STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Drug Regulatory Affiars) 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 – 136	Regulatory Affairs-I	4	-	30	-	70	-	100	4
4	MPHR – 137	Regulatory Affairs-II	4	-	30	-	70	-	100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR – 111 P	Advanced Analytical Techniques	-	8	-	30	-	70	100	4
6	MPHR – 136	Regulatory Affairs-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. (Drug Regulatory Affiars)
SEMESTER - II

Sl. No.	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 138	Regulatory Affairs-III	4	-	30	-	70	-	100	4
2	MPHR – 139	Regulatory Affairs-IV	4	-	30	-	70	-	100	4
3	MPHR – 140	Regulatory Affairs-V	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 – 139 P	Regulatory Affairs- IV	-	10	-	30	-	70	100	5
6	MPHR – 140P	Regulatory Affairs- V	-	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 (Drug Regulatory Affiars)
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 (Drug Regulatory Affairs)
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, macromeritic 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 Date 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 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 "Bias Decision".

Unit- V

Applications of Computers in Pharmaceutical Sciences

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

Book Recommended:

1. Bolton, S and Bon, C. Pharmaceuticals Statistics- Practical & Clinical 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. Buncher, 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- 136 **Regulatory Affiars-I** Indian Regulatory requirements

Unit- I

A. Drug Information

Introduction

Primary, Secondary & Tertiary Literature

Spectrum of information, finding and managing Drug Information

B. Licensing requirements for i) New Drug first time in India ii) New drug in 5th year after introduction iii) Import of drugs iv) registration of company producing API/Formulations for import in India v) I.V. Infusions

Unit- II

Drugs and Cosmetics Act and Rules with latest amendments , with special emphasis on Site master file, Rule 94 and 96, Schedules C,C1, G, H, L1, M, MIII, P, P1, R1, U, V, X,Y

Unit-III

New product approval, DPCO

Unit-IV

GCP compliance

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. Drug & Cosmetics Act, 1940, and Rules 1945
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. Wemlerg S., Good Laboratory Practices, 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. Swarlenick J., Boylan J., Encyclopedia / Pharmaceutical Technology

MPHR- 137 Regulatory Affiars-II (USFDA)

Unit- I

USFDA- Introduction and General Guidelines , CFR 21 Part 210 and 211

Unit-II

Regulatory considerations for pre-clinical and clinical testing

Unit-III

IND, NDA and ANDA, orphan drugs-Registration, application for markering approval

Unit-IV

Drug Master File

Unit-V

Regulations related to medical devices and emerging product categories

Books Recommended:

Gennaro A R., Remington- The science and practice of pharmacy, Lippincott, Williams & Wilkins.
Banker G S., Rhodes C T., Modern Pharmaceutics, Marcel Dekker.
Guarino R A., New Drug Approval Process, Marcel Dekker.
Rick N G., Drug from Discovery to Approval, Wiley Black Well.
Swarbrick J., Boylan J., Encyclopedia / Pharmaceutical Technology
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 exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.

3 Excersises 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 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, Elesevier 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

MPHR- 136 P

Case studies and practicals based on theory syllabus

Second Semester

MPHR- 138 Regulatory Affiars-III(European Union and UK)

Unit- I

EU & UK **Introduction and General Guidelines**

Unit-II

Regulatory considerations for pre-clinical and clinical testing

Unit-III

IND, NDA and ANDA, orphan drugs-Registration, application for marketing approval

Unit-IV

Drug Master File

Unit-V

Regulations related to medical devices and emerging product categories

Books Recommended:

Gennaro A.R., Remington- The science and practice of pharmacy, Lippincott, Williams & Wilkins.
Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.
Guarino R.A., New Drug Approval Process, Marcel Dekker.
Rick N.G., Drug from Discovery to Approval, Wiley Black Well.
Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology
Relevant websites
Orange Guide

MPHR- 139 Regulatory Affiars-IV

Unit- I

WHO - Introduction and General Guidelines

Unit-II

Regulatory considerations for pre-clinical and clinical testing

Unit-III

Regulations related to medical devices and emerging product categories

Unit-IV

ICH Guidelines

Unit-V

Common Technical Documents

Books Recommended:

Gennaro A.R., Remington- The science and practice of pharmacy, Lippincott, Williams & Wilkins.
Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.
Guarino R.A., New Drug Approval Process, Marcel Dekker.
Rick N.G., Drug from Discovery to Approval, Wiley Black Well.
Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology
WHO GMP
Relevant websites

MPHR- 140 Regulatory Affiars-V (Documentation process)

Unit- I

Practical aspects of regulatory compliance- an introduction to documentation process

Unit-II

Regulatory writing- IND, NDA and ANDA submissions

Unit-III

Regulatory writing- medical device, emerging product categories, orphan drugs, combination products, generics and biosimilar products

Unit-IV

Dossier preparation in common technical document format

Unit-V

Regulatory writing for Biotechnological products

Books Recommended:

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

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

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

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

Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology

Relevant websites

Drugs and Cosmetics Act 1940 and Rules 1945

Practicals

MPHR- 139 P

Case studies and assignments based on theory syllabus

MPHR-140 P

Case studies and documentation preparation as per the theory syllabus