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

Scheme of Teaching and Examination

Master of Pharmacy (M. Pharmacy)

(Pharmaceutical Analysis and Quality Assurance)

I – Semester

S. No.	Board of Study	Subject Code	Subject	Periods per week			Scheme of Examination 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	565121 (41)	Advanced Research Methods Lab	-	-	6	100	-	40	140	
6	Pharmacy	565122 (41)	Pharmacology and Biostatistics Lab	-	-	6	100	-	50	150	
7	Pharmacy	565123 (41)	Formulation Development Lab	-		6	100	-	50	150	
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.Pharmacy course shall remain common for all specializations.

Semester: **M. Pharmacy 1st Semester**
Subject: **Advance Research Methods**
Total Theory Periods: **50**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

Branch: **Pharmacy**
Code: **565111 (41)**
Total Tutorial Periods : **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-gravimentric 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, immunoprecipation, 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.

Semester: **M. Pharmacy 1st Semester**
Subject: **Pharmacology and Biostatistics**
Total Theory Periods: **50**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

Branch: **Pharmacy**
Code: **565112 (41)**
Total Tutorial Periods: **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.

Semester: **M. Pharmacy 1st Semester**
Subject: **Drug Regulatory Affairs and Quality Assurance**
Total Theory Periods: **50**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted**: 2**

Branch: **Pharmacy**
Code: **565113 (41)**
Total Tutorial Periods: **12**

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.

Semester: **M. Pharmacy 1st Semester** Branch: **Pharmacy**
Subject: **Formulation Development** Code: **565114 (41)**
Total Theory Periods: **50** Total Tutorial Periods: **12**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

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.

Semester: **M. Pharmacy 1st Semester** Branch: **Pharmacy**
Subject: **Advance Research Methods (Lab)** Code: **565121 (41)**
Total Practical Periods: **72**
Total Marks in the End Semester**: 100**

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.

Semester: **M. Pharmacy 1st Semester** Branch: **Pharmacy**
Subject: **Pharmacology and Biostatics (Lab)** Code: **565122 (41)**
Total Practical Periods: **72**
Total Marks in the End Semester: **100**

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
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.

Semester**: M. Pharmacy 1st Semester** Branch: **Pharmacy**
Subject: **Formulation Development (Lab)** Code: **565123 (41)**
Total Practical Periods: **72**
Total Marks in the End Semester: **100**

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.

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

Scheme of Teaching and Examination

Master of Pharmacy (M. Pharmacy)

(Pharmaceutical Analysis and Quality Assurance)

II – Semester

S. No.	Board of Study	Subject Code	Subject	Periods Per Week			Scheme of Examination			Total Marks	Credit L+(T+P)/2
							Theory/Practical				
				L	T	P	ESE	CT	TA		
1.	Pharmacy	502211 (41)	Pharmaceutical Analysis and Quality Assurance –I (**Advance pharmaceutical Analysis**)	4	1	-	100	20	20	140	
2.	Pharmacy	502212 (41)	Pharmaceutical Analysis and Quality Assurance –II **(Applied Pharmaceutical Analysis)**	4	1	-	100	20	20	140	
3.	Pharmacy	502213 (41)	Pharmaceutical Analysis and Quality Assurance –III **(Pharmaceutical Process Validation)**	4	1	-	100	20	20	140	
4.	Pharmacy	502214 (41)	Pharmaceutical Analysis and Quality Assurance –IV (**GMP and Quality Assurance of Pharmaceuticals)**	4	1	-	100	20	20	140	
5.	Pharmacy	502221 (41)	Pharmaceutical Analysis and Quality Assurance –I Lab	-	-	6	100		50	150	
6.	Pharmacy	502222 (41)	Pharmaceutical Analysis and Quality Assurance –II Lab	-	-	6	100		50	150	
7.	Pharmacy	502223 (41)	Pharmaceutical Analysis and Quality Assurance –III 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

Semester: **M. Pharmacy 2nd Semester** Branch: **Pharmacy**
Subject: Pharmaceutical Analysis and Quality Assurance –I Subject Code: **502211 (41)**
(**Advance pharmaceutical Analysis**) Total Tutorial Periods: **12**
Total Theory Periods: **40**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

Unit-1: Preparation of drug samples for analysis
Pharmaceutical samples, fundamental theories controlling preparation techniques, specific sample preparation techniques.

