

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	Paper based on Specialization	3	0	0	3
(A to G)					
M.PH. 1.6	Practical based on Specialization	0	0	6	4
(A to G)					
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 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 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 & 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