

BIJU PATNAIK UNIVERSITY OF TECHNOLOGY, ORISSA, ROURKELA
POST GRADUATE PROGRAMME IN PHARMACEUTICAL SCIENCES
(M. PHARM.)

SCHEME OF INSTRUCTIONS

M.PHARM. – I SEMESTER

Course Code	Subject Title	L	T	P	Credits
M.PH. 1.1	Modern Analytical Techniques (common to all specializations)	3	0	0	3
M.PH. 1.2	Modern Analytical Techniques Practical (common to all specializations)	0	0	6	4
M.PH. 1.3	Biostatistics (common to all specializations)	3	0	0	3
M.PH. 1.4	Drug Regulatory Affairs and Intellectual Property Rights (common to all specializations)	3	0	0	3
M.PH. 1.5 (A to G)	Paper based on Specialization	3	0	0	3
M.PH. 1.6 (A to G)	Practical based on Specialization	0	0	6	4
M.PH. 1.7	Seminar / Assignment (common to all specializations)	0	0	3	2
M.PH. 1.8	Comprehensive Viva (common to all specializations)	0	0	0	3
T O T A L :		12	0	15	25

Total Credits for I Semester - 25

Contact hours - 27 Hrs / Week

Details of Specialization Paper and Practical against M.PH. 1.5A to G and M.PH.1.6A to G for different Specializations in M. Pharm. – I semester:

<u>Specialization</u>	<u>Paper Code and Title</u>	<u>Practical Code and Title</u>
PHARMACEUTICS	M.PH. 1.5A / M.PH. 1.5G Formulation Development	M.PH. 1.6A / M.PH. 1.6G Formulation Development Practical
PHARMACEUTICAL CHEMISTRY	M.PH. 1.5B Stereo Chemistry of drugs and Mechanism of Reactions	M.PH. 1.6B Stereo Chemistry of drugs and Mechanism of Reactions Practical
PHARM. ANALYSIS & QUALITY ASSURANCE	M.PH. 1.5C Stability of Drugs and Drug Products	M.PH. 1.6C Stability of Drugs and Drug Products Practical
PHARMACOLOGY	M.PH. 1.5D Pharmacological Screening Methods	M.PH. 1.6D Pharmacological Screening Methods Practical
BIOTECHNOLOGY	M.PH.1.5E Advanced Pharm. Biotechnology - I	M.PH. 1.6E Advanced Pharm. Biotechnology – I Practical
PHARMACOGNOSY	M.PH. 1.5F Advanced Pharmacognosy -I	M.PH. 1.6F Advanced Pharmacognosy –I Practical
PHARMACEUTICAL TECHNOLOGY	M.PH. 1.5G/ M.PH. 1.5A Formulation Development	M.PH. 1.6G / M.PH. 1.6A Formulation Development Practical

M.PHARM. – II SEMESTER (PHARMACEUTICS)

Course Code	Subject Title	L	T	P	Credits
M.PH2A.1	Advanced Physical Pharmaceutics	3	0	0	3
M.PH2A.2	Bio-Pharmaceutics and Pharmacokinetics	3	0	0	3
M.PH2A.3	Bio-Pharmaceutics and Pharmacokinetics Practical	0	0	6	4
M.PH2A.4	Novel Drug Delivery Systems	3	0	0	3
M.PH2A.5	Novel Drug Delivery Systems Pract.	0	0	6	4
M.PH2A.6	Advanced Pharmaceutical Technology	3	0	0	3
M.PH2A.7	Seminar / Assignment	0	0	3	2
M.PH2A.8	Comprehensive Viva	0	0	0	3
TOTAL:		12	0	15	25

Total Credits for II Semester - 25

Contact hours - 27 Hrs / Week

NOTE: M.PH2A.2, M.PH2A.3, M.PH2A.4, M.PH2A.5 and M.PH2A.6 papers of M. Pharm. Pharmaceutics specialization are the same as M.PH2G.2, M.PH2G.3, M.PH2G.4, M.PH2G.5 and M.PH2G.6 papers respectively of M. Pharm. Pharmaceutical Technology specialization.

M.PHARM. – II SEMESTER (PHARMACEUTICAL (CHEMISTRY))

Course Code	Subject Title	L	T	P	Credits
M.PH2B.1	Advanced Medicinal Chemistry-I	3	0	0	3
M.PH2B.2	Advanced Medicinal Chemistry-II	3	0	0	3
M.PH2B.3	Advanced Medicinal Chemistry-III	3	0	0	3
M.PH2B.4	Advanced Medicinal Chemistry-III Practical	0	0	6	4
M.PH2B.5	Chemistry of Natural Products	3	0	0	3
M.PH2B.6	Chemistry of Natural Products Pract.	0	0	6	4
M.PH2B.7	Seminar / Assignment	0	0	3	2
M.PH2B.8	Comprehensive Viva	0	0	0	3
TOTAL:		12	0	15	25

Total Credits for II Semester - 25

Contact hours - 27 Hrs / Week

M.PHARM. – II SEMESTER (PHARM. ANALYSIS & QUALITY ASSURANCE)

Course Code	Subject Title	L	T	P	Credits
M.PH2C.1	Quality Assurance of Pharmaceuticals	3	0	0	3
M.PH2C.2	Advanced Pharmaceutical Analysis -I	3	0	0	3
M.PH2C.3	Advanced Pharm. Analysis - I Practical	6	0	0	4
M.PH2C.4	Advanced Pharmaceutical Analysis -II	3	0	0	3
M.PH2C.5	Phyto-pharmaceutical Analysis	0	0	6	4
M.PH2C.6	Phyto-pharmaceutical Analysis Practical	3	0	0	3
M.PH2C.7	Seminar / Assignment	0	0	3	2
M.PH2C.8	Comprehensive Viva	0	0	0	3
TOTAL:		12	0	15	25

Total Credits for II Semester - 25

Contact hours - 27 Hrs / Week

M.PHARM. – II SEMESTER (PHARMACOLOGY)

Course Code	Subject Title	L	T	P	Credits
M.PH2D.1	Pharmacokinetics & Drug metabolism	3	0	0	3
M.PH2D.2	Pharmacokinetics & Drug metabolism Practical	0	0	6	4
M.PH2D.3	General Pharmacology	3	0	0	3
M.PH2D.4	General Pharmacology practical	0	0	6	4
M.PH2D.5	Clinical Pharmacology and Toxicology.	3	0	0	3
M.PH2D.6	Recent Advances in Pharmacology	3	0	0	3
M.PH2D.7	Seminar / Assignment	0	0	3	2
M.PH2D.8	Comprehensive Viva	0	0	0	3

TOTAL : 12 0 15 25

Total Credits for II Semester - 25

Contact hours - 27 Hrs / Week

M.PHARM. – II SEMESTER (PHARMACEUTICAL BIOTECHNOLOGY)

Course Code	Subject Title	L	T	P	Credits
M.PH2E.1	Molecular Biology & Recombinant DNA Technology	3	0	0	3
M.PH2E.2	Molecular Biology & Recombinant DNA Technology Practical	0	0	6	4
M.PH2E.3	Animal Biotechnology & Immune Technology	3	0	0	3
M.PH2E.4	Advanced Pharm. Biotechnology-II	3	0	0	3
M.PH2E.5	Bioprocess Technology	3	0	0	3
M.PH2E.6	Bioprocess Technology Practical	0	0	6	4
M.PH2E.7	Seminar / Assignment	0	0	3	2
M.PH2E.8	Comprehensive Viva	0	0	0	3

TOTAL : 12 0 15 25

Total Credits for II Semester - 25

Contact hours - 27 Hrs / Week

M.PHARM. – II SEMESTER (PHARMACOGNOSY)

Course code	Subject Title	L	T	P	Credits
M.PH2F.1	Industrial Pharmacognosy - I	3	0	0	3
M.PH2F.2	Industrial Pharmacognosy - I (Practical)	0	0	6	4
M.PH2F.3	Herbal Drug Formulation & Standardization	3	0	0	3
M.PH2F.4	Herbal Drug Formulation & Standardization practical	0	0	6	4
M.PH2F.5	Chemistry of Natural Products	3	0	0	3
M.PH2F.6	Advanced Pharmacognosy-II(Medicinal Plant Biotechnology)	3	0	0	3
M.PH2F.7	Seminar/Assignment	0	0	3	2
M.PH2F.8	Comprehensive Viva	0	0	0	3
	Total	12	0	15	25

Total Credits for II Semester-25

Contact hours-27hrs/week

M.PHARM. – II SEMESTER (PHARMACEUTICAL TECHNOLOGY)

Course Code	Subject Title	L	T	P	Credits
M.PH2G.1	Biotechnology	3	0	0	3
M.PH2G.2	Bio-Pharmaceutics and Pharmacokinetics	3	0	0	3
M.PH2G.3	Bio-Pharmaceutics and Pharmacokinetics Practical	0	0	6	4
M.PH2G.4	Novel Drug Delivery Systems	3	0	0	3
M.PH2G.5	Novel Drug Delivery Systems Pract.	0	0	6	4
M.PH2G.6	Advanced Pharmaceutical Technology	3	0	0	3
M.PH2G.7	Seminar / Assignment	0	0	3	2
M.PH2G.8	Comprehensive Viva	0	0	0	3
TOTAL :		12	0	15	25

Total Credits for II Semester - 25

Contact hours - 27 Hrs / Week

NOTE: M.PH2A.2, M.PH2A.3, M.PH2A.4, M.PH2A.5 and M.PH2A.6 papers of M. Pharm. Pharmaceutics specialization are the same as M.PH2G.2, M.PH2G.3, M.PH2G.4, M.PH2G.5 and M.PH2G.6 papers respectively of M. Pharm. Pharmaceutical Technology specialization.

M.PHARM. – III SEMESTER (COMMON FOR ALL SPECIALIZATIONS)

Course Code	Subject Title	Credits
M.PH. 3.1	Seminar – I (Mid Semester / Literature Survey of the project)	2
M.PH. 3.2.	Seminar – II (End Semester / Progress of the project)	2

M.PHARM. – IV SEMESTER (COMMON FOR ALL SPECIALIZATIONS)

Course Code	Subject Title	Credits
M.PH. 4.1	Project Dissertation	30
M.PH. 4.2.	Project Seminar and Viva-voce	6

Credit Distribution:

I Semester	25
II Semester	25
III Semester	04
IV Semester	36
Total -----	90

**M.PH. 1.1 MODERN ANALYTICAL TECHNIQUES
THEORY**

3 Hrs/Week

UNIT – I

Theory, instrumentation and application with regard to drug analysis, decomposition product identification and estimation and metabolite analysis based on the following:

- (a) Ultraviolet – visible spectrophotometry (b) Infrared spectrophotometry

UNIT – II

Theory, instrumentation, practical considerations, structural elucidation and applications of the following:

- (a) H^1 N.M.R & C^{13} N.M.R (b) Mass spectroscopy

UNIT – III

Chromatographic methods: Gas Chromatography including GC-MS, High performance liquid chromatography; H.P.T.L.C and Super critical fluid chromatography.

UNIT – IV

Special Techniques like Immunological methods (RIA – ELISA) and electrophoreses (gel and capillary)

Basic concepts of Good laboratory practices (GLP) and laboratory maintenance. Standard Operating Procedures (SOPs) and validation of some analytical instruments..

