Study and Evaluation Scheme

Course:M.Pharm- Quality Assurance Techniques

Semester- I

S.No.	Course code	Subject	Period (Hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR-119C	Modern Analytical Techniques-I	4	-	30	-	70	-	100	4
2	MPHR-119C	Modern Analytical Techniques-II	4	-	30	-	70	-	100	4
3	MPHR-112	Pharmaceutical Statistics and Computer Applications	4	-	30	-	70	-	100	4
4	MPHR-113	DRA	4	-	30	-	70	-	100	4
PRACTICAL										
	MPHR-119C	Modern Analytical Techniques-I	-	10	-	30	-	70	100	5
	MPHR-119C	Modern Analytical Techniques-II	-	10	-	30	-	70	100	5
Total									600	26

T-Theory, P-Practical, IA-Internal Assessment, ESE-End Semester Examination

Note: Duration of ESE- Theory exam will be of 3 hrs and Practical exam will be of 8 hrs

Study and Evaluation Scheme

Course:M.Pharm- Quality Assurance Techniques

Semester- II

S.No.	Course code	Subject	Period (Hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR-136	Quality Assurance Techniques-I	4	-	30	-	70	-	100	4
2	MPHR-137	Quality Assurance Techniques-II	4	-	30	-	70	-	100	4
3	MPHR-138	Quality Assurance Techniques-III	4	-	30	-	70	-	100	4
4	MPHR-120	Seminar	4	-	30	-	70	-	100	4
PRACTICAL										
	MPHR-137P	Quality Assurance Techniques-II	-	10	-	30	-	70	100	5
	MPHR-138P	Quality Assurance Techniques-III	-	10	-	30	-	70	100	5
Total									600	26

STUDY AND EVALUATION SCHEME

Course: M.Pharm Quality Assurance Techniques

Semester-III

Sl. No	Course Code	Subject	ESE	Credits
1	MPHR – 231	Synopsis of The Proposed Project & Evaluation of Project Work after Six Months	150	6

STUDY AND EVALUATION SCHEME

Course: M.Pharm Quality Assurance Techniques

Semester-IV

Sl. No.	Course Code	Subject	ESE	Credits
1	MPHR – 241	Thesis	350	14
2	MPHR – 242	Presentation & Viva – voce	100	5

MPHR-119C MODERN ANALYTICAL TECHNIQUES-I

Unit –I:

a. **UV-Visible spectroscopy**- Introduction, energy levels, selection rules, Woodword's Fieser, Fieser Kuhn and Nelson rule, Chromophore and auxochrome concept, absorption law and its applications, solvent effect, difference spectra and derivative spectra. Instrumentation and applications in determination of pKa values, pharmaceutical quantitative and qualitative analysis. Spectral correlation with structures, Multicomponent assay.

b. **Atomic absorption and Plasma emission spectroscopy-**
Plasma Emission Spectroscopy- Principle, instrumentation, interferences and applications
Atomic Absorption Spectroscopy- Principle, instrumentation, interferences and applications

Unit –II:

a. **Infrared spectroscopy**- Introduction, basic principles, vibrational modes, characteristic regions of the spectrum, influence of substituents, ring size, hydrogen bonding and conjugation on frequency. Instrumentation and applications in Pharmacy. **FT-IR, Near-IR, Attenuated Total Reflectance (ATR)-** Principle, theory and applications.

b. **Raman Spectroscopy-** Introduction, theory, principle and applications of Raman Spectroscopy.

Unit –III:

a. **NMR-** Fundamental, principle, theory, instrumentation, solvents, chemical shifts, relaxation process, spin-spin coupling, coupling constants, quadrapoule broadening & decoupling, proton exchange reactions and applications. **FT-NMR, 2D-NMR, C-13 NMR, Solid state NMR** and its applications in pharmacy. Introduction to following techniques-DEPT, APT, COSY, NOESY and INADEQUATE.

b. **ESR-** Principle and correlation with proton magnetic resonance, derivatives curves, g-values, hyperfine splitting, instrumentation and applications.

Unit –IV:

Mass Spectrometry- Basic principle, instrumentation and applications in pharmacy. Ion formation and types, fragmentation pattern, McLafferty rearrangement, Retro Diels Alder. Introduction to CIMS (Chemical ionization mass spectroscopy), FIMS (Field ionization mass spectroscopy), FAB-MS (Fast Atom Bombardment mass spectroscopy), MALDI-MS, LC-MS, GC-MS and CE-MS.

