

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Scheme of Teaching and Examination

Master of Pharmacy (M. Pharma)

(Quality Assurance)

I Semester

S. No.	Board of study	Subject Code	Subject	Periods per week			Scheme of Exam. Theory/Practical			Total Marks	Credit L+(T+P)/2
				L	T	P	ESE	CT	TA		
1	Pharmacy	565111(41)	Advanced Research Methods	4	1	-	100	20	20	140	
2	Pharmacy	565112(41)	Pharmacology and Biostatistics	4	1	-	100	20	20	140	
3	Pharmacy	565113(41)	Drug Regulatory Affairs and Quality Assurance	4	1	-	100	20	20	140	
4	Pharmacy	565114(41)	Formulation Development	4	1	-	100	20	20	140	
5	Pharmacy	574121(41)	Advanced Research Methods Lab	-	-	6	100	-	50	150	
6	Pharmacy	574122(41)	Pharmacology and Biostatistics Lab	-	-	6	100	-	50	150	
7	Pharmacy	574123(41)	Formulation Development Lab	-	-	6	100	-	40	140	
Total				16	4	18	700	80	220	1000	

L- Lecture, T- Tutorial, P- Practical,

Duration of Theory paper: 3 hours

ESE – End Semester Examination, CT – Class Test, TA- Teacher Assessment

Note: The Syllabi, Scheme of teaching and exams for first semester M.Pharm course shall remain common for all specializations.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M-Pharm. 1st Semester**
Subject: **Advance Research Methods**
Total Theory period: **50**
Total marks in the end Semester: **100**
Minimum of class test to be conducted: **2**

Branch: **Pharmacy**
Code: 565111(41)
Total Tutorial period : **12**

Unit - 1 :

Spectroscopic Method – Introduction, application structure elucidation using UV, IR, NMR, Mass spectrometry with examples.

Unit - 2 :

Separation Techniques – Theory, Instrumentation and application of GLC, HPLC, HPTLC, Chiral chromatography, Ion Pair Chromatography.

Unit - 3 :

Thermal Analysis – Theory, Instrumentation and application of thermo-gravimetric analysis, differential thermal thermal analysis.

Unit - 4 :

Calorimetric analysis – theory, instrumentation, chemical application and structural elucidation, differential scanning calorimetric (DSC), Isothermal titration.

Unit - 5 :

Immunochemical techniques – Immunelectrophoresis, immunoprecipitation, ELISA, radioimmunoassay.

Books Recommended:

1. Practical Pharmaceutical Chemistry, Backett, and Stenlake.
2. Spectrophotometric identification of organic compound, Silverstein.
3. Vogel's Text book of Quality analysis, 5th and 6th edition, Svehla.
4. Textbook of Pharmaceutical chemistry, L. G. Chatten.
5. Instrumental Method of Chemical Analysis.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M-Pharm. 1st Semester**
Subject: **Pharmacology and Biostatistics**
Total Theory period: **50**
Total marks in the end Semester: **100**
Minimum of class test to be conducted: **2**

Branch: **Pharmacy**
Code: 565112(41)
Total Tutorial period: **12**

Unit - 1:

Drug dependence, tolerance, abuse drug allergy and resistance.

Unit - 2:

Genetics, gene cloning, gene delivery and recombinant DNA.

Unit - 3:

Molecular pharmacology, receptor theories, receptor isolation radio- ligand binding studies, Signal transduction mechanism of the cell.

Unit - 4:

Therapeutics regimens – therapeutics response and toxicity, dosage regimens, clinical trial studies, ADME – Pharmacokinetics, Drug – drug interaction and bioassay.

Unit - 5:

Biological screening of new compounds and New drug discovery.

Unit - 6:

Bio-statistics – Student “t” test, chi-square test, correlation probit analysis, analysis of variances.