REFERENCES:

- 1.Organic Spectroscopy by William Kemp
- 2.Instrumental Methods of Analysis by Scoog and West.
- 3.Practical pharmaceutical Chemistry Vol. I & II by Beckett & Stenlake
- 4.Vogel's textbook of Quantitative Chemical Analysis.
- 5.Instrumental methods of analysis by Willard Denn & Merrit.
- 6.High Performance Liquid Chromatography by P.D.Sethy.
- 7.A Text book of Pharmaceutical Analysis by K.A.Conners.
- 8.I.P.
- 9.B.P.
10. USP
11. Remington's Pharmaceutical Sciences

**M.PH. 1.2 MODERN ANALYTICAL TECHNIQUES
PRACTICAL**

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Use of spectrophotometer for analysis of pharmacopoeial compounds and their formulations.
2. Use of fluorimeter for analysis of pharmacopoeial compounds.
3. Use of Flame Photometer for analysis of Na, K^+ & Ca^{++} etc. in Biological fluids and formulations.
4. Use of Potentiometer and Conductometer for the analysis of Pharmacopoeial compounds.
5. Use of Nephelo-Turbidimetric analysis of dispersions and limit tests.
6. Experiments on electrophoresis.
7. Experiments on chromatography.
(a) Adsorption chromatography

- (b) Thin layer chromatography
 - (c) Paper chromatography :
 - Ascending technique
 - Descending technique
 - Circular technique
8. Assays involving following procedures :
Non-Aqueous, Diazotisation, Complexation and Redox titrations.

**M.PH. 1.3 BIOSTATISTICS
THEORY**

3 Hrs/Week

A study of the following with reference to their applications in pharmacy and Biological Sciences.

UNIT – I

Probability : Definition of laws of probability, probability distributions, properties of Normal, Binomial, Poisson distributions, sampling distributions of mean and variance, standard error and fiducial limits.

Regression and correlation : Linear and curvilinear regressions, methods of least squares, correlation coefficients, rank correlation multiple regression.

UNIT – II

Tests of significance : Testing hypotheses, errors of two kinds, power of test, test of significance based on normal distribution and t-test, test for significance of correlation coefficient.

F-test & Analysis of variance : 1-way, 2-way and 3-way classification.

UNIT – III

Chi-square test of

- (i) Variance of a normal population
- (ii) Goodness of fit.
- (iii) Independence in contingency tables.

Non-parametric tests, order statistics, sign test, run test, median test.

Design of experiments, Principles of randomization, replication and local control, completely randomized block and Latin square designs, factorial experiments, applications of the above designs in Pharmaceutical research.

UNIT – IV

Statistical quality control, process control, control charts, acceptance sampling- sampling plans.

REFERENCES:

1. Biostatistics by Alvin E.Lewis.
2. Introduction to probability & Statistics by Henry L.Alder & Edward B. Roessler.
3. Fundamentals of Applied Statistics by S.C.Gupta, V.K.Kapoor
4. Mathematics & Statistics for use in Pharmacy, Biology, Chemistry by Saunders & Flemming.
5. Practical Pharmacology by M.N.Ghosh.
6. Indian Pharmacopoeia & British Pharmacopoeia. 7. Remington's Pharmaceutical Sciences.

**M.PH 1.4 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS
THEORY**

3 Hrs/Week

UNIT – I

1. W.H.O. certification scheme on the quality of pharmaceutical products.
2. Quality management in the drug industry: philosophy and essential elements.
3. Guidelines on the inspection of pharmaceutical manufacture and drug distribution channels.

UNIT – II

4. Drugs Prices Control Order, 1995.
5. New Drug Policy, 1994.
6. ISO 9000 and 9002 documentation: Introduction and Support package: Guidance on the terminology used in ISO 9001:2000 and ISO 9004:2000.

UNIT – III

7. General Principles of Intellectual Property: Copyright, Trademark
Patents: need of patents, major types of patents, patent offices in India, US and Europe, International registration of patents, how patents are obtained for drugs and their impact on industry and patients, patent term and extension The Patents Act, 1970 – Salient features.
8. New Drug Application: Steps involved in the development of new drug. New drug applications as per WHO guidelines and abbreviated NDA. Requirement and guidelines on clinical trials.

UNIT – IV

9. Industrial safety: Industrial hazards due to fire, chemicals, pharmaceuticals, radiation and accidents - mechanical and electrical equipments. Monitoring and prevention systems, Industrial effluent testing.
10. Stability Studies: ICH guidelines and WHO guidelines and stability protocols for dosage forms.

REFERENCES :

1. Quality Assurance of Pharmaceuticals Vol I & II of WHO publications, 1999.
2. GMPs by Mehra
3. The Drugs and Cosmetic Act, 1940 by Vijay Mallik
4. ISO 9000 and Total Quality Management by S.K.Ghosh
5. How to Practice GMP by P.P.Sharma
6. GMP of Pharmaceuticals by Willing and Stoker.

M. PH. 1.5A/ M. PH. 1.5G FORMULATION DEVELOPMENT THEORY

3 Hrs/Week

UNIT – I

Preformulation Studies : pKa and solubility partition coefficient, crystal morphology, polymorphism, powder flow, structure characteristics, dissolution, compatibility studies, protocol for pre-formulation studies.

UNIT – II

Drug Stability : Solution stability, solid state stability, parameters for physical stability, protocol for physical stability testing, accelerated stability studies and shelf assignment.

UNIT – III

Formulation, stabilization and evaluation of tablets, capsules, parenteral dosage forms. Advances in pharmaceutical packaging.

UNIT – IV

Cosmetics:

Formulation and evaluation of:

Skin care products such as antiageing and sunscreen products.

Hair care products such as shampoos, hair dyes and hair tonics.

Safety testing of Cosmetic Products:

Microbiology in Cosmetics.

Knowledge of the various microbial contaminants in cosmetic products.

Knowledge of various preservative systems for cosmetic products.

Selection criteria for preservatives.

Efficacy and safety testing of preservatives in cosmetic products.

REFERENCES :

1. Modern Pharmaceutics by Rhodes and Banker.
2. Dissolution, Bio-availability and Bio-equivalence by Abdou H.M.
3. Industrial Pharmacy by Lachman
4. Tablets Vol. I, II and III by Leon Lachman
5. Remington Pharmaceutical Sciences
6. Pharmaceutics by M.E.Aulton.
7. Physical Pharmacy by Martin
8. Harry's cosmeticology by J.B.Wilkimsson.
9. Paucher's Perfumes, cosmetics & soaps by W.A.Paucher

M.PH. 1.6A/ M. PH. 1.6G FORMULATION DEVELOPMENT PRACTICAL

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Accelerated stability studies of various formulations or drugs with respect to
(a) Temperature (b) Effect of buffers / pH dependent (2 – 4 Expts.)
2. Formulations and evaluation of some liquid orals such as Analgesic-antipyretics, Antihistamines, Co-trimoxazole, suspensions etc. (2 – 3 Expts.)
3. Formulation and evaluation of stability of reconstituted dry syrups of Amoxicillin, Ampicillin etc. (2 Expts.)
4. Preparation and evaluation of diclofenac sodium gels containing two different bases. (2 Expts.)
5. Formulation and evaluation of semisolid dosage forms using different – bases and drugs (cetrimide, salicylic acid) of current interest.
6. To study the effect of particle size, moisture content and lubricants on flowability and compressibility of powders.
7. Study of effect of various binding agents on the properties of tables (2 Expts.)
8. Preparation and evaluation of Skin care and Hair care products (4-5 Expts)

M. PH. 1.5B STEREOCHEMISTRY OF DRUGS AND REACTION MECHANISM THEORY

3 Hrs/Week

UNIT – I

I. Stereochemistry of Carbon & Nitrogen Compounds:

(i) Optical Isomerism (due to Asymmetric carbon atoms)

Compounds with one asymmetric carbon atoms, compounds with two or more unequal asymmetric carbon atoms, compounds containing like asymmetric carbon atoms, compounds with asymmetric carbon atoms in branched chains.

(ii) Stereo-chemistry of Biphenyls.

(iii) Racemic modification:

Nature of modifications, formation of racemic modifications, (a) by mixing (b) by synthesis, (c) by racemization and by chemical transformation.

(iv) Configuration:

Definition, rotation, absolute configuration and relative configuration.

(v) Synthesis of optically active compounds :
Stereo selective synthesis.

(vi) Stereochemistry of Nitrogen compounds :

UNIT – II

II. Reaction with at least one application:

Free Radical Reaction: Kinetic characteristics of chain reaction, Structure reactivity relationship. Free radical substitution reaction, free radical addition reaction, Intramolecular free radical reaction, and Rearrangement and fragmentation reactions of free radical.

- Nucleophilic addition to carbonyl group
- Nucleophilic substitution at carbonyl group
- Nucleophilic substitution at carbonyl group with loss of C=O
- Nucleophilic substitution at saturated carbon
- Elimination reactions
- Electrophilic addition to Alkenes.
- Electrophilic Aromatic Substitution

Concerted Pericyclic Reaction: Electrocyclic reaction, Sigmatropic reaction, Cycloaddition reaction

UNIT – III

III. Oxidation & Reduction Reactions: Alcohol to carbonyl using chromium (VI) Oxidants, modified chromium (VI) Oxidants, dimethyl sulfoxide oxidation, Oxidation with other metal derivatives like TPAP, MnO₂, Oppenauer oxidation, oxidation with silver.

- Formation of Phenols & Quinone, Conversion of Alkenes to Epoxide, Conversion of Alkenes to Diols, Bayer-villiger Oxidation, Oxidative bond cleavage using KMnO₄, Osmium reagents, Ruthenium reagents and chromium reagents, LTA, Sodium per-iodate, Oxidation of alkyl or alkenyl fragments, Oxidation of sulphur, Selenium and nitrogen
- Reduction with complex metal hydrides, Alkoxy Aluminate reducing agents, Reduction with Boro hydrides, Alkoxy and alkyl Boro hydrides, Borane, aluminum hydride & derivatives, Catalytic hydrogenation, Dissolving metal reductions, Reduction with non-metallic reducing agents.

UNIT – IV

IV. Named Reactions : Acyloin condensation, Allylic rearrangement, Arndt-Eistert reaction, Bayer-villiger rearrangement, Beckmann rearrangement, Bischler Napieralski synthesis, Claisen condensation, Claisen-Schmidt reaction, Dakin reaction, Curtius reaction, Dieck-Mann reaction, Diels –Alder reaction, Fittig reaction, Fries rearrangement, Gabriel synthesis, Hell-Volhard Zelinsky reaction, Knoevenagel reaction, Leuckart reaction, Mannich reaction, Perkin reaction, Pechmann reaction, Pinacol-pinacolone Rearrangement, Reformatsky reaction, Schmidt reaction, Stobbe condensation, Wagner-Meerwein rearrangement. Willgerodt reaction, Wittig reaction, Wolff rearrangement, Suzuki coupling.

M. PH. 1.6B STEREOCHEMISTRY OF DRUGS AND REACTION MECHANISM

PRACTICAL

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. At least ten named reactions including reactions involving Grignard reagent and Reformatsky
2. At least five oxidation reactions involving different reagents
3. At least five reduction reactions involving different reagents

REFERENCES:

1. Advanced Organic Chemistry by Jerry March.
2. Structure & mechanism in Organic Chemistry by Ingold.
3. In Introductions to Chemistry of Heterocyclic Compounds by Acheson.
4. Heterocyclic Compounds by Elderfield.
5. Structure & reactions of heterocyclic Compounds by Piamer.
6. Stereochemistry of carbon Compounds by Eliel.
7. Organic Chemistry by Morrison & Byod.
8. Reactions & reagents by O.P. Agarwal.
9. Organic synthesis by Michael. B .Smith Mac Graw Hill
10. Vogel's A text book of Practical Organic Chemistry

M.PH1.5C STABILITY OF DRUGS AND DRUG PRODUCTS THEORY

3 Hrs/Week

UNIT – I

1. Overview of kinetic concepts – First, second and pseudo orders.
2. Complex order kinetics – concepts; equations and their application.
Series, consecutive and reversible reaction, steady state approximation.
3. Stability prediction by pharmacist and calculation protocols.

UNIT – II

4. Temperature as a stress : Arrhenius theory, activation energy calculations, Q10 value calculations.
5. Interpretation of kinetic data : Transition state theory, media effects, catalysis, pH effects. Some practical applications.

UNIT – III

6. Drug decomposition mechanisms :
 - (a) Hydrolysis and acyltransfers : Nature of reaction, structure and utility, stabilization of pharmaceutical examples.
 - (b) Oxidation : Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
 - (c) Photolysis : Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.
7. Solid state chemical decomposition
Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state methods of stabilization.

