Total No. of Questions : 4]

SEAT No. :

**P4684**

[Total No. of Pages : 1

# [4950] - 101
## M.Pharmacy
## ADVANCED ANALYTICAL TECHNIQUES
## (2013 Pattern) (Credit System) (Semester-I)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Write theory, instrumentation and applications of IR spectroscopy. **[10]**

***Q2)*** Attempt any three questions: **[15]**

a) Discuss factors affecting chemical shift

b) Give an account of derivatization in HPLC and GC

c) Write fundamental law of absorption and its application in analysis.

d) 2D NMR techniques

***Q3)*** Write short notes on (any three): **[15]**

a) Supercritical fluid Chromatography.

b) Applications of Differential Thermal Analysis

c) Hyphenated techniques

d) Chromophore and Auxochrome

***Q4)*** Elucidate the structure of compound from following data **[10]**

Mol wt = 116

UV = transparent below 210 nm

IR = 2924 $cm^{-1}$, 1745 $cm^{-1}$, 1456 $cm^{-1}$

NMR = $\delta$ 1.97 and $\delta$ 1.45 (1:3)

OR

Give an account of principles, instrumentation and applications of mass spectroscopy.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

**P4685**

[Total No. of Pages : 1

# [4950] - 102

## M.Pharmacy

## RESEARCH METHODOLOGY

## (2013 Pattern) (Semester-I)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Explain in detail the research proposal criteria for basic and patent oriented research. **[10]**

***Q2)*** Attempt any three **[3 × 5 =15]**

a) Differentiate between review article and research article

b) Explain the different types of skills of oral presentation.

c) Describe CSIR as research organization in India.

d) Elaborate on Chi square test ($X^2$).

***Q3)*** Short notes (any three): **[3 × 5 =15]**

a) Methods of literature survey

b) Importance of communication skill

c) Descriptive and inferential analysis

d) Central limit theorem

***Q4)*** Explain in detail role of statistics in research. **[10]**

OR

Explain in detail the steps involved in thesis writing.

✦ ✦ ✦ ✦

Total No. of Questions : 4]

SEAT No. :

**P4686**

[Total No. of Pages : 1

# [4950] - 103

## M.Pharmacy (Semester-I)

## ADVANCED PHARMACEUTICS

### (2013 Pattern) (Credit System)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Draw a well labeled diagrams wherever necessary.***
3) ***Figures to the right indicate full marks.***

***Q1)*** Define preformulation. Elaborate the preformulation studies of conventional tablets. **[10]**

***Q2)*** Solve any three: **[15]**

a) Quality control tests for pharmaceutical semisolids.

b) Evaluation of Microcapsules

c) Cyclodextrins

d) Importance of dissolution studies

***Q3)*** Write short notes on (any three): **[15]**

a) Biodegradable polymers

b) Degradation pathways

c) Directly compressible excipients

d) Concept of quality control and quality assurance

***Q4)*** Define validation. Discuss validation of a unit operation with one case study.**[10]**

OR

What is optimization? Explain in detail optimization by factorial design.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P4687

[Total No. of Pages : 1

# [4950] - 104
## M.Pharmacy
## (Spl. Pharmaceutical Chemistry)
## ADVANCED PHARMACEUTICAL CHEMISTRY
## (2013 Pattern) (Semester-I)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Outline mechanism and discuss the synthetic importance of Brich and Meerwin-Pondroff's reduction. **[10]**

***Q2)*** Solve any three: **[15]**

a) What is solid phase synthesis? Explain the mechanism of protection, deprotection and coupling reaction in solid phase synthesis.

b) Discuss the mechanism, stereochemistry and applications of Wagner-Meerwein Rearrangement.

c) Explain Sharpless oxidation.

d) Explain use of diazomethane and peracids in synthesis.

