

Subject	Advances in Pharmaceutical Sciences	
Subject code	AUPH-102	
Credits	04	
Examination	Theory	
	University	Internal Assessment
Maximum Marks	60	40

## INSTRUCTIONS

**1. Instruction for paper setters:** The questions are to be fairly distributed within the syllabus for maximum marks of 60. The question paper shall comprise five sections A, B, C, D and E. Section A, B, C and D shall contain two questions carrying 12 marks each. These questions shall be selected from the respective units of the syllabus. Section E shall contain four small compulsory questions selected from the entire syllabus carrying 3 marks each.

**2. Candidates:** The candidates are required to answer one question from every section (A, B, C and D) carrying 12 marks each and all four questions which are compulsory from Section E carrying 3 marks each.

### Section - A

Principles, methods, interpretation of data and pharmaceutical applications of various analytical techniques: UV-Visible, IR, NMR spectroscopy, Mass spectrometry, GC, HPLC

### Section - B

ADME pharmacokinetic characterization of drugs: Absorption kinetics, absorption rate constants, distribution kinetics, metabolic kinetics, dose and time dependencies, volume of distribution, renal clearance, mechanism of clearance, clearance ratio, determination of clearance, intrinsic clearance and hepatic clearance, plasma/serum concentrations

### Section - C

Extraction and Isolation techniques: Principle and applications of different extraction & isolation methods viz Soxhlet extraction, microwave extraction, supercritical fluid extraction, solid phase extraction, column chromatography, flash chromatography, isolation and characterization studies of different class of phytoconstituents (Alkaloids, Glycosides, Steroids, Saponins etc)

### Section - D

Intellectual property concepts and fundamentals: Intellectual property protection (IPP) and intellectual property right (IPR), copy right and trade mark protection, criteria for patentability, Indian patent act

Subject	Advanced Pharmacology	
Subject code	AUPH-103	
Credits	04	
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Maximum Marks	60	40

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### Section - A

Detailed study of guidelines for maintenance, breeding techniques and experimentation using laboratory animals: CPCSEA, ICH, GLP; Techniques for the study of Molecular Pharmacology: Western Blotting, Immunostaining, RT-PCR, Cell Cultures etc

### Section - B

Organization of screening: Pharmacological activity of new substances, Toxicity studies: acute, sub acute (Repeated dose), subchronic and chronic toxicity

### Section - C

Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidyl inositol, Ion channels and their modulators (calcium, potassium, sodium and chloride channels)

### Section - D

Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications

Subject	Pharmaceutical Product Development	
Subject code	AUPH-103	
Credits	04	
Examination	Theory	
Maximum Marks	University	Internal Assessment
	60	40

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### Section - A

Pre-formulation studies: Pre-formulation studies of drug substances, proteins and peptides. Pre-formulation work sheet

### Section - B

Solubilization: Solubility and solubilization of non electrolyte, drug solubilization in surfactant systems, use of co-solvents, solid-state manipulations and drug derivitization

### Section - C

Optimization and stability study: Statistical methods and factorial design, Quality by Design, Stability of dosage forms as per ICH guidelines

### Section - D

Physicochemical characterization of pharmaceuticals: Molecular level: Crystallinity, crystal habit, polymorphism, amorphous state, solvates, hydrates, analytical techniques for characterization (DSC, PXRD, SEM, FTIR); Particle level: Particle size, particle shape, porosity, surface area, compaction; Bulk level: Bulk density, compressibility, flow properties, compaction and consolidation cohesivity, electrostatics, aggregation, agglomeration, role in formulation development and processing

<b>Subject</b>	<b>Herbal Drug Formulation and Evaluation</b>	
<b>Subject code</b>	<b>AUPH-103</b>	
<b>Credits</b>	<b>04</b>	
<b>Examination</b>	<b>Theory</b>	
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### Section – A

Overview of novel herbal formulations: Phytosomes, liposomes, microspheres, novel vesicular herbal formulations etc

### Section – B

Standardization of herbal drugs/ formulations: Conventional and modern techniques, sources and uses of natural products in traditional medicines, potential of natural products, natural products in drug discovery and development