Unit-2:
A detailed study of the principles, instrumentations and applications in drug analysis of: GC-MS, LC-MS & FTIR with reference to drug metabolism, toxicologic and forensic studies, diagnosis of disease state, quantification of drugs in biological samples, Super critical fluid chromatography and size exclusion chromatography

Unit-3:
A detailed study of the principles, instrumentation and applications of the following Instrumental analysis: X-ray fluorescence spectrometry, atomic absorption spectroscopy, Inductively coupled plasma- mass spectroscopy

Unit-4:
Brief study of the theory, instrumentation and application of the following analytical techniques: atomic force microscopy, plasma atomic emission spectroscopy, photon correlation spectroscopy, X-ray diffraction.

Unit-5:
Microscopy: General aspects, hot stage microscopy, scanning electron microscopy (SEM), transmission electron microscopy (TEM): principle, instrumentation and applications.
Particles size analysis: Zetameter, Photon correlation spectroscopy, counter-counter apparatus, atomic force microscopy and confocal.

RECOMMENDED BOOKS:
1. Pharmaceutical Analysis by Ohannason
2. Chemical Analysis by Settle
3. Pharmaceutical Analysis Modern Methods by Munson
4. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
5. Instrumental methods of analysis by Willard Dean & Merrit.
6. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle pub. by Prentice Hall Inc.
7. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)
6. I.P. 1996, Vol.-I & II

Semester: **M. Pharmacy 2nd Semester** Branch: **Pharmacy**
Subject: Pharmaceutical Analysis and Quality Assurance –II Subject Code: **502212 (41)**
(Applied Pharmaceutical Analysis) Total Tutorial Periods: **12**
Total Theory Periods: 4**0**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

Unit-1:
Pharmacopoeial Assays with Suitable Examples of Various Drugs Pertaining to Chemical methods (Titrimetry)
Acid/base: Aspirin tablets, benzoic acid, boric acid, indomethacin, calamine, ephedrine, milk of magnesia, sodium bicarbonate.
Non aqueous: Ethosuximide, flourouracil, sulfafurazole, adrenaline, pentazocine.
Precipitation: Aminophylline, chlorbutol, lomustine.
Complexometry: Aluminium hydroxide tablets, calcium gluconate injection, magnesium sulphate
Redox: Potassium bromide, nifedipine tablets, ascorbic acid.
Gravimetry**:** Hydantoin, phenytoin, penicillin.

Unit-2:
A detailed study of the various principles and procedure involved in the quantitative analysis of pharmaceutical preparations and dosage forms containing the following groups of drugs included in I.P. (Biological and microbiological methods excluded)
(a) Analgesics and Antipyretics (b) Sedatives & Tranquillizers
(c) Antihypertensives (d) Antibiotics (e) Cardiovascular drugs (f) Vitamins (g) Antihistaminics

Unit-3:
A detailed study of the principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage form using the following reagents and reactions.
(i) Oxidative coupling reactions using MBTH (3-methyl-2-benzothiazolinone hydrazone hydrochloride)
(ii) Diazotization followed by coupling
(iii) Oxidation followed by complexation.
(iv) Oxidation followed by charge transfer reaction.
(v) Condensation reactions using the reagents Para Dimethyl Amino Benzaldehyde (PDAB), Para Dimethyl Amino Cinnamaldehyde (PDAC), Folin's reagent and Gibb's reagent.

Unit-4:
Detailed study of the principle and procedures involved in the quantitative determination of the organic functional groups: Amines, Aldehydes, Ketones, Ester and Hydroxy

Unit – 5:
Impurity Profile: Sources of impurities, their effect on drug stability and therapeutic action. Determination of impurities in bulk drugs - Isolation, characterization, and analytical methods. Formulation related impurities - Isolation, characterization, and analytical methods. ICH and WHO guidelines for impurity and related substances in the drugs.

RECOMMENDED BOOKS:

1. Instrumental methods of analysis by Scoog and West.
2. Chemical Analysis – Modern Instrumentation methods and techniques by Wiley.
3. Instrumental methods of analysis by Willard Dean & Merrit.
4. Hand book of Instrumental techniques for analytical chemistry edited by Frank settle pub. by Prentice Hall Inc.
5. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)
6. Pharmaceutical analysis edited by Higuchi and Brochmann. Christin GD. Analytical Chemistry. John Wiley and Sons, New York. Latest Edition.
7.Indian Pharmacopoeia, Central Indian Pharmacopoeia Laboratory, Govt. of India, Ministry of Health & Family Welfare, Ghaziabad, Latest Edition.