***Q3)*** Write short notes on (any three): **[15]**

a) Pinacol-Pinacolone rearrangement

b) Recemic mixtures

c) Wolff Rearrangement

d) Hydrogenation

***Q4)*** What are chiral drugs? Explain Asymmetric synthesis with examples. **[10]**

OR

What do you mean by Green Chemistry? Explain use of Microwave and Ultrasound assisted reactions.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

**P4688**

[Total No. of Pages : 1

# [4950] - 105

## M.Pharmacy

## ADVANCED PHARMACOLOGY-I

## (Preclinical Evaluation of Drugs)

## (2013 Pattern) (Semester-I)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw neat labeled diagrams wherever necessary.***

***Q1)*** Explain in detail the composition and functioning of IAEC. **[10]**

***Q2)*** Answer (any three): **[3 × 5 = 15]**

a) Methods for bioassay of histamine

b) OECD guidelines for acute oral toxicity studies.

c) Screening of antipyretics

d) Screening of nootropic agents

***Q3)*** Write short notes on (any three): **[3 × 5 = 15]**

a) High throughput screening

b) Preparation of research protocol as per form B.

c) Transgenic animals

d) Bioassay of digitals

***Q4)*** Discuss the preclinical evaluation of anti-arrhythmic agents. **[10]**

OR

Discuss the preclinical evaluation of sedatives and hypnotic agents

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

**P4689**

[Total No. of Pages : 1

# [4950] - 106

## M.Pharmacy

## ADVANCED PHARMACOGNOSY

## (2013 Pattern) (Semester-I)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Neat diagrams must be drawn wherever necessary.***

***Q1)*** Elaborate a detail account of biosynthetic pathway for flavonoids and stilbenes. **[10]**

***Q2)*** Answer the following (any three). **[15]**

a) Explain in detail structural modifications of Anthraquinones.

b) Explain in detail comparative account of primary and secondary metabolism.

c) Explain limitations of Ethnobotanical approach to drug discovery.

d) Explain process for identification of plants for targeted sets in HTS.

***Q3)*** Short notes (any three): **[15]**

a) Cyclization through Diels-Alder reaction

b) Morphine

c) Biosynthesis of Terpenoid quinones

d) Herbal Tablets

***Q4)*** Elaborate a detail account for biosynthesis pathway for flavonolignans. **[10]**

OR

Explain how, chemical diversity, molecular chirality and complexity like properties makes natural products appropriate material in discovering new drugs.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

**P4690**

[Total No. of Pages : 1

# [4950] - 107

## M.Pharmacy

## ADVANCED QUALITY ASSURANCE TECHNIQUES (cGMP and Documentation)

## (2013 Pattern) (Semester-I)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** What are the guidelines regarding 'Warehousing area' as per schedule M of Drugs & Cosmetics Act? **[10]**

***Q2)*** Attempt any three questions from the following. **[15]**

a) Write the contents and importance of equipment log.

b) Write details of SOP for personal hygiene for persons working in pharmaceutical manufacturing plant.

c) Write any five precautions during processing of intermediate or bulk products.

d) What is meant by drug product salvaging?

***Q3)*** Write short notes on (any three): **[15]**

a) Reference standards.

b) Expiration dating.

c) Production Record Review.

d) Water and steam system for sterile products.

***Q4)*** Discuss "PAT : Principles and Tools". **[10]**

OR

Discuss stages of application of HACCP principles.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

**P4691**

[Total No. of Pages : 1

# [4950] - 201

## M.Pharmacy

## DRUG REGULATORY AFFAIRS

## (2013 Pattern) (Semester-II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** Explain the WHO guidelines related to premises, sanitation & hygiene in pharmaceutical plant. **[10]**

***Q2)*** Solve any three: **[15]**

a) Write the ICH guidelines for stability testing of pharmaceuticals.

b) Explain the patent system in Europe.

c) Explain the trademark filing procedure.

d) Explain the provisions in schedule M and Y

e) Write case study of Haldi plant under Intellectual Property Rights and Patent.

***Q3)*** Write short notes on (any three): **[15]**

a) Different sections of NDA

b) GATT

c) Loan license manufacturing

d) Water system in pharmaceutical plant

e) CTD and eCTD

***Q4)*** Explain provisions in Indian Patent Act 1970, also write the procedure for patent application. **[10]**

OR

Explain the guidelines of GMP audit inspection.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

**P4693**

[Total No. of Pages : 1

# [4950] - 203

## M.Pharmacy

## NOVEL DRUG DELIVERY SYSTEM

## (2013 Pattern) (Semester-II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Explain various theories for formation of microemulsion. Write a note on ternary phase diagram. **[10]**

***Q2)*** Attempt any three. **[15]**

a) Describe general methods for dendrimer synthesis.

b) Describe methods of formulation of solid lipid nanoparticles.

c) Write a note on method of preparation of resealed erythrocytes.

d) Write a note on long acting contraceptives.

e) Write a brief note on biowavers for bioequivalence studies.

