STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Quality Assurance) **Effective From Session 2012-13**

SEMESTER – I

Sl. No.	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 111	Advanced Analytical Techniques	4	-	30	-	70	-	100	4
2	MPHR – 112	Pharmaceutical Statistics & Computer Application	4	-	30	-	70	-	100	4
3	MPHR – 113	Drug Regulatory Affairs & Intellectual Property Rights	4	-	30	-	70	-	100	4
4	MPHR – 119 A	**Quality Assurance-I**	4	-	30	-	70	-	100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR – 111 P	Advanced Analytical Techniques	-	8	-	30	-	70	100	4
6	MPHR – 119 AP	**Quality Assurance-I**	-	12	-	30	-	70	100	6
								TOTAL	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Quality Assurance)
SEMESTER – II

Sl. No.	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 130	Quality Assurance – II	4	-	30	-	70	-	100	4
2	MPHR – 131	Quality Assurance and Process Validation	4	-	30	-	70	-	100	4
3	MPHR – 132	Quality Assurance-III	4	-	30	-	70	-	100	4
4	MPHR – 120	Seminar (two of 50 marks each) internal evaluation only	-	-	-				100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR – 131 P	Quality Assurance and Process Validation	-	10	-	30	-	70	100	5
6	MPHR – 132 P	Quality Assurance-III	-	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 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M.Pharm (Quality Assurance)
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)
Semester-IV

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

SEMESTER -I
MPHR 111

ADVANCED ANALYTICAL TECHNIQUES

Unit –I:
UV-Visible spectroscopy- Introduction, Application in determination of pKa values, pharmaceutical quantitative analysis, preformulation and formulation. Difference spectrophotometry, derivative spectra
Solid State Analysis: X-ray diffraction and crystallography, thermal analysis and calorimetry, micromeritic measurements
Unit –II:
Infrared spectroscopy- Introduction, Application in structure elucidation and in identifying polymorphs. I.R as a fingerprint technique. Near IR analysis and its applications. FTIR.
Unit –III:
a) Atomic spectrophotometry :
Atomic emission spectrophotometry: principle, instrumentation, interferences and applications
Atomic absorption spectrophotometry: principle, instrumentation and applications
b) Molecular emission spectroscopy:
Fluorescence spectroscopy: Principles, molecules exhibiting fluorescence, factors interfering with fluorescence intensity, application. Raman spectroscopy: Principle, instrumentation and applications
Unit –IV:
a) Nuclear Magnetic Resonance Spectroscopy:
Introduction, instrumentation, chemical shifts, shielding and deshielding effects, spin-spin coupling, reference standard and solvents, proton NMR, carbon-13 NMR. Application to structure elucidation.
b) Mass Spectrometry:
Principle, instrumentation, mass spectra obtained under electron impact (EI) ionization conditions, molecular fragmentation patterns, molecular ion, metastable ion, McLafferty rearrangement, EI mass spectra of some drug molecules. GC-MS and LC-MS: principle and applications.
Unit –V:
Chromatographic techniques:
Chromatographic Theory: void volume, capacity factor, band broadening, calculation of column efficiency, parameters used in evaluating column performance (resolution and peak asymmetry). HPLC: instrumentation, stationary phases, mobile phases and its selection, columns and detectors, applications in quantitative analysis of drugs in formulations, specialized HPLC techniques.
HPTLC, GC, High performance capillary electrophoresis: principle, instrumentation and application.

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 Graphics: Introduction, the Histogram, Construction and Labeling 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 in 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 validity 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-Sample 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, Multicenter Studies, Interim Analysis.

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 "Bias Decision".

Unit- V

Applications of Computers in Pharmaceutical Sciences

Computer Intensive Methods: Advance Computer application and software applicable for treating Pharmaceutical Data.

Book Recommended:

1. Bolton, S and Bon, C. Pharmaceuticals Statistics- Practical & Clinical Applications. Marcel & Dekker. New York.
2. Fuller, R.A. Statistical Methods for Research Works. Oliver & Boyd. Edinburgh.
3. Chow, Statistical Design and Analysis of Stability Studies. Marcel Dekker. New York.
4. Boncher. Statistics in the Pharmaceutical Industry. Marcel Dekker, New York.
5. William S. Fassett, Computer Application in Pharmacy.
6. Ekins, S., Computer Applications 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, Lippucott, 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. Weinberg S., Good Laboratory Practices, Marcel Dekker
9. The Patent Act, 1970
10. The Trade Marks Act, 1999
11. The Copyright Act, 1958
12. Poldar 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 Websites of Regulatory Authorities of different countries

MPHR- 119A Quality Assurance-I

Unit- I

Quality Management in the pharmaceutical industry. Basic concept of Quality Assurance.