UNIT – IV

8. Physical stability testing of dosage forms :
 - (1) Solids – tablets, capsules, powder and granules
 - (2) Disperse systems
 - (3) Microbial decomposition
 - (4) Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.
9. Strategy and tactics of stability testing :

(1) Regulatory requirements	(2) Stability protocols
(3) Experimental Design	(4) Interpretation of data

REFERENCES:

1. Drug stability : Principles and practices by Jens T. Carstensen
2. Pharmaceutical Dosage Form Design : Tablets- Vol I,II & III by Lachmann.
3. Theory and Practice of Industrial Pharmacy by Lachman.
4. Stability Testing of Drug Products by W.Grimm.
5. Martin Physical Pharmacy – IVth Edition.
6. Physical Pharmaceutics by Manavalam and Ramaswamy.
7. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

M.PH1.6 C STABILITY OF DRUGS AND DRUG PRODUCTS

6 Hrs/Week

PRACTICAL
(A minimum of 20 experiments shall be conducted)

Experiments based on theory

M. PH. 1.5D PHARMACOLOGICAL SCREENING METHODS **3 Hrs/ Week**
THEORY

UNIT-I

Drug discovery process: Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics. Regulations for laboratory animal care and ethical requirements.

UNIT-II

Preclinical and clinical models employed in the screening of new drugs belonging to following categories:

Antipsychotic agents, antianxiety agents; nootropic drugs; antidepressant drugs; antiparkinsonian agents; opioid analgesics; anti-inflammatory drugs.

UNIT-III

Preclinical and clinical models employed in the screening of new drugs belonging to following categories.

Infarction; antiatherosclerotic drugs; antimalarials; anthelmintics; antidiabetics; models for antiepileptics; local anesthetics; activity on the GI tract, transgenic animals and other genetically prone animal models.

UNIT-IV

Alternatives to animal screening procedures, cell-line, patch-clamp techniques, in-vitro models, molecular biology techniques.

Principles of toxicity evaluations, ED₅₀, LD₅₀ and TD values. International guidelines (ICH recommendations).

REFERENCES :

1. Drug discovery and evaluation by Vogel
2. Screening Methods in Pharmacology by Robert A. Turner
3. I.P

M. PH. 1.6D PHARMACOLOGICAL SCREENING METHODS **6 Hrs/Week**
PRACTICAL

(A minimum of 20 experiments shall be conducted)

1. Administration of drugs by different routes in mice/rabbit
2. To study the effect of hepatic microsomal enzyme induction on the duration of action of pentobarbital sodium
3. To study the effect of pentobarbital on righting reflex (hypnosis) in mice
4. To study the effect of chlorpromazine on the locomotor activity of mice using actophotometer
5. To study the apomorphine induced compulsive behaviour (stereotype) in mice
6. To study the muscle relaxant property of diazepam in mice using rotarod apparatus
7. To study the analgesic effect of morphine in mice using the tail-flick method
8. To study the analgesic effect of morphine in mice using hot plate method
9. To study the analgesic effect of morphine against acetic acid-induced writhing in mice
10. To study the anti-inflammatory property of indomethacin against carrageenan-induced paw oedema

11. To study the anticonvulsant property of diazepam against pentylenetetrazol-induced convulsions in rats
12. To study the amnesic (loss of memory) effect of scopolamine using passive avoidance step-down task paradigm in mice
13. To study the antisecretory and ulcer-protective effect of cimetidine in pylorus-ligated rats
14. To study the local anaesthetic property of procaine hydrochloride using foot withdrawal reflex of frog
15. To determine the acute toxicity of the given drugs (To calculate LD₅₀ value) [4-5 experiments]

**M. PH. 1.5E: ADVANCED PHARMACEUTICAL BIOTECHNOLOGY – I 3 Hrs/Week
THEORY**

UNIT I

Principle, practice and historical overview of fermentation. Fermenters and their optimization. Isolation, screening of industrially important microbes, primary & secondary metabolites, maintenance of culture. Large Scale Production: Stationary, submerged process. Strain improvement ; genetic manipulation, protoplast fusion & modern technologies for strain improvements.

UNIT – II

Fermentation Kinetics & Reaction Engg: Rate of chemical reaction; Interpretation of batch reactors. Cell growth kinetics, Product formation kinetics (growth & non – growth associated), Monod equation.

UNIT III

Scale up of Fermentation: Principles of scale up & techniques. Fermentation media. Factors affecting mass transfer, Mass transfer in biochemical processes. Measurement of mass transfer coefficient. Effect of aeration & agitation on mass transfer Fundamental aspects, Production of alcohol, Penicillin, Streptomycin, Vitamin B₁₂, Lysine & lactobacillus by Bioprocess.

UNIT - IV

Bioreactor design & Advanced concepts: Different types of fermentation processes – Batch, Fed-batch & continuous, plug flow reactor (PFR), continuous stirred tank reactors (CSTR), fluidized bed reactor, bubble column, Hollow fiber reactor, air lift fermentor etc.

Design & operation of a bioreactor. Function of ancillary parts and monitoring of process parameters, animal cell bio reactor & its application in pharmaceutical industry.

REFERENCES :

- Industrial Microbiology, Prescott and Dunn,
- Biochemical Engineering and Biotechnology Handbook, Atkinson, B and Marituna, F., The Nature Press, Macmillan Publ. Ltd.
- Biochemical Engineering Fundamentals, Bailey & Olis. MGH
- Chemical Process Principles (Part one and two), Hougen, Watson & Ragatz, Asian Student Edition, Asia Publishing House
- Chemical Reaction Engineering, Wiley Eastern Ltd., Levenspiel, O.
- Fermentation and Biochemical Engineering Handbook, Vogel, H. C.

**M. PH. 1.6 E ADVANCED PHARMACEUTICAL BIOTECHNOLOGY - I 6 Hrs/Week
PRACTICAL**

(A minimum of 20 experiments shall be conducted)

1. Isolation & screening of industrially important microorganisms
2. Sterility testing of laminar airflow bench top.
3. Strain improvement by mutation (by UV radiation & Chemical mutagens)
4. Biomass estimation by monitoring C, N estimation.
5. Shake flask experiment on fermentative production.
6. Bioreactor experiments:
 - a.) Sterilization of air and calibration of Dissolved Oxygen electrode.
 - b.) Calibration of pH electrode and pH regulation.
 - c.) Manipulation of DO with airflow and stirrer speed regulation.
 - d.) Sterilisation & processing of a bioreactor.
7. Preparation of inoculum and fermentative production of any important product from a suitable microorganism using bioreactor.
8. ELISA & Western Blot.
9. Development of a suitable delivery system for proteins.

**M. PH. 1.5F :- ADVANCED PHARMACOGNOSY-I
THEORY**

3 Hrs/Week

UNIT-I

- Prospects and Problems encountered in discovering new drugs from plants.
- Anticancer, Antidiabetic, Antifertility and Antihepatotoxic drugs of natural origin and their current status.
- Drugs obtained from marine resources with special reference to Cardiovascular, Cytotoxic, Antimicrobial and Anti-inflammatory compounds.

UNIT-II

- Hallucinogenic, Allergic, Teratogenic and Toxic plants.
- Saponins and Terpenoids with biological activity of Pharmaceutical significance.
- Chemotaxonomy of natural drugs.

UNIT-III

Herbal Remedies - Toxicity & Regulations: Importance of Herbal Therapies, Herbal versus Conventional drugs, Efficacy of herbal therapies, safety in herbal drugs, toxicity in Herbals and their interaction, Herbal drug regulations in India.

UNIT-IV

- Quality control of herbal drugs as per WHO guidelines.
- Application of various Chromatographic and Spectrometric techniques like TLC, CC, GLC, HPLC, HPTLC, UV, IR, NMR, MS, Fluorimetry etc for standardization of plant drugs.

REFERENCES:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari

M. PH. 1.6F ADVANCED PHARMACOGNOSY-I

6 Hrs/Week

PRACTICAL
(A minimum of 20 experiments shall be conducted)

Experiments based on theory

M. PH. 1.5G/ M. PH. 1.5A FORMULATION DEVELOPMENT 3 Hrs/Week
THEORY

UNIT – I

Preformulation Studies : pKa and solubility partition coefficient, crystal morphology, polymorphism, powder flow, structure characteristics, dissolution, compatibility studies, protocol for pre-formulation studies.

UNIT – II

Drug Stability : Solution stability, solid state stability, parameters for physical stability, protocol for physical stability testing, accelerated stability studies and shelf assignment.

UNIT – III

Formulation, stabilization and evaluation of tablets, capsules, parenteral dosage forms. Advances in pharmaceutical packaging.

UNIT – IV

Cosmetics:

Formulation and evaluation of:

Skin care products such as antiageing and sunscreen products.

Hair care products such as shampoos, hair dyes and hair tonics.

Safety testing of Cosmetic Products:

Microbiology in Cosmetics.

Knowledge of the various microbial contaminants in cosmetic products.

Knowledge of various preservative systems for cosmetic products.

Selection criteria for preservatives.

Efficacy and safety testing of preservatives in cosmetic products.

REFERENCES :

1. Modern Pharmaceutics by Rhodes and Banker.
2. Dissolution, Bio-availability and Bio-equivalence by Abdou H.M.
3. Industrial Pharmacy by Lachman
4. Tablets Vol. I, II and III by Leon Lachman
5. Remington Pharmaceutical Sciences
6. Pharmaceutics by M.E.Aulton.
7. Physical Pharmacy by Martin
8. Harry's cosmeticology by J.B.Wilkimsson.
9. Paucher's Perfumes, cosmetics & soaps by W.A.Paucher

M.PH. 1.6G/ M. PH. 1.6A FORMULATION DEVELOPMENT 6 Hrs/Week
PRACTICAL

(A minimum of 20 experiments shall be conducted)

1. Accelerated stability studies of various formulations or drugs with respect to
- 2.(a) Temperature (b) Effect of buffers / pH dependent (2 – 4 Expts.)

3. Formulations and evaluation of some liquid orals such as Analgesic-antipyretics, Antihistaminics, Co-trimoxazole, suspensions etc. (2 – 3 Expts.)
4. Formulation and evaluation of stability of reconstituted dry syrups of Amoxicillin, Ampicillin etc. (2 Expts.)
5. Preparation and evaluation of diclofenac sodium gels containing two different bases. (2 Expts.)
6. Formulation and evaluation of semisolid dosage forms using different – bases and drugs (cetrimide, salicylic acid) of current interest.
7. To study the effect of particle size, moisture content and lubricants on flowability and compressibility of powders.
8. Study of effect of various binding agents on the properties of tablets (2 Expts.)
9. Preparation and evaluation of Skin care and Hair care products (4-5 Expts)

M.PH. 1.8 ELECTIVES / SEMINAR TOPICS

1. Intellectual property Rights.
2. Drug Price Control Order
3. ICH Guidelines.
4. Total Quality Management
5. W.H.O. Certification scheme for movement of drugs in international commerce.
6. ISO – 9000 certification.
7. GMP Certification.
8. Food Adulteration and detection.
9. Pharmaceutical Marketing
10. Drug Information Centre / services
11. Rational use of Drugs (RUD)
12. Essential Drug Programme (EDP)
13. Drugs and Therapeutics Committees.
14. Biotechnology products
15. Bio-assays
16. Computer applications in pharmacy
17. Computer Aided Drug Design
18. Novel Drug Delivery Systems
19. Patient Counseling
20. Drug interactions

Other related topics may also be selected by the teachers/students.

II Semester

M.PHARM (PHARMACEUTICS)

**MPH2A.1: ADVANCED PHYSICAL PHARMACEUTICS
THEORY**

3 Hrs/Week

UNIT - I

Solubility: Solubility of solid in liquids, Theory of solution formation.

Solubilisation techniques using surfactants, cosolvents, complexation, inclusion compounds, drug derivatization and solid state manipulation.

UNIT - II

Solid state properties: Crystal properties and polymorphism, techniques for study of crystal properties; solid state stability, flow properties of powders.