***Q3)*** Write short notes any three **[15]**

a) Active and passive drug targeting.

b) Clinical relevance of pulsatile drug delivery system.

c) Biochemistry and stability of protein drug.

d) Analysis of proteins and petptides.

e) Monoclonal antibodies and their applications.

***Q4)*** Explain formulation of ophthalmic products covering drug candidate selection, and Product Design. **[10]**

OR

Explain various approaches for colon targeting.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

**P4694**

[Total No. of Pages : 1

# [4950] - 204

## M.Pharmacy (Pharmaceutical Chemistry)

## ADVANCED MEDICINAL CHEMISTRY

## (2013 Pattern) (Semester-II) (Theory)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question No. one is compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** What are the different types of receptors? Discuss various theories of drug receptor interactions. **[10]**

***Q2)*** Attempt any three questions from following: **[15]**

a) Add a note on Human insulin.

b) Discuss Enzyme immobilization techniques.

c) Write a brief note on strategies of library synthesis.

d) Explain the applications of microorganisms in biotransformation of enzymes with suitable examples.

***Q3)*** Write short notes on (any three): **[15]**

a) Histamine receptors.

b) Anti-inflammatory steroidal agents.

c) Detailed Synthesis of Alprazolam.

d) Oral hypoglycemic agents.

***Q4)*** Sketch out synthetic strategies of following drugs : (any two) **[10]**

a) Ethinyl estradiol.

b) Cetrizine.

c) Fexofenadine.

OR

Add a detail note on gene therapy.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

**P4695**

[Total No. of Pages : 1

# [4950] - 205

## M.Pharmacy

## DRUG DESIGN

## (2013 Pattern) (Semester-II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Attempt all questions.***
2) ***Figures to the right indicate full marks.***

***Q1)*** Enlist various approaches of drug design. Explain in detail Craig plot & Tipliss tree **[10]**

***Q2)*** Attempt any three questions out of four **[15]**

a) Cluster analysis

b) Drug design based on antagonism

c) Significance of metabolism study in drug design

d) Bioprecursor prodrug.

***Q3)*** Attempt any three questions out of four **[15]**

a) Pharmacophore modeling

b) Antagonism concept in drug design

c) CoMFA

d) Role of drug design in drug discovery

***Q4)*** Explain concept of enzyme inhibition were proved to be excellent tools in the process of drug design with suitable examples. **[10]**

OR

What are prodrugs? Discuss designing of drug molecule based on metabolism studies with suitable examples.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

**P4696**

[Total No. of Pages : 1

# [4950] - 206

## M.Pharmacy

## CLINICAL PHARMACOLOGY

## (2013 Pattern) (Semester-II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number 1 is compulsory.***
2) ***Figures to the right indicates full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Define clinical pharmacology. Describe phases of clinical trials. Add a note on informed consent. **[10]**

***Q2)*** Solve any three **[15]**

a) Elaborate general principles of cancer chemotherapy

b) Describe therapeutic drug monitoring

c) Write about reverse transcriptase inhibitors

d) Describe Poly (ADP-Ribose) Polymerase

***Q3)*** Write short notes (any three) **[15]**

a) Renal dialysis

b) Drug resistance

c) Role of immunomodulators in immunopharmacology

d) Clinical practice guidelines for hepatitis

***Q4)*** Describe in detail the management of tuberculosis **[10]**

OR

Explain the detail pharmacotherapy of hyperlipidemia

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

**P4697**

[Total No. of Pages : 1

# [4950] - 207

## M.Pharmacy

## MOLECULAR PHARMACOLOGY

## (2013 Pattern) (Semester-II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Define Immunopharmacology and add note on types of immune responses. **[10]**

***Q2)*** Answer the following (any three) **[15]**

a) Discuss the recent advances in drugs acting on adrenoreceptors.

b) Write a note on cytokines.

c) Explain the concept of Human Genome Mapping.

d) Discuss implications of chronopharmacology in drug therapy.

