Management By Evans, Anderson and Williams

3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers

4. ISO 9000-Norms and explanations 148

5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

INDUSTRIAL PHARMACY PRACTICAL-I (MIP104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer

2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC

4. Experiments based on Gas Chromatography

5. Estimation of riboflavin/quinine sulphate by fluorimetry

6. Estimation of sodium/potassium by flame photometry

7. Effect of surfactants on the solubility of drugs.

8. Effect of pH on the solubility of drugs.

9. Dissolution methods of transdermal drug delivery systems.

10. Stability testing of solution and solid dosage forms for photo degradation..

11. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40^{o}C, 75% RH.

12. Compatibility evaluation of drugs and excipients.

13. Preparation and evaluation of different polymeric membranes.

14. Formulation and evaluation of sustained release oral matrix tablet.

15. Formulation and evaluation of sustained release oral reservoir system.

16. Formulation and evaluation of microspheres / microcapsules.

17. Formulation and evaluation of transdermal films.

18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

SEMESTER-II

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP201T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

Objectives

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

 The basic concepts in Biopharmaceutics and pharmacokinetics.

 The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

 To critically evaluate Biopharmaceutics studies involving drug product equivalency.

 To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY **60Hrs**

12Hrs

1. Drug Absorption From The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH– partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes– Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations.

12Hrs

3. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

12Hrs

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

12Hrs

5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics and Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985

4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book

5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982

6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.

10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.

11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip J Breen,pharmaceutical press, RPS Publishing,2009.

13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

SCALE UP AND TECHNOLOGY TRANSFER (MIP202T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:

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

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY **60Hrs**

12Hrs

1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentrals and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentrals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

12Hrs

2. Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

12Hrs

3. Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

12Hrs

4. Process validation: importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

12Hrs

6. Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.

2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.

3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.

4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.

5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.

6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.

8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

9. Subrahmanyam, CVS, Pharmaceutical production and Management,2007,Vallabh Prakashan,Dehli.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP203T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives

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

 Handle the scheduled activities in a Pharmaceutical firm.

 Manage the production of large batches of pharmaceutical formulations.

THEORY **60Hrs**

12Hrs

1. Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

12Hrs

2. Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

12Hrs

3. Lyophilization Technology: Principles, process, freeze-drying equipments.

12Hrs

4. Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Packaging Technology: Types of packaging materials, machinery, labeling, package printin for different dosage forms.

12Hrs

5. Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.

Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.

REFERENCES:

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.

2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.

3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.

5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.

6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.

7. Product design and testing of polymeric materials by N.P. Chezerisionoff.

8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.

9. Packaging Pharmaceutical and Health Care, H.Lockhard.

10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.

11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.

12. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK. 156

ENTREPRENEURSHIP MANAGEMENT (MIP204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives:

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

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

THEORY **60Hrs**

12Hrs

1. Conceptual Frame Work

Concept need and process in entrepreneurship development. Role of enterprise in national and global economy.Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management

12Hrs

2. Entrepreneur

Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency– Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

12Hrs

3. Launching And Organising An Enterprise

Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

12Hrs

4. Growth Strategies And Networking

Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

12Hrs

5. Preparing Project Proposal To Start On New Enterprise

Project work – Feasibility report; Planning, resource mobilisation and implementation.

REFERENCES:

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.

2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.

3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.

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Number of Practicals based on above mentioned Theory.