Books Recommended:

1. The Pharmacological basis of therapeutics-Goodman and Gill man’s
2. Pharmacology- Rang & Dale.
3. Pharmacology-Katzung.
4. Fundamentals of experimental Pharmacology-By M.N.Ghosh
5. Hand book of Experimental Pharmacology-S.K.Kulakarni
6. Text book of in vitro practical Pharmacology by Ian Kitchen
7. Pharmacological Experiments on intact preparations by Churchill Living stone.
8. Hand book of Clinical Pharmacokinetics Gibaldi and Prescott.
9. Indian Pharmacopoeia and other Pharmacopeias.
10. Screening methods in Pharmacology by Robert Turner.A
11. Clinical trials and tribulations by Allien E.Cato
12. Drug discovery and Evaluation by Vogel H.G.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M-Pharm. 1st Semester**

Branch: Pharmacy

Subject: **Drug Regulatory Affairs and Quality Assurance**

Code: 565113(41)

Total Theory period: **50**

Total Tutorial period: **12**

Total marks in the end Semester: **100**

Minimum of class test to be conducted: **2**

Unit - 1 :

Requirement of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 series.

Drug and cosmetics acts and rules. Drug regulatory affairs.

Unit - 2 :

Documentation – Protocols, forms and maintenance of record in Pharmaceuticals industry.

Unit - 3 :

Preparation of documentation of new drug approval and export registration, processing and its application intellectual property rights (patent, copyright and trade marks)

Sewage disposal and pollution control.

Unit - 4 :

Concept in validation of manufacturing, analytical and process, validation and its application.

Unit - 5 :

Basic concept of quality control and quality assurance system, source and control of quality variation of raw material, containers, closures personnel, environmental etc.

Unit - 6 :

In process quality control test, IPQC problem in pharmaceutical industries, ICH guidelines.

Unit - 7 :

Sampling plans, Sampling and characteristics curves, Master formula generation and maintenance, standard operating procedure (SOP) for different dosage forms.

Book Recommended:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M-Pharm. 1st Semester**

Subject: **Formulation Development**

Total Theory period: **50**

Total marks in the end Semester: **100**

Minimum of class test to be conducted: **2**

Branch: **Pharmacy**

Code: 565114(41)

Total Tutorial period: **12**

Unit - 1:

Stability, solubility, Pka, Dissolution rate, Partition Coefficient. In Vitro and In Vivo evaluation techniques, product formulation and CGMP.

Unit -2:

Designing of Pharmaceuticals - Tablets formulation, special tablets and preparation of components for compression. Characterization of granulation, Coating of tablets, evaluation of tablets. Equipment and processing problem in tablets.

Unit - 3:

Topical and rectal absorption of drug, formulations and evaluations.

Unit - 4:

Formulation consideration of oral liquids, suspension, emulsion, development of various products.

Unit - 5:

Formulation consideration of parenteral ophthalmic, depot products, large volume and small volume parenteral, environmental control and quality assurance in parenteral drug manufacturing.

Unit - 6:

Stability in pharmaceuticals and study of stability kinetics.

Unit - 7:

Introduction to controlled and novel drug delivery system, Sustained release dosage form, prodrug concept, Nanoparticals, Liposomes, Resealed erythrocytes, Transdermal and other Novel drug delivery systems.

Unit - 8:

Types of container and closures, packaging and stability assessment.
Optimization techniques in pharmaceutical formulations and processing.
Pilot plant and scale up techniques.

Book Recommended :

1. Controlled Drug Delivery System, J.R. Robinson and V.H.S.L. Lee.
2. Physical Pharmacy, 4th edition, A. Martin, J.C. Swarbrick.
3. Pharmaceutical analysis, 'Ramington' A. R. Gennaro.
4. The theory and practice of Industrial pharmacy, IIIrd edition, L. Lachman, H. A. Liberman.
5. Modern Pharmaceutics, IInd edition, G. S. Banker, C.T. Rhodes.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M-Pharm. 1st Semester**
Subject: **Advance Research Methods (Lab)**
Total practical period: **72**
Total marks in the end Semester: **100**
Minimum of class test to be conducted: **2**