Polymer Science: Types of polymers, properties of polymers, thermodynamics of polymer solution and polymers in solid state. Applications of polymers in pharmaceutical formulations.

UNIT - III

Diffusion: Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, thermodynamics of diffusion.

Dissolution: Theories of dissolution, dissolution models. Sink conditions in dissolution and its importance. In-vitro - in-vivo correlations.

UNIT - IV

Kinetics and Drug stability: Rate equation, kinetics of decomposition, stability testing protocol, drug degradation and methods of stabilization, methods of accelerated stability testing in dosage forms, freeze-thaw methods, centrifugal methods.

REFERENCES:

1. Physical Pharmacy by Martin, 4th Edition.
2. Bentley's Text Book of Pharmaceutics by E.A. Rawlin.
3. Pharmaceutical dosage forms: Tablets I, II, III.
4. Theory and Practice of Industrial Pharmacy by L. Lachman.
5. Physicochemical Principles of Pharmacy by A.T. Florence and D. Altwood.
6. Pharmaceutical preformulation by J.T. Cartensen.

MPH2A.2 / MPH2G.2: BIO-PHARMACEUTICS & PHARMACOKINETICS 3 Hrs/Week

THEORY

UNIT - I

- I. Bioequivalence and its determination, study design for the assessment of bioavailability and bioequivalence, factors influencing bioavailability and bioequivalence. Statistical concepts in estimation of bioavailability and bioequivalence. Software used in biopharmaceutics and pharmacokinetics study and their significance.

UNIT – II

- II Basic concepts of pharmacokinetics: Compartmental models: One and two compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine various pharmacokinetic parameters pertaining to.
- Absorption: Mechanism and path ways of drug absorption, absorption rate constant, absorption half life, lag time and extent of absorption, AUC.
 - Distribution: Physiological influence of drug distribution, protein binding of drug, determination of protein binding sites, clinical significance of drug protein binding. Apparent volume of distribution and its determination.
 - Elimination: Overall apparent elimination rate constant, and half life.
under the following conditions:
 - Intravenous bolus injection
 - Intravenous infusion
 - Single dose oral administration
 - Multiple dosage oral administration
 - Concept of clearance: Organ clearance, total clearance, hepatic clearance, gut wall clearance and renal clearance.

UNIT – III

- III Non-linear Pharmacokinetics: Concepts of linear and non linear pharmacokinetics, Michaelis – Menton kinetics characteristics, basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses.
- IV Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics and Chronotherapeutics.

UNIT – IV

- V Non-compartmental pharmacokinetics:
- Physiologic Pharmacokinetic Model: Concept, applications and limitations.
 - Statistical moments theory: Concept and applications, mean residence time, mean absorption time, mean dissolution time.

REFERENCES:

- Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
- Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
- Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
- Pharmaceutical Codex.
- Applied Biopharmaceutics and Pharmacokinetics by Leon. Shargel, Andrew B.C. Yes.

MPH2A.3 / MPH2G.3: BIOPHARMACEUTICS & PHARMACOKINETICS 6 Hrs/Week PRACTICAL

(A minimum of 20 experiments shall be conducted)

- To perform bioequivalence testing on marketed analgesic / sulphonamide tablets.
- Comparison of dissolution of different marketed products of co-trimoxazole and other suspensions.
- To determine K_a , biological half-life, AUC and other pharmacokinetic parameters of rifampicin / nitrofurantoin by urinary excretion method.
- To determine protein-binding of drugs by equilibrium dialysis method (2 expts.)

5. Bioavailability studies of paracetamol or any other drug by salivary data (2 expts.)
6. To study the influence of urinary pH on salicylate excretion.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} and T_{max} from the given data (2 expts.)
8. Calculation of AUC and bioequivalence from the given data (2 expts.)

MPH2A.4 / MPH2G.4: NOVEL DRUG DELIVERY SYSTEMS
THEORY

3 Hrs/Week

UNIT - I

Fundamentals of controlled drug delivery systems, terminology, potential advantages, drug properties relevant to formulation, pharmacokinetic and pharmacodynamic basis of controlled drug delivery.

Design, fabrication, evaluation and applications of the following controlled release systems:

1. Controlled release oral drug delivery systems.
2. Modulated GI retentive drug delivery systems.

UNIT - II

3. Parenteral controlled drug delivery systems
4. Implantable therapeutic systems.
5. Transdermal therapeutic systems.
6. Ocular and intrauterine delivery systems.

UNIT - III

7. Bioadhesive drug delivery systems.
8. Proteins and peptide drug delivery
9. Resealed erythrocytes
10. Colloidal drug delivery systems: Liposomes, microspheres, nanoparticles and polymeric micelles

UNIT - IV

Drug targeting: Concepts and drug carrier systems.

Approaches to active drug targeting: Monoclonal antibodies, Targeting to particular organs such as brain, lungs, liver and targeting to neoplastic diseases.

REFERENCES:

1. Remington's Pharmaceutical Sciences.
2. Novel Drug Delivery Systems by Y.W.Chein, Marcel Dekker, Inc.
3. Controlled Drug Delivery Systems by Joseph R.Robinson and Vincent ILL.Lee.
4. Bentley's Text book of Pharmaceutics by Rawlins, EL. Publications.
5. Microencapsulation by Simon Benita, Pub. By Marcel Dekker Inc.
6. Drug Targeting and Delivery edited by H.E.Junginger
7. Specialized Drug Delivery Systems edited by Praveen Tyle, Pub. By Marcel Dekker Inc.
8. Colloidal Drug Delivery System by Jorg Kreuter.

MPH2A.5 / MPH2G.5 NOVEL DRUG DELIVERY SYSTEMS
PRACTICAL

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Study on diffusion of drugs through various polymer members (2 expts.)
2. Preparation and study on invitro dissolution of various sustained action products and comparison with marketed products (3 expts.)
3. Preparation of matrix tablets using various polymers like PVP etc and studying their release patterns (2 expts.)
4. Preparation and evaluation of microcapsules by different microencapsulation techniques like:
 - (a) Simple coacervation techniques: Gelatin-water-ethanol.
 - (b) Coacervation by temperature changes : Ethylcellulose in cyclohexane for phenobarbitone.
 - (c) Coacervation by non-solvent-addition: cellulose acetate butyrate in methyl ethyl ketone using isopropylether as non-solvent (1 expt. in each).
5. Preparation and evaluation of wax embedded micro-spheres of diclofenac sodium and theophylline (2 expts.)
6. Preparation of various polymer films containing different drugs and studying the film characteristics and release patters (3 expts.).
7. To perform sugar coating and nonenteric and enteric film coating on tablet and their evaluation (3 expts.)

**MPH2A.6: / MPH2G.6 ADVANCED PHARMACEUTICAL TECHNOLOGY 3 Hrs/Week
THEORY**

UNIT - I

1. Formulation Development:
 - (a) Solid dosage forms:

Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, physics of tablet compression and computerization for in process quality control of tablets.
 - (b) Powder dosage forms:

Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.
 - (c) Liquid and semi-solid dosage forms:

Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.

- (d) Aerosols:

Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, manufacture & quality control.

UNIT - II

2. Aseptic processing operation and parenteral dosage form development:

Introduction, Contamination control, Microbial environmental monitoring, Microbiological testing of water, Microbiological air testing, Characterization of aseptic process, Media and incubation conditions, Theoretical evaluation of aseptic operations. Advances in materials and production techniques for parenteral dosage forms.

UNIT - III

3. Scale-up Techniques:

Effect of scale up on formulation, process parameters like mixing, granulation, drying, compression, coating, packaging, stability, selection and evaluation of suitable equipments.

4. **Process Validation:**
Regulatory basis, Validation of solid dosage forms, Sterile products, Liquid dosage forms, Process validation of raw materials, Validation of analytical methods, Equipment and Process.

UNIT - IV

5. **Optimization techniques in pharmaceutical and processing:**
Optimization parameters, statistical design and other applications, design, development and optimization of in-vitro test systems to evaluate and monitor the performance of different types dosage forms, the relevance and importance of in-vitro/in-vivo associations at every stage of product development and manufacture, the regulatory evolution and current thinking on this aspect, application of statistical techniques in product development and evaluation including quality control.

MPH2A.7: SEMINAR / ASSIGNMENT

MPH2A.8. COMPREHENSIVE VIVA

M.PHARM (PHARMACEUTICAL CHEMISTRY)

MPH 2B.1 ADVANCED MEDICINAL CHEMISTRY-I THEORY

3 Hrs/Week

UNIT – I

1. **Physico-chemical properties in relation to Biological action:**
Complex events between drug administration and drug action, route of administration, absorption, site of loss (storage site, protein binding, neutral fat), metabolism and excretion, biological activities of Homologous series, drug receptor interactions, isosterism, steric features of drugs, concept of drug receptor, forces involved theories on interaction, selected physico-chemical properties influencing biological action like ionization, hydrogen bonding chelation, oxidation-reduction potential, surface activity, solubility and partition coefficient.

Receptors, their types, location, isolation, Transduction mechanism

UNIT – II

2. **Metabolism of drugs:**
Role of cytochrome P-450 monooxygenase in oxidative biotransformation, oxidation of aromatic moieties, olefins, benzylic carbon all cyclic carbon, carbon nitrogen systems, carbon oxygen systems, carbon sulphur systems with examples of drugs, reductive reactions involving aldehydes, ketones, nitro and azo compounds, hydrolytic reactions with examples conjugation pathway with glucuronic acid, glycine, glutamine with specific example, acetylation and methylation of drugs.
Stereo chemical aspects of drug metabolism, production of pharmacologically active metabolites. Relationship of drug metabolism and drug design.

UNIT – III

3. **Combinatorial chemistry:** High through put organic synthesis : Solid phase organic synthesis : Solution phase synthesis ;
Library construction strategy: Parallel synthesis, pooled synthesis,
Compound design within combinatorial library: Library diversity, controlling Molecular properties.
Looking for leads, Discovery Library : Synthesis of oligomers, efficient constructions, branching strategy, leveraging knowledge, targeted libraries.
The fundamentals of Pharmacophore under lying in combinatorial chemistry.

UNIT – IV

4. Strategies for synthesis of Candidate Drug:

- Target selection
- Retro- synthesis (The disconnection approach, Consecutive versus convergent synthesis)
- Various strategic approaches including **LHASA**
- Strategic bond approach
- Strategic bond in ring approach
- Degradation techniques as a tool for Retro-synthesis.

REFERENCES:

1. Medicinal Chemistry by Alfred Burger
2. Drug Design by Ariens
3. Introduction to the principles of drug design by Smith and Williams
4. Strategy of drug design by Purcell
5. Textbook of medicinal and pharmaceutical chemistry by Wilson and Gisvold
6. Principles of medicinal chemistry by William Foye
7. Combinatorial library design & Evaluation by Arup. K. Ghosh & Vellarkad. N. Vishwanathan by Marcel Dekker. NYC

MPH-2B.2 ADVANCED MEDICINAL CHEMISTRY-II THEORY

3 Hrs/Week

UNIT – I

A Revisit to 2-D QSAR: Free- Wilson Model, Fugita- Ban Model, Hansch analysis, Electronic factors, steric factors, & hydrophobic factors. Comparison between Free-Wilson model and Hansch analysis. Molecular Connectivity Index (**MCI**).

UNIT – II

- Recent techniques and applications in **Pharmacophore Mapping**.
- **3-D QSAR Analysis:** Receptor independent 3-D QSAR Analysis, Receptor dependent **3-D QSAR** Analysis.
- Receptor pre-organization for activity and its role in identifying Ligand-binding sites on
- Docking molecules into protein binding sites
- *de-novo* Ligand design

UNIT – III

Enzyme Inhibitors: A detailed study of the following types of enzyme inhibitors, related drugs and their pharmaceutical significance;

- a) P.G.Synthetase (cyclooxygenase and lipoxygenase inhibitors)
- b) Phosphodiesterase (PDE) inhibitors.
- c) Carbonic anhydrase inhibitors.
- d) Angiotensin converting enzyme (ACE) Inhibitors
- e) Acetyl choline Esterase (AChE) inhibitors.