Semester: **M. Pharmacy 2nd Semester** Branch: **Pharmacy**
Subject: Pharmaceutical Analysis and Quality Assurance III Subject Code: **502213 (41)**
(Pharmaceutical Process Validation) Total Tutorial Periods: **12**
Total Theory Periods: **40**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

Unit – 1:

Introduction to Pharmaceutical Validation:

Definition, Manufacturing Process Model, Government regulation, scope of Validation Advantage of Validation, Organization for Validation, Validation Master plan, URS, D.Q., IQ, OQ & P.Q. of facilities. Regulatory Basis for process validation. Process validation and Quality Assurance, Process validation as a Quality assurance tool, Prospective, retrospective and concurrent process validation.

Unit – 2:

Validation of Equipment

Concept of URS, DQ, IQ, OQ & PQ, Validation of following equipment

- Dry Powder Mixers
- Fluid Bed and Tray dryers.
- Tablet Compression M/c.
- Dry Heat Sterilization/Tunnels
- Autoclaves
- Capsule filling machines.
- Validation of Integrated lines by media fill test.
- Validation of existing equipment.
- Sterile product validation,
- Validation of water systems for sterile and non-sterile products.

Unit – 3:

Validation of Utilities

Validation of Pharmaceutical Water System & pure steam, Validation of HAVC system. Validation of Compressed air . Cleaning of Equipment, Cleaning of Facilities. Computer System Validation.

Unit – 4:

Equipment and Analytical Method Validation

General principles of analytical method validation, Validation of following analytical Instruments include UV-visible spectrophotometer, FT-IR spectrometer, HPLC and GC-MS.

Unit – 5:

Process Validation

Prospective, concurrent, retrospective & revalidation, Process validation of following formulations

- Coated tablets
- Capsules
- Ampoules & Vials
- Ointment/Creams
- Liquid Orals

RECOMMENDED BOOKS

1. How to Practice GMPs , P.P.Sharma, Vandana Publication, 5th Ed.
3. Q.A. Mannual, D.H.Shah, Business Horizon, 1st Ed.
4. SOP Guidelines, D.H.Shah, Business Horizon, 2nd Ed.
5. The International Pharmacopoeia Vol 1,2,3,4, General Methods of Aalysis & Quality Specifications for Pharmaceutical Substances, Excipients, Dosage forms.,CBS (WHO), 3rd Ed.
6. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 & Vol.2, WHO, 1999
7. Pharmaceutical Process Validation, Wachter & Mash, M.Dekker, 3rd Ed.
8.Pharmaceutical Process Validation, Berry & Mash, M.Dekker, 3rd & 4thEd.

Semester: **M. Pharmacy 2nd Semester** Branch: **Pharmacy**
Subject: Pharmaceutical Analysis and Quality Assurance –IV Subject Code: **502214 (41)**
(**GMP and Quality Assurance of Pharmaceuticals)** Total Tutorial Periods: **12**
Total Theory Periods: **40**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

Unit – 1:

1. Concept of total quality management, philosophy of GMP, CGMP and GLP.

Introduction to GMPs-MHRA, GMPs-HPFBI, GMPs-MCC, GMPs-EDQM etc

2. Audits: GMP compliance audit, Audit policy, Internal, external, second party and third party audits. Preparation for audit, conducting audit, audit analysis, audit report and follow up.

Unit-2:

3. Organization and personnel, responsibilities, training hygiene.

4. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

5. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place.

6. Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

7. Manufacture of and controls on dosage forms: Manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.

Unit-3:

8. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc. Guidelines for Quality assurance of Human Blood products and Large volume parenterals.

9. Packaging and labeling controls, line clearance and other packaging materials.

10. Quality control laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.

Unit-4:

11. Finished products release: Quality review, quality audits, batch release document.

12. Distribution and distribution-records: Handling of returned goods recovered materials and reprocessing.

13. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

Unit-5:

14. Good Laboratory Practices: Scope, Organization, personnel- technical competence, desirable qualities of analyst, analyst validation, QBD (quality by design) responsibilities of key personnel in the QC laboratories. Routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities, raw data maintenance.

RECOMMENDED BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.

2. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)

3. Basic tests for pharmaceutical substances – WHO (1988)

4. Basic tests for pharmaceutical dosage forms – WHO (1991)

5. GMP-Mehra

6. How to Practice GMPs – P.P.Sharma

7. The Drugs and Cosmetic Act 1940 – Vijay Malik

8. Pharmaceutical Process Validation by Berry and Nash.

9. Q.A. Mannual by D.H.Shah

10. SOP Guidelines by D.H.Shah

11. Quality Assurance Guide by OPPI

Semester **: M. Pharmacy 2nd Semester** Branch : **Pharmacy**
Subject : Pharmaceutical Analysis and Quality Assurance-I Subject Code : **502221 (41)**
(Advance Pharmaceutical Analysis) Total Tutorial Periods: **12**
Total Practical Periods: **72**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

List of experiments:

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
8. Separation of protein drug substances by electrophoresis.
9. Use of Flame Photometer for analysis of Na, K^{+} & Ca^{++} etc. in Biological fluids and formulations.
10. Use of Potentiometer and Conductometer for the analysis of Pharmacopoeial compounds.
11. Use of Nephelo-Turbidimetric analysis of dispersions and limit tests.
12. Use of fluorimeter for analysis of pharmacopoeial compounds.

Semester **: M. Pharmacy 2nd Semester** Branch : **Pharmacy**
Subject : Pharmaceutical Analysis and Quality Assurance –II Subject Code : **502222 (41)**
(Applied Pharmaceutical Analysis) Total Tutorial Periods: **12**
Total Practical Periods: **72**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

List of Experiments

1. 1. Qualitative and quantitative analysis of some pharmaceutical dosage form using the following reagents and reactions:
    a. Oxidative coupling reactions using 3-methyl-2-benzothia zolinone hydrazone (MBTH).
    b. Condensation reaction using the reagent.
    c. P-Dimethyl amino cinnamaldehyde (PDAC).
    d. Folin Ciocatecu reagent (FC) reagent.
    e. Diazotization followed by coupling reaction.
    f. Oxidation followed by complexation reaction.
2. Analysis of active pharmaceutical ingredients (API) (2 experiments).
3. Identification of impurities and related substances in API's (Albendazole, metronidazole, diclofenac, paracetamol, aspririn, ibuprofen) (2 experiments).
4. Quantitative determination of pharmaceutical dosage forms belonging to alkaloids, antibiotics, vitamins, glycosides, steroids and diuretics (2 experiments).
5. Quantitative determination of functional groups present in drugs. (2 experiments).

Semester **: M. Pharmacy 2nd Semester** Branch : **Pharmacy**
Subject : Pharmaceutical Analysis and Quality Assurance –III Code : **502223 (41)**
(Pharmaceutical process validation) Total Tutorial Periods: **12**
Total Practical Periods: **72**
Total Marks in the End Semester: **100**
Minimum of Class Test to be Conducted: **2**

List of experiments:

1. Calibration of instruments (UV, IR, HPLC etc).
2. Validation of (analytical) instruments. (IQ,OQ & PQ) (UV, IR, HPLC).
3. Validation of analytical methods.
4. Standard operating procedure (SOP) for analytical instrumentation.
5. Standard operating procedure (SOP) for cleaning validation.
6. Standard test procedure (STP) for monograph analysis including COA (certificate of analysis).
7. Comparison of methods available in the official methods mentioned in IP, BP, USP etc for various dosage forms.
8. Analytical method validation for evaluation of drugs from biological samples.
9. Analysis of drugs in biological fluids.
10. Cleaning validation method, swab and rinse sample, maximum allowable concentration calculations.

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

Scheme of Teaching and Examination

Master of Pharmacy (M. Pharmacy)

(Pharmaceutical Analysis and Quality Assurance)

III – Semester

S. No.	Board of Study	Subject Code	Subject	Periods Per Week			Scheme of Examination			Total Marks	Credit L+(T+P)/2
							Theory/Practical				
				L	T	P	ESC	CT	TA		
1.	Pharmacy	502321 (41)	Minor Dissertation (synopsis submission) Seminar &Viva		**3**	**36**	**300**		**100**	**400**	
Total					**3**	**36**	**300**		**100**	**400**	

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

ESE – End Semester Examination,

CT – Class Test, TA – Teacher Assessment

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

Scheme of Teaching and Examination

Master of Pharmacy (M. Pharmacy)

(Pharmaceutical Analysis and Quality Assurance)

IV– Semester

S. No.	Board of Study	Subject Code	Subject	Periods Per Week			Scheme of Examination Theory/Practical			Total Marks	Credit L+(T+P)/2
				L	T	P	ESC	CT	TA		
1	Pharmacy	502421(41)	Major Dissertation (Seminar & Viva)		**3**	**36**	**400**	**-**	**200**	**600**	
Total					**3**	**36**	**400**	**-**	**200**	**600**	

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

ESE – End Semester Examination,

CT – Class Test, TA – Teacher Assessment