## Study and Evaluation Scheme
### Course: M.Pharm - Quality Assurance Techniques
### Semester - I

<table>
<thead>
<tr>
<th>S.No</th>
<th>Course code</th>
<th>Subject</th>
<th>Period (Hours/week)</th>
<th>IA</th>
<th>ESE</th>
<th>Subject Total</th>
<th>Credits</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>1</td>
<td>MPHR-119C</td>
<td>Modern Analytical Techniques-I</td>
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### PRACTICAL

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<th>Period (Hours/week)</th>
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<th>ESE</th>
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| 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

<table>
<thead>
<tr>
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</tbody>
</table>

| Total       | 600 | 26 |
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.

Unit –III:
   a. **NMR** - Fundamental, principle, theory, instrumentation, solvents, chemical shifts, relaxation process, spin-spin coupling, coupling constants, quadrupole 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.


MPHR-119D MODERN ANALYTICAL TECHNIQUES-II

Unit –I:


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. Instrumentation and applications of DCCC (Droplet counter current chromatography) and LC-DAD.


Unit –III:

Immunochemical Techniques- Immunoelectrophoresis, Immunoprecipitaion, ELISA, Radiointmuno 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 Q2 (R1) 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)
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 Data Distributions.

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


Unit II


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

Unit III


Analysis of Variance: One-Way Analysis of Variance Planned Versus a Posteriori (Unplanned) Comparisons in ANOVA, Another Example of One-Way Analysis of Variance: Unbalanced 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


Unit V

Applications of Computers in Pharmaceutical Sciences

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

Book Recommended:
5. Williams E, Fasset, Computer Application in Pharmacy.
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:
8. Weinberg S., Good Laboratory Practices, Marcel Dekker.
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
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)

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