UNIT – IV

Miscellaneous classes of drugs: Recent advances in the following classes of drugs:

- a) Proton-pump Inhibitors as antiulcer agents.
- b) Immunosuppressive and immunostimulant agents.
- c) Antiviral agents
- d) Beta – Adrenergic blockers (Beta 1 and Beta 2)

REFERENCES:

1. Medicinal Chemistry by Alfred Burger
2. Drug Design by Arie4ns.
3. Introduction to the principles of drug design by Smith & Williams.
4. Strategy of drug design by Purcell.
5. Textbook of medicinal and pharmaceutical chemistry by Wilson and Gisvold.
6. Principles of medicinal chemistry by William Foye
7. Organic synthesis by Michael. B .Smith Mac Graw Hill

**MPH-2B.3 ADVANCED MEDICINAL CHEMISTRY-III
THEORY**

3 Hrs/Week

UNIT – I

I. Psychopharmacological agents: a) Biochemical basis of mental disorders:- Abnormal protein factors, endogenous amines and related substances, faulty energy metabolism, genetic factors and nutritional disorders, Phenothiazines; chemistry and synthesis and evaluation methods. The important pharmacological activities of phenothiazines. SAR of phenothiazines, Toxicity and clinical significance of phenothiazines.

b) **Antidepressants:** MAO inhibitors and tricyclic antidepressants and Miscellaneous. Mechanism of action, clinical and biological uses, side effects and their SAR studies. Synthesis of clinically useful drugs of each of the above classes.

UNIT – II

II. Chemotherapy of cancer: Molecular Biology of Carcinogenesis. A detailed classification of antineoplastic agents, mechanisms of action of different classes; Alkylating agents and radiomimetic agents, antimetabolites their SAR studies, sex hormones and analogs, antibiotics. A mention of natural products used in cancer treatment; vinca alkaloids (Vincristine and Vinblastine) podophyllum and Taxol.

UNIT – III

III. Drugs Related to Hormones and other autocooids: A study of the following hormones autocooids with a special reference to their agonists and antagonists;

- a) Peptide Hormones: Insulin, Vasopressin and oxytocin,
- b) Histamine (H¹ and H²) and 5-HT.
- c) Thyroid Hormones (T₃ and T₄)
- d) Prostaglandins
- e) Angiotensins

UNIT – IV

IV. Study of the following with emphasis on recent advances:

- a) Antilipedemic agents
- b) Biomarkers
- c) Diagnostic agents
- d) Antiparkinsonian agents
- e) Antialzheimer agents
- f) Antirheumatics and antigout agents
- g) Orphan drugs

REFERENCES:

2. Medicinal Chemistry Vol. I & II by A. Burger.
3. Drug Design by Ariens.
4. Principles of Medicinal Chemistry by Foye.
5. A.T.B. of organic, Pharmaceutical and Medicinal Chemistry by Wilson, Gisvold, & Duerge
6. Progress in Drug Research by E. Zucker.

**MPH-2B.4 ADVANCED MEDICINAL CHEMISTRY-III
PRACTICAL**

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Synthesis of various Barbiturates and determination of pKa value of Barbiturates in relation to their biological activity.
2. Synthesis of local anesthetics and evaluation of their biological activity.
3. Synthesis of some Anticonvulsants (other than Barbiturates) and their evaluation.
4. Synthesis and evaluation of non-narcotic analgesics.
5. Suitable synthesis and the evaluation of drugs based on theory topics.

**MPH-2B.5 CHEMISTRY OF NATURAL PRODUCTS
THEORY**

3 Hrs/Week

UNIT – I

1. General methods of isolation and separation of plant constituents. Qualitative reactions employed for the detection of plant constituents. .Application of G.L.C., HPLC and counter current distribution to separation and analysis of plant constituents Determination of Organic structures through Interpretation of - **Infrared spectroscopy, H¹ N.M.R & C¹³ N.M.R, MASS spectroscopy.**

2. Study of biogenesis: The acetate hypothesis, Isoprene rule Biogenetic hypotheses relation to alkaloids.

UNIT – II

3. Alkaloids: Isolation and study of the constitution of ergot alkaloids, opium alkaloids, atropine and reserpine.

4. Steroids: Chemistry and stereo-chemistry of cholesterol. Preparation and chemistry of corticosteroids.

5. Glycosides: A general study of glycosides with detailed treatment of cardiac glycosides, Digoxin, Scilarin-A and ovabain.

UNIT – III

6. Antibiotics: A general study of the chemistry of antibacterial antibiotics, antifungal antibiotics and anti viral antibiotics with detailed treatment of newer semi synthetic penicillins and cephalosporins.

UNIT – IV

7. Vitamins: Detailed study including commercial preparations of vitamin-A, vitamin - C, cyanacobalamin, Nicotinamide, folic acid, thiamine, riboflavine and pyridoxine.

REFERENCES:

1. Organic Chemistry by I.L.Finar.
2. Alkaloids – Chemical and biological perspective by S. William Pelletier.
3. Alkaloids by Manske.
4. Hormone Chemistry Butt.
5. Steroids by Fischer and Fischer.
6. Pharmacognosy by Trease and Evans.
- 7.

**MPH-2B.6 CHEMISTRY OF NATURAL PRODUCTS
PRACTICAL**

3 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Exercise involving the extraction, isolation and separation characterization by modern methods and quantitative estimation of therapeutically important phytoconstituents.
2. Screening of natural products for biological activities mentioned as below:
 - a) Anti-inflammatory activity
 - b) Hypoglycemic activity
 - c) Diuretic activity
 - d) Cardiac activity
 - e) Antimicrobial activity
 - f) Anti-neoplastic activity
 - g) Psychopharmacological activity
 - h) Anti-fertility activity.

MPH-2B.7 SEMINAR / ASSIGNMENT

MPH-2B.8 COMPREHENSIVE VIVA

M.PHARM (PHARM. ANALYSIS & QUALITY ASSURANCE)

MPH2C.1 QUALITY ASSURANCE OF PHARMACEUTICALS 3 Hrs/Week **THEORY**

UNIT-I

1. Concept of total quality management, philosophy of GMP, CGMP and GLP.
2. Organization and personnel, responsibilities, training hygiene.
3. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

UNIT-II

4. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place.
5. Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.
6. Manufacture of and controls on dosage forms: Manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.

UNIT-III

7. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc. Guidelines for Quality assurance of Human Blood products and Large volume parenterals.
8. Packaging and labeling controls, line clearance and other packaging materials.
9. Quality control laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.

UNIT-IV

10. Finished products release: Quality review, quality audits, batch release document.
11. Distribution and distribution-records: Handling of returned goods recovered materials and reprocessing.
12. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

REFERENCES :

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
3. Basic tests for pharmaceutical substances – WHO (1988)
4. Basic tests for pharmaceutical dosage forms – WHO (1991)
5. GMP-Mehra
6. How to Practice GMPs – P.P.Sharma
7. The Drugs and Cosmetic Act 1940 – Vijay Malik
8. Pharmaceutical Process Validation by Berry and Nash.
9. Q.A. Manual by D.H.Shah
10. SOP Guidelines by D.H.Shah
11. Quality Assurance Guide by OPPI

MPH2C.2 ADVANCED PHARMACEUTICAL ANALYSIS - I 3 Hrs/Week
THEORY

UNIT – I

Preparation of drug samples for analysis: Pharmaceutical samples, fundamental theories controlling preparation techniques, specific sample preparation techniques.

UNIT – II

A detailed study of the principles, instrumentations and applications in drug analysis of: GC-MS, LC-MS with reference to drug metabolism, toxicologic and forensic studies, diagnosis of disease state, quantification of drugs in biological samples, Super critical fluid chromatography and size exclusion chromatography

UNIT – III

Thermal analysis: Thermogravimetry, Differential thermal analysis, differential scanning calorimetry, Purity determination using DSC, Interpretation of curves. Thermooptometry, Thermomechanical analysis (TMA), dynamic mechanism analysis (DMA), evolved gas analysis (EGA) and reaction kinetics thermal analysis.

UNIT – IV

Brief study of the theory, instrumentation and application of the following analytical techniques: atomic force microscopy, plasma atomic emission spectroscopy, photon correlation spectroscopy, atomic absorption spectroscopy..

MPH2C.3 ADVANCED PHARMACEUTICAL ANALYSIS – I 6 Hrs/Week
PRACTICAL
(A minimum of 20 experiments shall be conducted)

Experiments based on theory

REFERENCES:

1. Pharmaceutical Analysis by Ohannason
2. Chemical Analysis by Settle
3. Pharmaceutical Analysis Modern Methods by Munson
4. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
5. Instrumental methods of analysis by Willard Dean & Merrit.
6. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle pub. by Prentice Hall Inc.
7. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)

UNIT-I

1. A detailed study of the principles, instrumentation and applications of the following Instrumental analysis:
- X-ray fluorescence spectrometry
 - X-ray diffraction
 - Scintillation counter
 - Inductively coupled plasma-atomic emission spectroscopy
 - Electron spin resonance spectroscopy (ESR)

UNIT-II

2. Interpretation of spectral data of Infrared spectroscopy, H^1 N.M.R & C^{13} N.M.R and MASS spectroscopy. for structural elucidation of organic molecules

UNIT-III

3. A detailed study of the various principles and procedure involved in the quantitative analysis of pharmaceutical preparations and dosage forms containing the following groups of drugs included in I.P. (Biological and microbiological methods excluded)
- | | |
|---------------------------------|----------------------------------|
| (a) Analgesics and Antipyretics | (b) Sedatives & Tranquillizers |
| (c) Antihypertensives | (d) Antibiotics & Antibacterials |
| (e) Cardiovascular drugs | (f) Vitamins |
| (g) Antihistaminics | (h) Antidiabetics |

UNIT-IV

4. A detailed study of the principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage form using the following reagents and reactions.
- (i) Oxidative coupling reactions using MBTH (3-methyl-2-benzothiazolinone hydrazone hydrochloride)
 - (ii) Diazotization followed by coupling
 - (iii) Oxidation followed by complexation.
 - (iv) Oxidation followed by charge transfer reaction.
 - (v) Condensation reactions using the reagents Para Dimethyl Amino Benzaldehyde (PDAB), Para Dimethyl Amino Cinnamaldehyde (PDAC), Folin's reagent and Gibb's reagent.
 - (vi) Folincioalteu reagent (FC reagent)

REFERENCES:

1. Instrumental methods of analysis by Scoog and West.
2. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
3. Instrumental methods of analysis by Willard Dean & Merrit.
4. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle pub. by Prentice Hall Inc.
5. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)
6. Spectrometric identification of organic compounds by silver stein (7th Edition) 1981.
7. Pharmaceutical analysis edited by Higuchi and Brochmann.
8. Organic Spectroscopy by William Kemp

**M.PH 2C.5 PHYTOPHARMACEUTICAL ANALYSIS
THEORY**

3 Hrs/Week

UNIT – I

Methods of systematic phytochemical analysis including extraction and identification of plant constituents using chromatographic techniques.

Quality control of crude drugs : proximate analysis including ash and extractive values, crude fibre content, U.V. and fluorescence analysis of powdered drugs.

UNIT – II

Qualitative & quantitative microscopy and microchemical tests.

Detection of common adulterants and insects infestation in whole and powdered drugs.

UNIT – III

Analysis of official formulations derived from crude drugs including some Ayurvedic preparations.

Brief study of quality control of plant-products and their high-throughput screening.

UNIT – IV

Microbiological screening methods for antimicrobial activity.

WHO guidelines for the quality control of raw materials used in herbal formulations.

**M.PH 2C.6 PHYTOPHARMACEUTICAL ANALYSIS
PRACTICAL**

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Spectrophotometric determination of caffeine from tea powder.
2. The Estimation of curcumin from curcuma longa by spectrophotometric methods.
3. Determination of sugars by descending paper chromatography.
4. Determination of bitterness value of crude drugs.
5. Determination of extractive values of crude drugs.
6. Fluorimetric analysis of iso-quinoline alkaloids.
7. Determination of R_f values of different amino acids and alkaloids.
8. Antimicrobial activity of some plant extracts using different pathogenic and non-pathogenic organisms.
9. Colorimetric analysis of some plant drugs.