Unit –V:

a. **ORD-** Principle, Plain curves with cotton effect, octant rule and its applications with examples, circular dichorism and its relation to ORD.
b. **Thermal Analysis-** Theory, instrumentation and applications of TGA, DTA, DSC, ITC and Thermo mechanical analysis.
c. **X-Ray Diffraction-** Theory of x-ray diffraction, Bragg's law and crystallography, x-ray diffraction methods. **Powder X-ray Diffraction-** Instrumentation and applications.

MPHR-119D MODERN ANALYTICAL TECHNIQUES-II

Unit –I:

Reference Standards- Source, preparation, characterization, usage, storage and records preparation of reference standards of Active pharmaceutical drugs.

Unit –II:

a. **Chromatography-** Chromatographic theory, void volume, capacity factor, bond broadening, calculation of column efficiency, parameters used in evaluating column performance (including resolution and peak asymmetry). Principle, elution techniques, instrumentation, derivatization and applications of GAS, HPLC and HPTLC. Principle, elution techniques, instrumentation and applications of ion-exchange, affinity chromatography, supercritical fluid chromatography(SFC), UPLC (Ultra performance liquid chromatography) and chiral chromatography. Instrumentaion and applications of DCCC (Droplet counter current chromatography) and LC-DAD.

b. **Electrophoresis-** Theory, principles, classification, instrumentation and its applications. Moving boundary electrophoresis, Zone electrophoresis (ZE), Isoelectric focusing (IEF), High-performance capillary electrophoresis and applications

Unit –III:

Immunochemical Techniques- Immunoelectrophoresis, Immunoprecipitaion, ELISA, Radioimmuno assays, Magnetic immunoassay (MIA), EMIT, Dual-polarization interferometry.

Unit –IV:

a. Basic principle and classification of Laser
b. Analysis of drugs from Biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.
c. Interpretation of various analytical results (including spectra of UV, IR, NMR, MASS etc) with specific examples and case studies.

Unit –V:

Validation of analytical methods of pharmaceutical analysis- Principle of method validation of small molecules and formulation.

Physiochemical methods for biotechnological and biological products.
Current regulatory guidance on validation namely ICH Q_2 (R_1) and FDA, EMA.

MPHR- 119 C (P) MODERN ANALYTICAL TECHNIQUES-I

a. UV-visible spectrum scanning of a few organic compounds for UV absorption and correlations of structures and isobestic points in case of mixtures
b. Effect of pH and solvents on UV spectrum of drugs
c. Simultaneous estimation of combination formulation eg-
Vitamins, Oral antidiabetics, NSAID's, Antimicrobials, Antihistamins, Antihypertensives etc
d. Interpretation and structural elucidation of drugs by IR, NMR and MASS Spectroscopy
e. Any other relevant experiments based on theory

MPHR- 119 D (P) MODERN ANALYTICAL TECHNIQUES-II

a. Quantitative estimation by HPLC techniques
b. Separation of protein drugs by electrophoresis
c. Method development and validation using HPLC and HPTLC
d. Quantization of different phytoconstituents from extracts and herbal formulation by HPLC and HPTLC
e. Quantitative estimation of drugs in biological fluids
f. Any other relevant experiments based on theory

Books Recommended: (Latest Edition)

1. Watson, D.G., Pharmaceutical Analysis, A Textbook for Pharmacy Students and Pharmaceutical Chemists, Elsevier Churchill Livingstone.
2. Lee, D.C., Webb, M., Pharmaceutical Analysis, Blackwell Publishing, CRC Press, Wiley India Pvt. Ltd.
3. Willard, H. H., Merrit, L.L., Dean, J. A., Settle P. A., Instrumental Methods of Analysis, Von Nostrand.
4. Skoog, D.A., Holler, F.J., Nieman, T.A., Principles of Instrumental Analysis, Thomson Brooks/Cole.
5. Christian, G, D., Analytical Chemistry, John Wiley and Sons.
6. Ahuja,S., Rasmussen,H., HPLC method development for Pharmaceuticals, Elsevier Academic Press.
7. Silverstein, Spectrometric identification of Organic Compounds, Willy.
8. Kemp William, Organic Spectroscopy, Pal grave, New York.
9. Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS Publishers, New Delhi.
10. Sethi, P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations, CBS Publishers, New Delhi.

11. Introduction to spectroscopy, 3rd edition, Pavia, Lampman, Kriz, Thomson Publisher.
12. Indian Pharmacopoeia
13. British Pharmacopoeia
14. US Pharmacopoeia

MPHR- 112 Pharmaceutical Statistics and Computer Applications

Unit- I.

Basic Definitions and Concepts: Variables and Variation, Frequency Distributions and Cumulative Frequency Distributions, Sample and Population. Measures Describing the center of Date Distributions.

