## STUDY AND EVALUATION SCHEME

### SEMESTER – I

<table>
<thead>
<tr>
<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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<tbody>
<tr>
<td>1</td>
<td>MPH-111</td>
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<td>70</td>
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<td>2</td>
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<td>Drug Regulatory Affairs &amp; Intellectual Property Rights</td>
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<td>Quality Assurance-I</td>
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<td>30</td>
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<td>Day to Day Evaluation</td>
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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

### SEMESTER – II

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<td>MPH-122</td>
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<td>Seminar (two of 50 marks each) internal evaluation only</td>
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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

<table>
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<tr>
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<td>Synopsis of the Proposed Project &amp; Evaluation of Project Work after Six Months</td>
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STUDY AND EVALUATION SCHEME

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

<table>
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<th>Credits</th>
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<td>1</td>
<td>MPH 241</td>
<td>Thesis</td>
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<tr>
<td>2</td>
<td>MPH 242</td>
<td>Presentation &amp; Viva-voce</td>
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SEMESTER-IV

MPH 211

ADVANCED ANALYTICAL TECHNIQUES

Unit-I:
Solid State Analysis: X-ray diffraction and crystallography thermal analysis and calorimetry, microporous measurements.

Unit-II:
Infrared spectroscopy: Introduction. Applications in structure elucidation and in identifying polymorphs. IR as a fingerprint technique. Near IR analysis and its applications. FTIR.

Unit-III:
(a) Atomic absorption spectrophotometry:
Atomic emission spectrophotometry: Principle, instrumentation, interferrand applications
Atomic absorption spectrophotometry: Principle, instrumentation and applications
(b) Molecular emission spectrophotometry:
Fluorescence spectrophotometry: Principles, molecules exhibiting fluorescence, factors interfering with fluorescence intensity, applications.
Raman spectroscopy: Principle, instrumentation and applications.

Unit-IV:
(a) Nuclear Magnetic Resonance Spectroscopy:
Introduction, instrumentation, chemical shifts, shielding and de-shielding 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) ionisation 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 to evaluate 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, HPLC, High-performance capillary electrophoresis: Principle, instrumentation and application.
Unit I:

Unit II:

Unit III:

Unit IV:

Unit V:
Applications of Computer in Pharmaceutical Sciences, Computer Intensive Methods: Advances Computer application and software applicable to treating data critical.

Books Recommended:
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 SFM, 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:
3. Malik V., Vig., Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow
5. Sharma P. P., How to practice GMP, Vandana Prakashan, New Delhi
7. World Health Organization, quality assurance of Pharmaceuticals I & II, Pharma Book Syndicate, Hyderabad
8. Wernagor 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 Black Well

MPHR- 119A Quality Assurance-I

Unit - I
Quality Management in the pharmaceutical industry: Basic concept of Quality Assurance.

Unit - II
CDSCO & Drug & Cosmetics Act 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 Tests, Contract Act

Books Recommended
India Pharmacopoeia
British Pharmacopoeia
U.S.P./N.F.
Relevant Acts with latest Amendments
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. Illustration of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectrophotometric (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)


MPHR 119A

Practicals and case studies based on theory

SECOND SEMESTER

MPHR 130 Quality Assurance-II

Unit-I
USEDA- 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
Process quality control of various dosage forms- sterile and non-sterile SOP’s for various operations like cleaning, filling, drying, compression, sorting, disinfection, filtration, 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
Qualifications validation and calibration of equipment. Analytical and bioanalytical method validation, personnel & process validation with regard to sterile and non-sterile products. Aseptic validation

Unit-V
Introduction to validation of manufacturing facilities [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.

Books Recommended
c. Pharmaceutical Quality Assurance- Mr. Mamoor A. Pridie
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, FHS, 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