### Section – C

WHO Guidelines for assessment of crude drugs:

- a) Evaluation of identity, purity and quality of crude drugs
- b) Determination of pesticide residue
- c) Determination of Micro-organisms
- d) Determination of arsenic and heavy metals

### Section – D

Herbal Drug Regulatory affairs: Role and importance of national and international regulatory bodies in assessment of quality of herbal drugs and formulations

<b>Subject</b>	<b>Research Methodology</b>	
<b>Subject code</b>	<b>AUPH-101</b>	
<b>Credits</b>	<b>04</b>	
<b>Examination</b>	<b>Theory</b>	
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### Section – A

Literature Survey: Accessing required information in a systematic manner from abstracts, books, journals, Proceedings of conferences, theses and dissertations, CD ROMs, internet and such other sources

### Section - B

Scientific Writing: Writing of papers, articles and thesis, preparation of title, abstracts, introduction, methodology, results and discussion, summary-conclusion, preparation of tables and figures using software like MS Office, Open Office, etc; organization of dissertations and thesis; conventions adopted in writing; citing references; preparation of oral presentations and posters

### Section - C

Data collection and statistical estimation: measures of describing the center of data distributions, measurement of spread of data, binomial and normal distributions; confidence intervals, tests for statistical significance, T-test, F-test, analysis of variance (ANOVA), Chi-square test, linear regression and correlation

### Section – D

Statistical software: Introduction to statistical software such as SPSS, Graph Pad, Sigma Stat, MS Excel, open source software for statistical analysis

Subject	Advanced Pharmaceutical Chemistry	
Subject code	AUPH-103	
Credits	04	
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### Section – A

Pharmaceutical Organic Chemistry: Methods of determining reaction mechanisms (kinetic and non-kinetic methods), reaction intermediates, crossover experiments and isotopic labeling, order of reactions, reversible, consecutive and parallel reactions, solvent, ionic strength and salt effects, Multi-component reactions of pharmaceutical importance such as Biginelli reaction, Hantzsch reaction, Ugi reaction, Passerini reaction

### Section – B

Pharmaceutical Medicinal Chemistry: General principles, identification and study of targets for development of various therapeutic agents, rational approach for drug design, computer aided drug design

### Section – C

Assay of drugs and metabolites in pharmaceuticals and biological fluids

### Section - D

Analytical and bioanalytical methods validation using ICH Guidelines

## **RESEARCH AND PUBLICATION ETHICS**

### **Theory**

#### **Unit-I PHILOSOPHY AND ETHICS**

Introduction to philosophy: Definition, nature and scope, concept, branches  
Ethics: definition, moral philosophy, nature of moral judgments and reactions.  
Publication Misconduct: Group discussions: subject specific ethical issues, FFP, authorship, conflicts of interest, complaints and appeals: example and fraud from India and abroad

#### **Unit-II Scientific misconduct**

Ethics with respect to science and research; Intellectual honesty and research integrity; scientific misconducts: falsification, fabrication, and plagiarism (FFP); redundant publications: duplicate and overlapping publications, salami slicing; selective reporting and misrepresentation of data. Software tools: Use of plagiarism software like Turnitin, Urkund, and other open access software tools.

#### **Unit-III Publication Ethics**

Definition, introduction and importance, Best practices/ standards setting initiatives and guidelines: COPE, WAME, etc. Conflicts of interest; publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types; violation of publication ethics, authorship and contributorship; identification of publication misconduct, complaints and appeals; Predatory publishers and journals. Databases and Research Metrics: Databases: Indexing databases, Citation databases, web of science, Scopus, etc.

### **Practice**

#### **Unit-IV Open access publications**

Open access publications and initiatives; SHERPA/RoMEO online resources to check to check publisher copyright & self-archiving Policies; Software tool to identify predatory publications developed by SPPU; Journal finder/ journal suggestion tools viz. UGC care listed journal, Elsevier Suggested journal finder, Springer journal suggester, Impact factor of journal as per journal citation report, SNIP, SJR, IPP, Cite Score; Metrics: h-Index, g-Index, i-10 index, Publons, Google Scholar etc.