Data Graphics: Introduction. the Histogram. Construction and Labelling of Graphs. Scatter Plots (Correlation Diagrams), Semilogarithmic Plots, Other Descriptive Figures.

Introduction to Probability The Binomial and Normal Probability Distributions : Introduction, Some Basic Probability, Probability Distributions, the Binomial Distribution..

Unit- II

Choosing Samples Sample Size and Power : Introduction. Random Sampling, Other Sampling Procedures: Stratified, Systematic, Cluster Sampling, Sampling in Quality Control Introduction. Determination of Sample Size for Simple Comparative Experiments for Normally Distributed Variables. Determination of Sample Size for Binomial Tests..

Statistical Inference: Estimation and Hypothesis Testing: Statistical Estimation (Confidence Intervals). Statistical Hypothesis Testing. Comparison of Variances an Independent Samples. Test of Equality of More than Two Variances confidence limits for variance Tolerance Intervals.

Unit- III

Linear Regression and Correlation: Introduction of linear and non linear regression .Analysis of Standard Curves in Drug Analysis: Application of Linear Regression and Drug stability studies.

Analysis of Variance: One- Way Analysis of Variance Planned Versus a Posteriori (Unplanned) Comparisons in ANOVA. Another Example of One- Way Analysis of Variance: Unequal Sample Sizes and the Fixed and Random Models. Two-Way Analysis of Variance (Randomized Blocks), Statistical Models, Analysis of Covariance. ANOVA for pooling regression lines as related to stability data

Nonparametric Methods: Data Characteristics and an Introduction to Nonparametric Procedures. Sign Test, Wilcoxon Signed Rank Test, Wilcoxon Rank Sum Test (Test for Differences Between Two Independent Groups), Kruskal Wallis Test (One- Way ANOVA).

Factorial Designs : Definitions Two Simple Hypothetical Experiments to Illustrate the Advantages of Factorial Designs. Performing Factorial Experiments: Recommendations and Notation. A Worked Example of a Factorial Experiment. Fractional Factorial Designs.

Unit- IV

Experimental Design in Clinical Trials: Introduction. Some Principles of Experimental Design and Analysis. Parallel Design. Crossover Designs and Bioavailability / Bioequivalence Studies. Repeated Measures (Split- Plot) Designs. Multiclinic Studies. Interim Analyses.

Quality Control: Introduction. Control Charts. Acceptance Sampling and Operating Characteristic Curves. Statistical Procedures in Assay Development. Establishing In- House Limits. Some Statistical Aspects of Quality and the "Barr Decision".

Unit- V

Applications of Computers in Pharmaceutical Sciences

Computer Intensive Methods: Advance Computer application and software applicable for treating (data statical.

Book Recommended:

1. Bolton. S and Boo. C. Pharmaceuticals Statistics- Practical & Clincal Applications. Marcel & Dekker. New York.
2. Fisher. R.A.. Statistical Methods for Research Works. Oliver & Boyd. Edinburgh.
3. Chow. Statistical Design and Analysis of Stability Studies. Marcel Dekker. New York.
4. Bunchet. Statistics in the Pharmaceutical Industry. Marcel Dekker. New York.
5. William E. Fassett. Computer Application in Pharmacy.
6. Ekins. S., Computer Application in Pharmaceutical Research & Development. Wiley

MPHR- 113 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS

Unit- I

A. Drug Information

Introduction

Primary, Secondary & Tertiary Literature

Spectrum of information, finding and managing Drug Information.

B. Drugs and Cosmetics Act and rules with special reference to schedule M and Y

Unit- II

International Drug Regulatory affairs- registration procedure (Pharmaceutical products) for International Marketing. Including preparation of dossiers SMF, Validation, Calibration and other documents like product development, stability data for different countries.

Unit- III

Facilities for manufacturing pharmaceutical products qualifying.

CGMP requirements - 21 CFR parts 210 and 211, Orange Guide, TRS, ICH, etc.

Unit- IV

Facilities for quality control lab qualifying GLP requirements, facilities for warehouse qualifying GWP requirements.

Unit- V

Intellectual property rights, patents Act, Trademark and Copyright Act

Books Recommended:

1. Gennaro A.R., Remington- The science and practice of pharmacy, Lippincott, Williams & Wilkins.

2. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.

