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

M.PHARM. – I SEMESTER	**M.PHARM. – II SEMESTER (PHARMACEUTICS)**
M.PH. 1.1 Modern Anal Techniques	M.PH2A.1 Advanced Physical Pharmaceutics
M.PH. 1.2 Modern Anal Technques **(P)**	M.PH2A.2 Bio-Pharm and Pharmacokinetics
M.PH. 1.3 Biostatistics	M.PH2A.3 Bio-Pharm and Pharmacokinetics **P**
M.PH. 1.4 Drug Regulatory Affairs and Intellectual Property Rights	M.PH2A.4 Novel Drug Delivery Systems
M.PH. 1.5A Formulation Development	M.PH2A.5 Novel Drug Delivery Systems **(P)**
M.PH. 1.6A Formulation Development **P**	M.PH2A.6 Advanced PharmTechnology
M.PH. 1.7 Seminar / Assignment	M.PH2A.7 Seminar / Assignment
M.PH. 1.8 Comprehensive Viva	M.PH2A.8 Comprehensive Viva
M.PHARM. – III SEMESTER	**M.PHARM. – IV SEMESTER**
M.PH. 3.1 Seminar – I (Mid Semester / Literature Survey of the project)	M.PH. 4.1 Project Dissertation
M.PH. 3.2. Seminar – II (End Semester / Progress of the project)	M.PH. 4.2. Project Seminar and Viva-voce

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) 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 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, Poison 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. 1.5A/ M. PH. 1.5G 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 cosmetics.; 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 6 Hrs/Week PRACTICAL

(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)