Unit- II

CDSCO & Drug & CosmeticsAct and Rules with latest amendments. Drug Price control order

Unit- III

Consumer protection Act, Factory Act, Loan License, Compulsory Licensing

Unit- IV

Environment protection Act, Pollution control Act

Unit- V

Law of Torts, Contract Act

Books Recommended

Swarbrick James & Boylan J.C. " Encyclopedia of pharmaceutical technology", Marcel Dekker.

Lachman, Leon, . Lieberman H.A, Kanig J. L., The theory & practice of industrial pharmacy", Varghese Publication House, Bombay.

Indian Pharmacopoeia

British Pharmacopoeia

U.S.P./ N.F.

Relevant Acts with latest Amendment

Relevant Websites.

MPHR – 111P

Advanced Analytical Techniques Practicals

1. Combination Drug Analysis (Any Five)
a. Vitamins
b. Oral antidiabetics
c. NSAIDs
d. Antimicrobials
e. Antihistamines
f. Antihypertensive

2. Illustrations of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectro-photometric (including flamephotometric) methods, HPLC etc. The students should be exp to handling of as many instruments as possible by themselves or under the guidance of a teacher.

3 Exercises on interpretation of IR, MASS and NMR spectra

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 F. 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, Wiley.
8- Kemp William, Organic Spectroscopy, Pal grave, New York.
9- Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS Publishers, New Delhi.
10- Setia, P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations, CBS Publishers, New Delhi.

MPHR 119A

Practicals and case studies based on theory

SECOND SEMESTER

MPHR- 130 Quality Assurance-II

Unit- I

USFDA- ANDA, IND, NDA, Clinical Trial Monitoring, Drug Master File

Unit- II

Dossier preparation for regulated market -UK, EU, TGA, MCC, ANVISA

Unit- III

Dossier preparation for Non-regulated market

Unit- IV

Dossier preparation for WHO

Unit- V

Accountability of Quality Assurance and Quality Control Personnel

Books Recommended

Indian Pharmacopoeia
British Pharmacopoeia
U.S.P./N.F.
Relevant Acts with latest Amendment
Relevant Websites.

MPHR- 131 Quality Assurance & Process validation

Unit- I

In Process quality control of various dosage forms- sterile and non- sterile SOP's for various operations like cleaning, filling, drying, compressions, coating, disinfection, fumigation, sterilization, membrane filtration etc. QA guidelines for human blood products and large volume, parenterals.

Unit-II

Quality control laboratory- responsibilities and laboratory practices. Routine controls on instruments, reagents, sampling plans, standard test procedures and protocols, control on animal house, data generation and storage.

Unit-III

Quality control documentation and audits of QC facilities. Finished product release, quality review, quality audits and batch release documents.

Unit-IV

Qualification validation and calibration of equipment. Analytical and Bioanalytical method validation, personel & process validation with regard to sterile and non-sterile products, Aseptic validation

Unit-V

Introduction to validation of manufacturing facilites (Q / Q Q and certification, preparation of validation protocols. Validation and security measures for electronic data and computer assisted process. Validation of water and air handling systems.

Book Recommended

a. Pharmaceutical Process Validation- Robert A. Nash, Alfred H. Wachter
b. Process Validation in manufacturing of biopharmaceuticals: Guidelines- Anurag Singh Rathore, Gail Sofer, G.K. Sofer
c. Pharmaceutical Quality Assurance- Mr. Manohar A. Potdar
d. Quality Assurance of Pharmaceuticals A compendium of Guidelines and Related Materials (v 1) by WHO

MPHR- 132 Quality Assurance-II

Unit- I

Concept of total quality management

Unit- II

Quality by design- facility design and inspection

Unit- III

Good Automated manufacturing practices

Unit- IV

Guidelines- guidelines & regulatory agencies-CPCSEA, OECD, EPA, FHSA, ICH

Unit- V

Globalization of drug industry and introduction to export and import policy of drugs and pharmaceuticals

Books Recommended

Indian Pharmacopoeia
British Pharmacopoeia
U.S.P./N.F.
Relevant Acts with latest Amendment
Relevant Websites.
Automation and validation of information in pharmaceutical processing by Joseph F. deSpautz

Practicals

MPHR-130(P)

Practicals based on theory syllabus

MPHR-131(P)

Practicals based on theory syllabus