***Q3)*** Write a note on following (any three) **[15]**

a) Chloride channel and it's modulators

b) Opiod receptors

c) Phophodiesterase enzyme and inhibitors.

d) Immunostaining techniques in molecular pharmacology.

***Q4)*** Explain the process of Apoptosis with its clinical implications. **[10]**

OR

Discuss the recent advances in drugs acting on dopamine receptors.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

**P4698**

[Total No. of Pages : 2

# [4950] - 208

## M.Pharmacy

## (Special Pharmacognosy)

## PHYTOCHEMISTRY AND PHYTOPHARMACEUTICALS

## (2013 Pattern) (Semester - II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Neat diagrams must be drawn wherever necessary.***

***Q1)*** Why is super critical fluid extraction technique preferred for extraction of flavonoids? Support your answer with suitable examples. Describe the protocol for extraction of flavonoids using above technique. **[10]**

***Q2)*** Solve any three questions from the following: **[15]**

a) Describe extraction and isolation method for Sennosides.

b) Comment on pharmacological importance of Taxol. Describe in brief procedure for its extraction.

c) Give structural elucidation of morphine by spectroscopic data.

d) State the importance of WHO guidelines in standardization of herbal drugs.

***Q3)*** Solve any three questions from the following: **[15]**

a) Write a note on microwave assisted extraction method along with its applications.

b) Describe the role of HPTLC in separation and identification of Andrographolides.

c) What are various techniques involved in extraction of essential oils.

d) Describe in brief principle and procedure for determination of Pestiside residue.

***P.T.O.***

***Q4)*** Give procedure for extraction and isolation of piperine. Also give the spectroscopic data for confirmation of its structure. **[10]**

OR

Describe in details In-Vitro and In-Vivo methods for screening of antidiabetic drugs.

Total No. of Questions : 4]

SEAT No. :

P4699

[Total No. of Pages : 1

# [4950] - 209

## M.Pharmacy (Semester - II)

## INDUSTRIAL PHARMACOGNOSY

## (2013 Pattern)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Attempt all questions.***
2) ***Figures to the right indicate full marks.***
3) ***Do not write on the question paper.***

***Q1)*** Elaborate in brief the provisions applicable to the manufacturing of Ayurvedic and Unani drugs including Siddha drugs in the purview of herbal drugs regulation in India. **[10]**

***Q2)*** Explain the role of Government agencies involved in development and promotion of herbs and herbal industry. **[10]**

***Q3)*** What is pharmacovigilance? Describe the functions of National Pharmacovigilance center for safety monitoring of herbal medicines. **[10]**

OR

Comment on, "Important medicinal plants used in indigenous system of medicine".

***Q4)*** Write notes on (any four): **[20]**

a) Patentable inventions

b) Commercialization of natural products in India

c) Stability of Herbal medicines

d) Objectives of WHO Guidelines on safety monitoring of Herbal drugs in pharmacovigilance system

e) Potential of Herbal-drug interaction

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

**P4700**

[Total No. of Pages : 1

# [4950] - 210

## M.Pharmacy

## (spl Quality Assurance Techniques)

## PHARMACEUTICAL VALIDATION

## (2013 Pattern) (Semester-II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** Explain validation master plan in detail. **[10]**

***Q2)*** Solve any three **[15]**

a) Harmonisation of GMP and validation

b) Write about performance qualification of UV visible spectrophotometer

c) Write about cleaning validation protocol for double cone blender

d) Explain validation of integrated line by media fill test for powder.

***Q3)*** Write a short note on any three **[15]**

a) Write about calibration master plan

b) Computer system validation

c) Discuss any five parameters of analytical method validation.

d) Processes validation tablet by wet granulation.