REFERENCES:

1. Pharmacopoeia of India
2. Textbook of Pharmacognosy by Trease & Evans.
3. Textbook of Pharmacognosy by Tyler, Brady & Robber.
4. Phytochemical Methods by J.B.Harborne
5. Instrumental methods of Analysis by Willard, Merrit, Dean
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Application of Absorption spectroscopy in Organic compounds by J.R.Dyer.
8. The Quantitative Analysis of Drugs by D.C.Garrat.
9. Analytical Microbiology by Kavanaagh.F.
10. Microbiological Assays by Barton J.Wright.

MPH2C.7: SEMINAR / ASSIGNMENT

MPH2C.8: COMPREHENSIVE VIVA

M.PHARM (PHARMACOLOGY)

MPH2D.1 PHARMACOKINETICS & DRUG METABOLISM THEORY 3 Hrs/Week

UNIT-I

Drug absorption: Gastrointestinal, Percutaneous and rectal kinetics and factors affecting drug absorption and bioavailability

UNIT-II

Drug distribution: Plasma protein binding – Factors affecting plasma protein binding, Tissue binding, transfer of drugs through biological barriers and their therapeutic implication in drug action.

Elimination of drugs: Concept of renal clearance and excretion of drugs, biological half-life.

UNIT-III

Reaction of body to foreign substances: Biotransformation of drugs, phase I and phase II metabolic reactions. Microsomal and non microsomal reactions.

Drug metabolism in liver, kidney, intestine and placenta. Drug metabolism in fetus and new born. In-vitro and In-vivo studies in drug metabolism

UNIT-IV

Factors influencing drug metabolism: 1. Stereo chemical, and physico chemical factors, 2. Physiological factors: species difference, strain difference, sex, age and environmental factors. 3. Pathological states, 4. Genetic factors: Pharmacogenetics, heritable factors recognized in man by use of drugs.

MPH2D.2 PHARMACOKINETICS AND DRUG METABOLISM PRACTICAL 6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Pharmacokinetic study of sulphonamides after oral administration in humans from urine samples.
2. Pharmacokinetic study of sulphonamides after oral administration in rabbits from blood data.
3. Pharmacokinetic study of sulphonamides after I.V. administration in rabbits from blood data
4. Calculation of bioavailability of sulphonamide from the above blood data in rabbits
5. To determine Protein binding studies of any three drugs by using equilibrium dialysis method.
6. Bioavailability studies of sulphonamide/paracetamol or any other drug from salivary data of humans.
7. To study the influence of urinary pH on salicylate excretion.
8. Calculation of different Pharmacokinetic parameters like K_a , K_e , $t_{1/2}$, C_{max} , T_{max} and AUC from the given blood data.

REFERENCES:

1. Gibaldi, M. and Donald Perrier – Pharmacokinetics

2. Rowland, M. and Tozer, T.N. , Clinical Pharmacokinetics – Concepts and applications, Lea and Fibiger, USA
3. Abdou, H.M., Dissolution, Bioavailability and Bioequivalence, Mack Publishing Co. Ltd., Easton, PA
4. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna WU – Pong & Andrew B.C. Yu
5. Principles of Medicinal Chemistry by William O. Foye, Thomas L. Lemke and David A. Williams
6. Wilson and Gisvold's text book of Organic Medicinal and Pharmaceutical Chemistry by Jaime N. Delgado & William A. Remers

**MPH2D.3 GENERAL PHARMACOLOGY
THEORY**

3 Hrs/Week

UNIT-I

Drugs acting on ANS:

- Cholinergic drugs and Cholinergic blocking drugs
- Ganglionic stimulants, ganglionic blockers
- Neuromuscular blockers
- Adrenergic (or) Sympathomimetic drugs
- Antiadrenergic (or) sympathetic blockers

UNIT-II

Drugs acting on CNS:

General anesthetics, Anxiolytics & hypnotic drugs, Antiepileptics, Analgesics, CNS stimulants, NSAID's, Antigout drugs, Antipsychotic drugs, Antidepressants and Anti Parkinsonian drugs

Drugs acting on peripheral nervous system: Local anesthetics

UNIT-III

Drugs acting on CVS: Cardiotonics, Antiarrhythmic drugs, Antianginal drugs, Antihypertensives
Diuretics

Drugs acting on Digestive system: Drugs used in gastric ulcer, purgatives, antiemetics, antidiarrhoeals

Drugs acting on Respiratory System: Bronchodilators, Expectorants and Antitussive agents

UNIT-IV

Chemotherapy: Basic principles of chemotherapy; chemotherapy of bacterial infections (antibacterial and antibiotics); chemotherapy of tuberculosis and leprosy; chemotherapy of viral and fungal infections, malaria, amoebiasis, cancer and AIDS.

REFERENCES:

Pharmacology by H.P. Rang, M.M. Dale, J.M. Ritter & P.K. Moore

Pharmacology and Pharmacotherapeutics by R.S. Satoskar, S.D. Bhandarkar and S.S. Ainaure

Pharmacology (Lippincott's) by Mary J. Mycer, Richard A. Harvey and Pamela C. Champe
Essentials of Medical Pharmacology by K.D. Tripathi

The Pharmacological basis of therapeutics by Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman

**MPH2D.4 GENERAL PHARMACOLOGY
PRACTICAL**

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Dose response curve of acetylcholine by using the rectus abdominis muscle of frog

2. 1.1 bio-assay of acetylcholine on the rectus abdominis muscle of frog
3. 2.1 bioassay of acetylcholine on the rectus abdominis muscle of frog
4. Effect of an agonist on acetylcholine using rectus abdominis muscle of frog
5. Effect of an antagonist on acetylcholine using rectus abdominis muscle of frog
6. 2.1 bioassay of histamine in the guinea pig ileum
7. To calculate pA₂ value for atropine using acetylcholine as an agonist employing guinea pig ileum preparation
8. To estimate the strength of an unknown sample of acetylcholine by four point bioassay using rectus abdominis muscle of frog
9. To estimate the strength of an unknown sample of histamine by four point bioassay using guinea pig ileum
10. To record the CRC of 5-hydroxytryptamine using rat fundus strip preparation
11. To record the CRC of oxytocin using rat uterus preparation

Demonstration:

- Effect of autonomic drugs on rabbit intestine
- Bronchodilation on guinea pig tracheal chain
- To study the effect of drugs on the coronary blood flow and heart rate of isolated rat heart (Langendorff's heart preparation)
- To demonstrate the effect of various drugs on the blood pressure of anaesthetized dog

MPH2D.5 CLINICAL PHARMACOLOGY & TOXICOLOGY THEORY

3 Hrs/Week

UNIT-I

Drugs interactions: Mechanism, Pharmacokinetic & Pharmacodynamic drug-drug interaction, Food-drug and drink interaction

Adverse drug reactions: Definition and classification, epidemiology, predisposing factors, pharmacovigilance & pharmacoepidemiology, mechanism of ADR & different types of ADR, Therapeutic Drug Monitoring

UNIT-II

- a) Drug therapy in
 - Geriatrics
 - Pediatrics
 - Pregnancy & lactation
- b) Drug induced diseases, (Iatrogenic diseases), Teratogenicity and Carcinogenicity

UNIT-III

Various disorders and their therapeutic monitoring

- **CVS disorders** : Hypertension, Ischaemic heart disease, CHF, Cardiac arrhythmias
- **CNS disorders** : Epilepsy, Parkinsonism, Psychotropic disorders(Schizophrenia depression and mania)
- **Infectious disorders** : Gastrointestinal, respiratory and urinary infections, Endocarditis and Meningitis
- **Endocrine disorders** : Diabetes mellitus, Hypo / Hyperthyroidism, Cushing's syndrome, Addison's disease, Sexually transmitted diseases

UNIT-IV

- Clinical evaluation of drugs : Clinical trials
- Testing of Acute, Subacute and Chronic toxicity
- Determination of LD₅₀ and ED₅₀

REFERENCES:

1. Clinical Pharmacy and Therapeutics by Roger Walker and Clive Edwards
2. Clinical Pharmacy by D.R. Laurence, P.N. Bennett and M.J. Brown
3. Clinical Pharmacology by Herphendol

**MPH2D.6 RECENT ADVANCES IN PHARMACOLOGY
THEORY**

3 Hrs/Week

UNIT-I

Neurohumoral transmission in Central and Autonomic Nervous system : Mechanism of Neurohumoral transmission in CNS and ANS, Adrenergic cholinergic, dopaminergic, Serotonergic, Histaminergic, GABA ergic, Glutamate and Purinergic systems.

UNIT-II

Autacoid Pharmacology : A study of the mechanism involved in the formation, release Pharmacological actions and possible physiological role of histamine, serotonin, kinins, prostaglandins, Opioid autacoids, cyclic 3.5 AMP, leukotrienes, polypeptides & nitric oxide in central and peripheral tissues.

UNIT-III

Renin-angiotensin system: Its physiological role, essential hypertension, Interrelationship between rennin angiotensin system and sympathetic nervous system – Pharmacology of Drugs acting on Renin-angiotensin system

UNIT-IV

Theories of Drug action: Principles of drug action, ion channels, enzymes, Drug receptor theory : Types of receptors : G-Proteins, Second messengers and gentry, Principle of drug design, structure activity relationship of selected groups like opioid drugs, catecholamines, penicillins, barbiturates, benzodiazepines.

REFERENCES:

1. The Pharmacological basis of therapeutics by Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman
2. Principles of Medicinal Chemistry by William O. Foye, Tomas L. Lemke & David A. Williams
3. Pharmacology by H.P. Rang, M.M. Dale, J.M. Ritter & P.K. Moore
4. Essentials of Pharmacotherapeutics by F.S.K. Barar
5. Principles of drug action by Golsteins, Aranow and Kalman.

MPH2D.7: SEMINAR / ASSIGNMENT

MPH2D.8: COMPREHENSIVE VIVA

M.PHARM (PHARMACEUTICAL BIOTECHNOLOGY)

**M.PH2E.1: MOLECULAR BIOLOGY & RECOMBINANT DNA TECHNOLOGY
THEORY**

3 Hrs/Week

UNIT – I

Molecular Biology: Organization of Genome, DNA replication, damage and repair systems, transcription, translation, their control system, post-translational modifications. Regulation of gene expression in eukaryotic & prokaryotic systems.

UNIT – II

Recombinant DNA Technology: Restriction Endonucleases, cloning vectors: plasmid, phagemid, cosmids, Ti plasmid, Yeast artificial chromosome, BAC (Bacterial Artificial Chromosome) Expression vectors employed in rDNA. Gene cloning & manipulation. Control & optimization of

expression of cloned gene in recombinant cells – Production of Biomolecules by rDNA technology with examples (insulin & hepatitis B vaccine, activase).

UNIT – III

Chemical synthesis of gene sequencing and amplification of DNA, PCR & its application. DNA labeling : Isotopic & non-isotopic methods, Southern, Northern, Western blotting, DNA finger printing, Microarray technology, cDNA and genomic DNA library.

UNIT – IV

Application of Gene manipulation: Introduction to Antisense and ribozyme technology. Gene Therapy: *ex-vivo* & *in-vivo* therapy. Gene Therapy models – Cystic Fibrosis Transmembrane Receptor (CFTR), Somatic cell and genetic gene therapy, Human Genome Project and its application to mankind.

Current Biopharmaceutical Issues: Ethics; Biosafety; Intellectual Property Rights (IPR); Regulatory Affairs of biotechnology products – national & international scenario.

