

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

<p><u>M.PHARM. – I SEMESTER</u> M.PH. 1.1 Modern Analytical Techniques M.PH. 1.2 Modern Analytical Techniques (P) M.PH. 1.3 Biostatistics M.PH. 1.4 Drug Regulatory Affairs and Intellectual Property Rights M.PH. 1.5B Stereo Chemistry of drugs and Mechanism of Reactions M.PH. 1.6B Stereo Chemistry of drugs and Mechanism of Reactions(P) M.PH. 1.7 Seminar / Assignment M.PH. 1.8 Comprehensive Viva</p>	<p>(PHARMACEUTICAL (CHEMISTRY)) M.PHARM. – II SEMESTER M.PH2B.1 Advanced Medicinal Chemistry-I M.PH2B.2 Advanced Medicinal Chemistry-II M.PH2B.3 Advanced Medicinal Chemistry-III M.PH2B.4 Advanced Med Chemistry-III (P) M.PH2B.5 Chemistry of Natural Products M.PH2B.6 Chemistry of Natural Products(P) M.PH2B.7 Seminar / Assignment M.PH2B.8 Comprehensive Viva</p>
<p><u>M.PHARM. – III SEMESTER</u> M.PH. 3.1 Seminar – I (Mid Semester / Literature Survey of the project) M.PH. 3.2. Seminar – II (End Semester / Progress of the project)</p>	<p>M.PHARM. – IV SEMESTER M.PH. 4.1 Project Dissertation M.PH. 4.2. Project Seminar and Viva-voce</p>

M.PH. 1.1 MODERN ANALYTICAL TECHNIQUES 3 Hrs/Week (THEORY)

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) ^1H N.M.R & ^{13}C 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 6 Hrs/Week (PRACTICAL) (20 experiments)

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 3 Hrs/Week THEORY

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

M.PH 1.4 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS THEORY 3 Hs

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 Pharmaceutics 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. 1.5B STEREOCHEMISTRY OF DRUGS AND REACTION MECHANISM THEORY 3 Hs 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, MnO_2 ,

Oppenauer oxidation, oxidation with silver.

• Formation of Phenols & Quinone, Conversion of Alkenes to Epoxide, Conversion of Alkenes to Diols, Bayer-villegger Oxidation, Oxidative bond cleavage using $KMnO_4$, Osmium reagents, Ruthenium reagents and chromium reagents, LTA, Sodium per-iodoate, 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-villegger 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

(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 & Boyd.
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