3. Malik Vijay, Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow.

4. Guarino R.A., New Drug Approval Process, Marcel Dekker

5. Sharma P.P., How to practice GMP, Vandana Prakashan, New Delhi

6. Sharma P.P., how to practice GLP, Vandana Prakashan, New Delhi.

7. World Health Organization, quality assurance of Pharmaceuticals I & I, Pharma Book Syndicate, Hyderabad.

8. Weinlerg S., Good Laboratory Poactices, Marcel Dekker.

9. The Patent Act, 1970

10. The Trade Marks Act, 1999.

11. The Copyright Act, 1958.

12. Potdar M.A., Current Good Manufacturing Practices for Pharmaceuticals, Pharma Med Press, Hyderabad.

13. Rick N.G., Drug from Discovery to Approval, Wiley Black Well.

14. Swarbrick J., Boylan J., Encyclopedia / Pharmaceutical Technology Relevant Welesites of Regulatory Authorter of different countries.

MPHR- 136 QUALITY ASSURANCE TECHNIQUES-I (Concept of Quality)

Unit-I Concept of Quality, Internal and External; Quality control, Quality Assurance, Quality management Framework, Total Quality management as applicable to Pharmaceutical industry.

Unit-II Quality improvement and cost reduction, Control of Quality, developing Quality Culture-theories of motivation, Quality Awareness Programme Empowerment

Unit-III Quality Assurance-Basic concept, Quality planning audits, performing audits, audit reports, quality circle.

Unit-IV Quality benchmarking, International Standards ISO, ISI, GMP, GLP

GMP- Defining quality responsibilities, Corrective Action & Preventive Action (CAPA)
GAMP- Good Automated Manufacturing Practices
GLP- Concept, Implementation of GLP

Unit-V ICH guidelines

Q8- Pharmaceutical development
Q9- Quality risk management
Q10- Pharmaceutical Quality System

Books recommended: (Latest edition)

1. Quality planning and analysis, Juran and Gryan, Tata McGraw Hill, India
2. Juran's Quality handbook, Juran, Tata McGraw Hill, India
3. ISO, ISI, GMP, GLP, GAMP and ICH Documents

MPHR- 137 QUALITY ASSURANCE TECHNIQUES-II
(PHARMACEUTICAL VALIDATION)

UNIT I

- **Introduction to Pharmaceutical Validation:**

Definitions, Manufacturing Process Model, Government regulation, scope of Validation Advantage of Validation, Organization for Validation, Validation Master plan,URS,DQ.,IQ,OQ & PQ.of facilities.

- **Calibration Master Plan**

UNIT II

- **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.

UNIT III

- **Vendor Certification**
- **Utilities Validation**

Validation of Pharmaceutical Water System & Pure steam, Validation of HAVC system Validation of Compressed air

UNIT IV

- **Cleaning Validation**
  Cleaning of Equipment, Cleaning of Facilities
- **Computer System Validation**

UNIT V

- **Process Validation**
  Prospective, concurrent, retrospective & revalidation, Process validation of following formulations
  - Coated tablets
  - Capsules

- Ampoules & Vials
- Ointment/Creams
- Liquid Orals

Books Recommended: (Latest Edition)

1. Pharmaceutical Process Validation, Second Edition. Ira R. Berry & Robert Nash, Marcel Dekker Inc.
2. Validation of pharmaceutical Process (Sterile Products), Second Edition Revised & Expanded, F.J. Carleton, Marcel Dekker Inc.
3. Pharmaceutical Quality Assurance, M.A. Potdar, Nirali Prakashan. Pune.
4. Current Good Manufacturing Practices, M.A. Potdar, Pharma-Med Press, Hyderabad.
5. Pharmaceutical Validation, P.P.Sharma.

MPHR- 138 QUALITY ASSURANCE TECHNIQUES-III

Unit-I Documentation in Pharmaceutical Industry

- NDA and ANDA requirements, Data presentation
- Calibration and Validation Records, Batch Manufacturing Records, Routine Records
- Internal audits, SOP, Storage records

Unit-II Documentation in Pharmaceutical Industry

- Store reconciliation records for Raw materials, Finished products and Packaging materials
- Records related to Maintenance and Environment control
- Records related to product recall, complaint traceability

Unit-III Statistical Process Control- definition and importance, Quality measurement, statistical control chart and their analysis, process capability, process control and quality improvement

Unit-IV Inspection, Test and Measurement- terminology, conformance to specification, inspection planning, accuracy and errors of measurement, disposal of non-conforming products

Unit-V Inspection and Test Sampling Plans- types of sampling, concept of acceptance sampling, sampling risk, parameters affecting acceptance sampling plans, quality indices for acceptance sampling plans,

Books recommended: (Latest edition)

1. Statistical Quality Control , Grant, Tata McGraw Hill, India
2. Juran's Quality handbook, Juran, Tata McGraw Hill, India
3. ISO, ISI, GMP, GLP, GAMP and ICH Documents

Practicals

MPHR-137(P)
Practicals based on theory syllabus

MPHR-138(P)
Practicals based on theory syllabus