REFERENCES:

- D.M. Glover, Genetic Engineering, Cloning DNA, Chapman and Hall, New York, 1980
Recombinant DNA, 2nd Edition, Watson.
Molecular Biotechnology – Principle and Application of recombinant DNA – B.R. Glick & J.J. Pasternak.
Genes VIII, Lewin Benjamin.
Pharmaceutical Biotechnology ; S.P. Vyas and V. K. Dixit, 2005, CBS Publishers.
Pharmaceutical Biotechnology – An Introduction for Pharmacists & Pharmaceutical Scientists – D.J.A. Crommelin & R.D. Sindelar (Eds.), 2002, Routledge (Pub.).
Principles of Biochemistry, CBS Publishers, Lehninger, Nelson & Cox.
The Principles of Gene Manipulation – Old, R.W & Primrose, S.B.
Biochemistry, Freeman & Co, NY, Lubert Stryer.
Molecular Biology of Gene, Pearson Education, Watson.

M.PH2E.2: MOLECULAR BIOLOGY & RECOMBINANT DNA TECHNOLOGY 6 Hrs/Week **PRACTICAL**

(A minimum of 20 experiments shall be conducted)

- Isolation of DNA / RNA.
- Qualitative & Quantitative analysis of Nucleic acids
- Isolation of plasmid DNA.
- Restriction Digestion DNA/plasmid
- Agarose gel electrophoresis
- Southern Blotting, Northern Blotting.
- DNA Ligation.
- Computational Biology:
 - Database Searching.
 - BLAST, FASTA
 - ClustalW
 - Secondary/Tertiary Structure Prediction of proteins.
 - Molecular modeling and drug designing.

REFERENCES:

1. Biotechnology – A Laboratory Course – J.M. Becker, G.A. Cladwell, E.A. Zachgo, 2004, Academic Press.
2. Molecular Cloning – A Laboratory Manual – Sanbrook, Fritsch and Maniatis, Cold Spring Harbor Laboratory Press.
3. Introduction to Bioinformatics, Parry & Attwood-Smith.
4. A Practical Guide to Analysis of Genes & Proteins, Baxavenis & Oulette.

M.PH2E.3: ANIMAL BIOTECHNOLOGY & IMMUNE TECHNOLOGY 3 Hrs/Week THEORY

UNIT – I

Animal Cell Culture: Laboratory requirement of animal cell culture, principles of animal cell culture, establishment and maintenance of cell lines, cell type and biological characterization. Introduction to stem cell biology.

UNIT – II

Cell growth characteristics and kinetics, Micro-carrier attached growth, Cell culture in continuous, perfusion and hollow fibre reactor, Mass transfer in mammalian cell culture.

UNIT – III

Immune system: Defence and immunity, MHC, Antigen Processing & presentation, molecular basis of Antibody diversity, immune response and its regulation, Transplantation immunology, Graft vs host rejection, Autoimmunity. Immunodeficiency disease & Approaches for correcting immune dysfunctions.

UNIT – IV

Hybridoma technology: History, Principle, Production, Screening & selection, preservation & application of monoclonal antibodies.

Vaccinology: Immunization, Vaccines (Live, attenuated, dead & subunit) vaccines & rDNA vaccines, Synthetic peptide vaccines. Adjuvants, delivery systems & formulation considerations, Plant Based Vaccines (Plantibodies).

REFERENCES:

1. Balasubramanian, Bryce, Dharmalingam, Green and Jayaraman (Eds.), Concepts in Biotechnology, University Press, 1996
2. Hood L.E., Weissman I., Wood W.B. and Wilson J.H. Immunology, Benjamin Cummings, 1989.
3. Biotol Series – Butterworth and Heineman, Oxford, 1992.
4. Essential Immunology, Roitt, I.M., 9th Ed. (1997), Blackwell Scientific, Oxford, UK.
5. Immunology, Kubly, J. 3rd Ed. (1997), Freeman, W.H., Oxford.
6. Biotechnology V, M. K. Sateesh.
7. Culture of Animal Cells- I.Freshrey (Willy)

**M.PH2E.4: ADVANCED PHARMACEUTICAL BIOTECHNOLOGY – II 3 Hrs/Week
THEORY**

UNIT – I

Plant Tissue Culture: Principles and practice in plant tissue culture, tissue culture media. Initiation of callus, organogenesis, somatic embryogenesis, clonal propagation, shoot – tip culture, embryo culture, protoplast isolation culture and fusion; Vector and vectorless gene delivery, GMP (Genetically Modified Plant)

UNIT – II

Microbial Transformation: Microbial transformation of steroids, peptides & alkaloids. Advantages & commercial applications.

UNIT – III

Bioinformatics: Introduction, Evolution & role of bioinformatics in modern pharmaceutical biotechnology; Biological databases: Primary, secondary & tertiary databases (GenBank, EMBL, SWISS-PROT, NBRF-PIR, & PDB. Basic ideas of the other types of biological databases.

Bioinformatics Tools: Sequence Analysis – Dot Plot, Global, Local alignment. Database search techniques: FASTA, BLAST. Multiple Sequence Analysis (MSA): Introduction, Importance of MSA in Protein structure, protein family, using bioinformatics tools like Clustal W

UNIT IV

Secondary Structure prediction tools: Chou-Fasman, GOR, Hidden Markov Model (HMM), & Neural Network methods (PHD); Structural alignment: Basics of Structural alignment.

Tertiary protein structure analysis: Homology Modelling, Fold recognition, Ab Initio methods, Molecular modeling, Drug Design.

REFERENCES:

1. Plant Biotechnology, Slater, OUP.
2. Tissue Culture & Plant Science, Street.
3. Biotechnology V, M.K. Sateesh.
4. Plant Tissue & Organ Culture, Gamburg & Philips.
5. Introduction to Bioinformatics, Lesk.
6. Introduction to Bioinformatics, Parry & Attwood-Smith.
7. Bioinformatics, Sequence & Genome Analysis, D.Mount.
8. Industrial Microbiology, Arora.

**M.PH2E.5: BIOPROCESS TECHNOLOGY
THEORY**

3 Hrs/Week

UNIT – I

Protein: Structure, type & function. Protein folding & sorting, Chaperonis prions. Protein sequencing, site directed mutagenesis.

Enzyme & cell immobilization techniques & its kinetics. Application of cell & enzyme immobilization in pharmaceutical industrial.

UNIT - II

Downstream Processing: Basic concepts of Bio-separation, Characteristics of bio-products; Flocculation and conditioning of broth,

Mechanical separation processes: Filtration at constant pressure and at constant rate; equations for batch and continuous filtration, centrifugal and cross-flow filtration.

Centrifugation: basic principles, Type and applications of centrifugation.

Membrane Filtration: Micro-filtration, Reverse osmosis, Ultrafiltration, concentration polarization, rejection.

UNIT - III

Foam-fractionation; Solvent extraction, aqueous two-phase extraction; Salt precipitation (basic concepts without mathematical consideration);

Chromatographic separations; Electrophoretic separation. SDS-PAGE (Polyacrylamide) & Agarose Gel (horizontal and vertical type).

UNIT - IV

Formulation of Biotechnology Products: Introduction, Basic consideration of stability, Freeze drying, protein stabilization. Drug delivery (protein & peptide drugs), Drug targeting,. Barrier to protein & peptide drug delivery, factors responsible for drug delivery.

REFERENCES:

1. Pharmaceutical Biotechnology -An Introduction for Pharmacists and Pharmaceutical Scientists - D.J.A. Crommelin and R.D. Sindelar (Eds.), 2002, Routledge (Pub.)
2. Pharmaceutical Biotechnology – S. P. Vyas & V. K. Dixit, 2005, CBS Publishers.
3. G. Francis, Modelling and Simulation

M.PH2E.6: BIOPROCESS TECHNOLOGY PRACTICAL

6 Hrs/Week

(A minimum of 20 experiments shall be conducted)

Experiments based on theory

MPH2E.7: SEMINAR / ASSIGNMENT

MPH2E.8: COMPREHENSIVE VIVA

M.PHARM (PHARMACOGNOSY)

M.PH2F.1: INDUSTRIAL PHARMACOGNOSY-I THEORY

3 Hrs/Week

UNIT-I

1. Technology for production of crude drugs
 - Factors involved in cultivation, collection, preservation and storage of plant drugs.
 - Medicinal plant growth regulators.
 - Disease management of medicinal and aromatic plants.
 - Mutation, polyploidy, hybridization with special reference to natural drugs

UNIT-II

2. Profiles for commercial cultivation technology and post harvest care of following medicinal and aromatic plants - Aswagandha, Senna, Ergot, Opium poppy, Aloe, Digitalis, Periwinkle, Safed musli, Ginseng, Squill, Strophanthus, Jethropha, Lemon grass, Geranium, Patchouli, Clove, Sandalwood.

UNIT-III

3. Isolation, Estimation and Utilization of Sennosides, Digoxin, Quinine, Podophyllotoxin, Caffeine, Taxol, Atropine, Solasodine, Ginsengoside, Vincristine and Vinblastine, Ouabain, Strychnine, Nimbidine.

4. Profile for manufacture and commerce of Papain, Pectin, Starch and Gelatin.

UNIT-IV

5. Distribution of chemical groups and its confirmation
6. Distribution of unorganized drugs in nature and its importance
7. Surgical Sutures and Ligatures
8. Traditional system of medicines-Ayurveda, Siddha, Unani, Homeopathy, TCM (Traditional Chinese Medicine)

M.PH2F.2: INDUSTRIAL PHARMACOGNOSY-I PRACTICAL

3 Hrs/Week

(A minimum of 20 experiments shall be conducted)

1. Standardization of starch of natural origin to be useful as additives for the preparation of tablets.
2. Isolation of Pharmaceutically important phytochemicals from crude drugs.
3. TLC characterization of medicinal plant extracts and isolation of phytochemicals.
4. CC characterization of medicinal plant extracts and isolation of phytochemicals.
5. Identification of chemical groups distributed in the plant.
6. Characterization of plant drugs by histologic study and establish its correlation with adulterant and substitute variety available in nature.
7. Microscopic measurement of cell and cell contents and other parameters to be useful for standardization of plant drug.

REFERENCES:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Wealth of India, CSIR Publication
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Phytochemical Methods by J.B.Harborne
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai
8. Practical Pharmacognosy by T.E.Wallis

M.PH2F.3: HERBAL DRUG FORMULATION AND STANDARDIZATION 3 Hrs/Week THEORY

UNIT-I

1. Preparation of herbal formulation for Diabetes, Liver disorders, Inflammation, Fever using indigenous medicinal plants.
2. Preparation of herbal cosmetics using Indian traditional medicines.

UNIT-II

3. Ethno medicinal documentation of medicinal plants to be useful for preparation of herbal formulation to cure the ailments in human beings.
4. Traditional approach of herbal formulation and its scientific exploration.
5. Recent trends in poly-herbal medicines.

UNIT-III

6. Study of Ayurvedic formulations- Asava, Aritsa, Gutika, Bhasma, Ghrita.
7. Study of formulations using herbal extracts/pure phytopharmaceuticals.

UNIT- IV

8. Evaluation and Standardization of herbal formulations .

**M.PH2F.4: HERBAL DRUG FORMULATION AND STANDARDIZATION 3 Hrs/Week
PRACTICAL
(A minimum of 20 experiments shall be conducted)**

1. Preparation of herbal formulation and its biological evaluation.
2. Standardization of some herbal formulations.
3. Biological Screening of plant extracts – Anti-inflammatory, Antidiabetic, Diuretics, Antimicrobial, Antipyretic, Antiulcer, Analgesic
4. Preparation of extractive values of plant materials using various solvents.
5. Extraction of volatile oil from plant and its characterization.

REFERENCES:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Wealth of India, CSIR Publication
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Phytochemical Methods by J.B.Harborne
7. Herbal Drug Industry by R.D.Chaudhury
8. Drug Discovery & Evaluation by Vogel

**M.PH2F.5: CHEMISTRY OF NATURAL PRODUCTS
THEORY**

3 Hrs/Week

UNIT-I

1. General methods of isolation and separation of plant constituents.
2. General techniques of biosynthetic studies and brief introduction to biogenesis of secondary metabolites.
3. Factors affecting production of secondary metabolites in medicinal plant.

