## STUDY AND EVALUATION SCHEME

**Course:** M. Pharm. (Drug Regulatory Affairs) effective from session 2012-13  
**SEMESTER - I**

<table>
<thead>
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<th>Sl. 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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**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 Affairs)  
**SEMESTER - II**

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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 hours and Practical exam of 8 hours
## STUDY AND EVALUATION SCHEME

**Course:** M.Pharm (Drug Regulatory Affairs)
**Semester-III**

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## STUDY AND EVALUATION SCHEME

**Course:** M.Pharm (Drug Regulatory Affairs)
**Semester-IV**

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<td>MPHHR – 242</td>
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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. IR 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 spectrometry:**

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:**
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 Labeling 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: 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).

Unit IV

Unit V
Applications of Computers in Pharmaceutical Sciences
Computer Intensive Methods: Advance Computer application and software applicable for treating I data statistical.

Book Recommended:
5. William E. Fussert, Computer Application in Pharmacy.
MPHR: 126 Regulatory Affairs | 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 a) New Drug first time in India b) New drug in 5th year after introduction c) Import of drugs d) registration of company producing API Formulations for import in India e) I.V. Infusions

Unit II
Drugs and Cosmetics Act and Rules with latest amendments, with special emphasis on Site master file, Rules 94 and 96, Schedules C, C1, G, H, L, M, MII, PI, 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:
3. Drug & Cosmetics Act, 1940, and Rules 1945
8. Wenley S., Good Laboratory Practices, Marcel Dekker.
10. The Trade Marks Act, 1999
11. The Copyright Act, 1958
13. Rick N.G., Drug from Discovery to Approval, Wiley Blackwell
14. Swedendik J., Boylan J., Encyclopedia / Pharmaceutical Technology
MPHR- 137 Regulatory Affairs-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 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.
Riek N G . Drug from Discovery to Approval, Wiley Black Well.
Swarbrick J., Bovian J., Encyclopedia / Pharmaceutical Technology
Relevant websites
Advanced Analytical Techniques Practicals

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

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. 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
10. Sethi, P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations, CBS Publishers, New Delhi

MPHR-136P

Case studies and practicals based on theory syllabus
**MPHR-138 Regulatory Affairs III**

**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 Blackwell
- Swarbrick J., Bovlan J., Encyclopedia / Pharmaceutical Technology
- Relevant websites
- Orange Guide

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**MPHR-139 Regulatory Affairs 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 Blackwell
- Swarbrick J., Bovlan J., Encyclopedia / Pharmaceutical Technology
- WHO GMP
- Relevant websites
MPHR-140 Regulatory Affairs V (Documentation process)

Practicals 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, Lippincott, Williams & Wilkins.
- Bunker G. S., Rhodes C. T., Modern Pharmaceutics, Marcel Dekker.
- Rick N. G., Drug from Discovery to Approval, Wiley Black Well.
- Swartzendruck 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