Branch: **Pharmacy**
Code: 574121(41)
Total Tutorial period: **12**

List of Experiment:

1. Determination of α_{\max} and Linearity of methylene blue by spectroscopic method.
2. To determine the absorption curve of aromatic hydrocarbons and the analysis of binary mixture.
3. Estimation of Aspirin by colorimetry.
4. Assay of Paracetamol tablet by UV spectroscopy.
5. Determination of the active constituents in a medicinal preparation by derivative spectroscopy.
6. Estimation of Paracetamol by HPLC.
7. Identification of given sample by paper chromatography.
8. Identification of drug's by TLC.
9. To determine the purity of commercial benzoic acid using compressed discs (IR).
10. Interpretation of given sample by IR spectra.

Books Recommended:

1. Practical Pharmaceutical Chemistry, Backett, and Stenlake.
2. Spectrophotometric identification of organic compound, Silverstein.
3. Vogel's Text book of Quality analysis, 5th and 6th edition, Svehla.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M-Pharm. 1st Semester**
Subject: **Pharmacology and Biostatistics (Lab)**
Total practical period: **72**
Total marks in the end Semester: **100**
Minimum of class test to be conducted: **2**

Branch: **Pharmacy**
Code: 574122(41)
Total Tutorial period: **12**

List of Practicals:

1. To Study the maintenance of common laboratory animals.
2. Bioassay of the more important biogenic agents by various methods.
3. Pharmacological Screening methods used for CNS, Local anesthetics, Endocrine and In-vitro microbial screening.
4. Protocol design of Clinical Trials.
5. Biostatistical study of given data.

Books Recommended:

1. The Pharmacological basis of therapeutics-Goodman and Gill man's
2. Pharmacology- Rang & Dale.
3. Pharmacology-Katzung.
4. Fundamentals of experimental Pharmacology-By M.N.Ghosh
5. Hand book of Experimental Pharmacology-S.K.Kulakarni
6. Text book of in vitro practical Pharmacology by Ian Kitchen
7. Pharmacological Experiments on intact preparations by Churchill Living stone.
8. Hand book of Clinical Pharmacokinetics Gibaldi and Prescott.
9. Indian Pharmacopoeia and other Pharmacopeias.
10. Screening methods in Pharmacology by Robert Turner.A
11. Clinical trials and tribulations by Allien E.Cato
12. Drug discovery and Evaluation by Vogel H.G.

JOURNALS

1. Indian Journal of Pharmacology.
2. Indian Journal of Physiology and Pharmacology.
3. Indian Journal of Experimental Biology.
4. Pharmacological research.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M-Pharm. 1st Semester**

Subject: **Formulation Development (Lab)**

Total practical period: **72**

Total marks in the end Semester: **100**

Branch: **Pharmacy**

Code: 574123(41)

Total Tutorial period: **12**

Minimum of class test to be conducted: **2**

1. To prepare and evaluate aspirin tablets by wet granulation method.
2. To evaluate and compare at least three marketed Paracetamol tablets.
3. To study the effect of various binders on the hardness and dissolution rate of ascorbic acid tablets, at different concentration.
4. To prepare 10gm of sustained release granules of ascorbic acid by Microencapsulation method.
5. To perform the pre-formulation studies of the given sample of ascorbic acid.
6. To study the dissolution profile of marketed sustained release products of aspirin.
7. To prepare and evaluate partially flocculated suspension of Paracetamol by using electrolyte.
8. To prepare and evaluate suspension of aspirin.
9. To study the effect of various suspending agents on sedimentation rate at different concentration.

Book Recommended :

1. Controlled Drug Delivery System, J.R. Robinson and V.H.S.L. Lee.
2. Physical Pharmacy, 4th edition, A. Martin, J.C. Swarbrick.
3. Pharmaceutical analysis, 'Ramington' A. R. Gennaro.
4. The theory and practice of Industrial pharmacy, IIIrd edition, L. Lachman, H. A. Liberman.
5. Modern Pharmaceutics, IInd edition, G. S. Banker, C.T. Rhodes.