UNIT-II

4. Alkaloids- Isolation and Chemistry of Atropine, Quinine, Morphine and Ephedrine.
5. Steroid- Chemistry and Stereochemistry of Cholesterol.
6. Preparation and Chemistry of Corticosteroids.
7. Glycosides- A general study of glycosides with detail treatment of Digoxin, Scillarin A, Ouabain.

UNIT-III

8. Antibiotics- Chemistry and therapeutic activity of Penicillin, Streptomycin, Tetracycline and Cephalosporin.
9. Terpenes- Chemistry of Citral, Menthol, Camphor

UNIT-IV

10. Vitamins- Detailed study including commercial production and chemistry of Vitamin-A, Cyanocobalamin, Nicotinamide, Folic acid, Riboflavin .
11. Chemical and Spectral approaches to simple molecules of natural origin.

REFERENCES:

1. Phytochemical Methods by J.B.Harborne
2. Organic Chemistry of Natural Products by A.Singh & S.Singh

3. Organic Chemistry of Natural Products by G.Chatwal
4. Organic Chemistry of Natural Products by O.P.Agrawal
5. Chemistry of Natural Products Alkaloids & Terpenoids by A.Singh
6. Organic Chemistry by I.L.Finar
7. Steroids by Fieser & Fieser
8. Alkaloids by Manske

**M.PH2F.6: ADVANCED PHARMACOGNOSY-II (MEDICINAL PLANT BIOTECHNOLOGY)
THEORY** **3 Hrs/Week**

UNIT-I

1. Historical perspectives, prospects for development of plant biotechnology as source of medical agents. Applications in pharmacy and allied fields.
2. Types, techniques, nutritional requirements and growth of plant tissue cultures, Organogenesis and embryogenesis. Protoplast fusion and cultures, artificial seeds, micropropagation of medicinal and aromatic plants, Genetic stability of tissue cultures.

UNIT-II

3. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents and its impact in pharmacy. Screening and selection of high yielding cell lines. Effect of cultural practices, precursors and elicitors on production of biomedicinals.

UNIT-III

4. Biotransformation, bioreactors, industrially potential tissue culture systems for pilot and large scale cultures of plant cells, cellular totipotency, cryopreservation and retention of biosynthetic potential in cell cultures.
5. Immobilised plant cells culture systems, immobilization techniques, effect of immobilization on secondary metabolism and realization of chemosynthetic potential in immobilized cells.

UNIT-IV

6. Techniques employed in elucidation of biosynthetic pathway, biogenesis of tropane, quinoline, imidazole, isoquinoline and indole alkaloids, sterols, anthraquinone and saponin glycosides, flavanoids and isoprenoid compounds of pharmaceutical significance.

REFERENCES:

1. Pharmaceutical Biotechnology- Vyas and Dixit
2. Industrial Microbiology- Prescott & Dumm
3. Text Book of Pharmacognosy – Trese and Evans

MPH2F.7: SEMINAR / ASSIGNMENT

MPH2F.8. COMPREHENSIVE VIVA

M.PHARM (PHARMACEUTICAL TECHNOLOGY)

M.PH.2G.1 BIOTECHNOLOGY THEORY

3 Hrs/Week

UNIT-I

1. Nanotechnology: Introduction and History of Nanotechnology and Nanobiology General and Medical/Therapeutic applications of nanobiology and nanotechnology - Techniques used in nanotechnology.

UNIT-II

2. Genetic Engineering: Techniques of gene manipulation, cloning strategies, procedures, cloning vectors, expression vectors, recombination selection and screening. Application of R-DNA technology for the production and bioprocess technology of the following products: Insulin, Interferon, erythropoietin, Hepatitis B Vaccine, and Tissue plasminogen activator.

UNIT-III

3. Enzyme technology: Sources of enzymes, production, isolation and purification of enzymes. Applications of enzymes in pharmaceutical industry, therapeutics and clinical analysis.

UNIT-IV

4. Immuno technology: Hybridoma techniques, fusion methods for myeloma cells and b-lymphocytes. Selection and screening techniques, production and purification and monoclonal antibodies and their applications.

REFERENCES:

1. Selected topics in enzyme engineering by Wingard Jr. L.B.
2. Introduction to genetic engineering by R.W. Old & S.B. Primrose.
3. Therapeutic peptides & proteins, formulation, processing and delivery systems by Ajay K. Banga.
4. Gene transfer & expression protocols – methods in molecular Biology, Vol-VII, Edit by E.T. Murry.
5. Controlled and Novel Drug delivery by N.K. Jain.
6. Modern Pharmaceutics by G.S. Banker.
7. Novel drug Delivery by Y.W. Chein.

MPH2G.2 / MPH2A.2: BIO-PHARMACEUTICS & PHARMACOKINETICS 3 Hrs/Week THEORY

UNIT - I

- I. Bioequivalence and its determination, study design for the assessment of bioavailability and bioequivalence, factors influencing bioavailability and bioequivalence. Statistical concepts in estimation of bioavailability and bioequivalence. Software used in biopharmaceutics and pharmacokinetics study and their significance.

UNIT – II

- II Basic concepts of pharmacokinetics: Compartmental models: One and two compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these

approaches. Application of these models to determine various pharmacokinetic parameters pertaining to.

- i) Absorption: Mechanism and path ways of drug absorption, absorption rate constant, absorption half life, lag time and extent of absorption, AUC.
- ii) Distribution: Physiological influence of drug distribution, protein binding of drug, determination of protein binding sites, clinical significance of drug protein binding. Apparent volume of distribution and its determination.
- iii) Elimination: Over all apparent elimination rate constant, and half life.
under the following conditions:
 - a) Intravenous bolus injection
 - b) Intravenous infusion
 - c) Single dose oral administration
 - d) Multiple dosage oral administration
- iv) Concept of clearance: Organ clearance, total clearance, hepatic clearance, gut wall clearance and renal clearance.

UNIT – III

- III Non-linear Pharmacokinetics: Concepts of linear and non linear pharmacokinetics, Michaelis – Menton kinetics characteristics, basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses.
- IV Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics and Chronotherapeutics.

UNIT – IV

- V Non-compartmental pharmacokinetics:
 - i) Physiologic Pharmacokinetic Model: Concept, applications and limitations.
 - ii) Statistical moments theory: Concept and applications, mean residence time, mean absorption time, mean dissolution time.

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
3. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
4. Pharmaceutical Codex.
5. Applied Biopharmaceutics and Pharmacokinetics by Leon. Shargel, Andrew B.C. Yes.

MPH2G.3 / MPH2A.3: BIOPHARMACEUTICS & PHARMACOKINETICS 6 Hrs/Week PRACTICAL

(A minimum of 20 experiments shall be conducted)

1. To perform bioequivalence testing on marketed analgesic / sulphonamide tablets.
2. Comparison of dissolution of different marketed products of co-trimoxazole and other suspensions.
3. To determine K_a , biological half-life, AUC and other pharmacokinetic parameters of rifampicin / nitrofurantoin by urinary excretion method.
4. To determine protein-binding of drugs by equilibrium dialysis method (2 expts.)
5. Bioavailability studies of paracetamol or any other drug by salivary data (2 expts.)
6. To study the influence of urinary pH on salicylate excretion.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} and T_{max} from the given data (2 expts.)
8. Calculation of AUC and bioequivalence from the given data (2 expts.)

UNIT - I

Fundamentals of controlled drug delivery systems, theory of mass transfer, use of polymers in controlled drug delivery pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled release systems:

1. Controlled release oral drug delivery systems.
2. Parenteral controlled release drug delivery systems.

UNIT - II

Fundamentals of controlled drug delivery systems, theory of mass transfer, use of polymers in controlled drug delivery pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled release systems:

1. Implantable therapeutic systems.
2. Transdermal therapeutic systems and Iontophoresis.
3. Ocular and intrauterine delivery systems.
4. Bioadhesive drug delivery systems.
5. Proteins and peptide drug delivery.

UNIT - III

Biochemical and molecular biology approaches to controlled drug delivery.

1. Micro particulate drug carriers: Liposomes, Neosomes, Microspheres, Nanoparticles and Resealed erythrocytes.
2. Monoclonal antibodies for drug delivery.

UNIT - IV

a. Drug targeting to particular organs:

1. Drug delivery to respiratory system.
 2. Problems of drug delivery to the brain and targeting to brain.
 3. Drug delivery to eye
 4. Drug targeting in Neoplastic diseases.
- b. Drug carrier systems targeted to widely dispersed cells.
1. Delivery to Macrophages
 2. Delivery to lymphoid cells of immune network
 3. Delivery to lysosomal storage diseases.

REFERENCES:

1. Remington's Pharmaceutical Sciences.
2. Novel Drug Delivery Systems by Y.W.Chein, Marcel Dekker, Inc.
3. Controlled Drug Delivery Systems by Joseph R. Robinson and Vincent ILL. Lee.
4. Bentley's Text book of Pharmaceutics by Rawlins, EL. Publications.
5. Microencapsulation by Simon Benita, Pub. By Marcel Dekker Inc.
6. Drug Targeting and Delivery edited by H.E. Junginger
7. Specialized Drug Delivery Systems edited by Praveen Tyle, Pub. By Marcel Dekker Inc.
8. Colloidal Drug Delivery System by Jorg Kreuter.

PRACTICAL**(A minimum of 20 experiments shall be conducted)**

1. Study on diffusion of drugs through various polymer members (2 expts.)
2. Preparation and study on invitro dissolution of various sustained action products and comparison with marketed products (3 expts.)
3. Preparation of matrix tablets using various polymers like PVP etc and studying their release patterns (2 expts.)
4. Preparation and evaluation of microcapsules by different microencapsulation techniques like:
 - (a) Simple coacervation techniques: Gelatin-water-ethanol.
 - (b) Coacervation by temperature charges : Ethylcellulose in cyclohexane for phenobarbitone.
 - (c) Coacervation by non-solvent-addition: cellulose acetate butyrate in methyl ethyl ketone using isopropylether as non-solvent (1 expt. in each).
5. Preparation and evaluation of wax embedded micro-spheres of diclofenac sodium and theophylline (2 expts.)
6. Preparation of various polymer films containing different drugs and studying the film characteristics and release patters (3 expts.).
7. To perform sugar coating and nonenteric and enteric film coating on tablet and their evaluation (3 expts.)

**MPH2G.6: / MPH2A.6 ADVANCED PHARMACEUTICAL TECHNOLOGY 3 Hrs/Week
THEORY****UNIT - I**

1. Formulation Development:
 - (a) Solid dosage forms:

Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, physics of tablet compression and computerization for in process quality control of tablets.
 - (b) Powder dosage forms:

Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.
 - (c) Liquid and semi-solid dosage forms:

Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.
 - (d) Aerosols:

Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, manufacture & quality control.

UNIT - II

2. Aseptic processing operation and parenteral dosage form development:

Introduction, Contamination control, Microbial environmental monitoring, Microbiological testing of water, Microbiological air testing, Characterization of aseptic process, Media and incubation conditions, Theoretical evaluation of aseptic operations. Advances in materials and production techniques for parenteral dosage forms.

UNIT - III

3. Scale-up Techniques:

- Effect of scale up on formulation, process parameters like mixing, granulation, drying, compression, coating, packaging, stability, selection and evaluation of suitable equipments.
4. Process Validation:
Regulatory basis, Validation of solid dosage forms, Sterile products, Liquid dosage forms, Process validation of raw materials, Validation of analytical methods, Equipment and Process.

UNIT - IV

5. Optimization techniques in pharmaceutical and processing:
Optimization parameters, statistical design and other applications, design, development and optimization of in-vitro test systems to evaluate and monitor the performance of different types dosage forms, the relevance and importance of in-vitro/in-vivo associations at every stage of product development and manufacture, the regulatory evolution and current thinking on this aspect, application of statistical techniques in product development and evaluation including quality control.

MPH2G.7: SEMINAR / ASSIGNMENT

MPH2G.8: COMPREHENSIVE VIVA