# CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI (C.G.)

## Scheme of Teaching and Examination

### Master of Pharmacy (M. Pharm)

**(Pharmaceutics)**

### I Semester

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Board of Study</th>
<th>Subject Code</th>
<th>Subject</th>
<th>Periods per Week</th>
<th>Scheme of Examination</th>
<th>Total Marks</th>
<th>Credit</th>
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<td>Pharmacy</td>
<td>565111(41)</td>
<td>Advanced Research Methods</td>
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<td>565112(41)</td>
<td>Pharmacology and Biostatistics</td>
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<td>Pharmacy</td>
<td>565113(41)</td>
<td>Drug Regulatory Affairs and Quality Assurance</td>
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<td>Pharmacy</td>
<td>565114(41)</td>
<td>Formulation Development</td>
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<td>Pharmacy</td>
<td>565121(41)</td>
<td>Advanced Research Methods Lab</td>
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<td>Pharmacy</td>
<td>565122(41)</td>
<td>Pharmacology and Biostatistics Lab</td>
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<td>6 100 - 50 150</td>
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<td>565123(41)</td>
<td>Formulation Development Lab</td>
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* L – Lecture, T – Tutorial, P – Practical,
* Duration of Theory Paper 3 Hours
* ESE – End Semester Examination, CT – Class Test, TA – Teacher Assessment
CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY, BHILAI (C.G.)

Semester: M-Pharm. 1st Semester  
Subject: Advance Research Methods  
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:
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 analysis.

Unit – 4:
Calorimetric analysis – theory, instrumentation, chemical application and structural elucidation, differential scanning calorimetric (DSC), Isothermal titration.

Unit – 5:
Immonochemical techniques – Immunelectrophoresis, immunoprecipitation, ELISA, radioimmunoassay.

Books Recommended:
5. Instrumental Method of Chemical Analysis.
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
7. Pharmacological Experiments on intact preparations by Churchill Living stone.
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.
Semester: M-Pharm. 1st Semester
Subject: Drug Regulatory Affairs and Quality Assurance
Total Theory period: 50
Total Tutorial period: 12
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
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
8. Physical Pharmacy; By Alfred martin
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
Unit – 1:
Stability, solubility, Pka, Dissolution rate, Partition Coefficient. In Vitro and In Vivo evaluation techniques, product formulation and CGMP.

Unit – 2:

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:
CHHATTISGARH SWAMI VIVEKANAND TECHNICAL UNIVERSITY,
BHILAI (C.G.)

Semester: M-Pharm. 1st Semester Branch: Pharmacy
Subject: Advance Research Methods (Lab) Code: 565121(41)
Total practical period: 72 Total Tutorial period: 12
Total marks in the end Semester: 100
Minimum of class test to be conducted: 2

List of Experiment:

1. Determination of $a_{\text{max}}$ 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.
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:

**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. Biostatical study of given data.

**Books Recommended:**

1. The Pharmacological basis of therapeutics-Goodman and Gill man’s
7. Pharmacological Experiments on intact preparations by Churchill Living stone.
9. Indian Pharmacopoeia and other Pharmacopoeias.
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.
4. Pharmacological research.
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 :**