***Q4)*** What is importance of Equipment validation? Give Performance qualification (PQ) protocol for tablet compression machine. **[10]**

OR

Explain URS, DQ, IQ, OQ & PQ for purified water system.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

P4701

[Total No. of Pages : 1

# [4950] - 211

## M.Pharmacy

## Quality Assurance Techniques

## QUALITY PLANNING AND ANALYSIS

## (2013 Pattern) (Semester-II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** Discuss relationship between Quality, Productivity, Cost, Cycle time and value. **[10]**

***Q2)*** Attempt any three questions from the following **[15]**

a) What are the steps of 'Improve phase' in six sigma concept?

b) Comment on "Overall Review of Manufacturing and planning".

c) Enlist examples of quality measurement in manufacturing operations.

d) Explain application of PRE-control

***Q3)*** Write short notes on (any three) **[15]**

a) Trouble shooting

b) Quality culture

c) Criteria for self-inspection

d) Inspection Accuracy

***Q4)*** Discuss various types of sampling plans. **[10]**

OR

Write characteristics of a good acceptance plan.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

**P4702**

[Total No. of Pages : 1

# [4950] - 212

## M.Pharmacy

## QUALITY CONTROL AND ASSURANCE OF PHARMACEUTICALS

## (2013 Pattern)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Drawn well labeled diagrams wherever necessary.***

***Q1)*** Provide typical MPCR for Dry powder oral suspension formulation. **[10]**

***Q2)*** Answer any three of the following: **[15]**

a) Provide your view on requirements of pharmaceutical premises and relevant documentation to comply regulatory requirements.

b) Provide contents of typical site master file.

c) Give in brief contents of change control SOP.

d) Discuss post manufacturing materials management issues.

***Q3)*** Write note on (any three): **[15]**

a) MVP

b) Equipment qualification

c) Cleaning validation

d) Third party quality audit

***Q4)*** What are the process validation options? Describe in detail concurrent process validation. **[10]**

OR

What are the personnel related legal aspects as per different regulatory authorities?

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

P4703

[Total No. of Pages : 1

# [4950] - 213

## M.Pharmacy (Semester-I)

## PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

## (2013 Pattern) (Credit System)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Discuss the design, layout and operational facilities with services and utilities for tablets. **[10]**

***Q2)*** Attempt any three from following **[15]**

a) What is effluent? Write importance of effluent treatment

b) Explain layout and operational facilities for ointments

c) Discuss operation of Q.C Laboratory

d) Write in short design of effluent treatment plant

***Q3)*** Short note (any three) **[15]**

a) Design of compressed air

b) Operational facilities with services and utilities for liquid orals.

c) Design of security office, vehicle parking, and fuel storage

d) Design and layout for sterile powder ready for reconstitution.

***Q4)*** Explain design of water stream as utility services. **[10]**

OR

Discuss in detail revised schedule M and factory Act.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

P4704

[Total No. of Pages : 1

# [4950] - 214

## M.Pharmacy

## BIOPHARMACEUTICS AND PHARMACOKINETICS

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** With respect to Noye's Whitney equation explain the film theory. Also describe various dissolution testing apparatus as per USP. **[10]**

***Q2)*** Answer any three: **[3 × 5 = 15]**

a) Briefly discuss the causes and detection of non-linearity.

b) Illustrate dosage form design for transportation through placental barrier.

c) Explain protein binding, its significance and factors affecting it.

d) Describe various in vitro and in vivo models for prediction of absorption and permeability.

***Q3)*** Write short notes on (any three): **[3 × 5 = 15]**

a) Protocol for bioavailability studies of conventional dosage forms.

b) *In vitro* dissolution testing models.

c) Determination of absorption rate constant($K_a$)

d) ABC transporters.

***Q4)*** What is plasma concentration-time profile? Derive an equation for determination of concentration in plasma for a drug given as I.V. infusion through one compartment model. **[10]**

OR

Derive and describe the michaelis menten equation for determination of $K_m$ and $V_{max}$ for drugs undergoing non-linear pharmacokinetics.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

P4705

[Total No. of Pages : 1

# [4950] - 215

## M.Pharmacy

## STERILE PRODUCTS FORMULATION AND TECHNOLOGY

## (2013 Pattern) (Semester - I & II) (Elective)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** Explain in brief formulation and manufacturing considerations in ophthalmic gels. **[10]**

***Q2)*** Solve any three from the following questions. **[15]**

a) Explain in brief formulation of liposomes.

b) Give the layout of parenteral facility.

c) Describe the sterile plastic devices with their materials.

d) Explain formulation parameters in SVP's.

***Q3)*** Write a short note on any three. **[15]**

a) BFS technology

b) Total Parenteral nutrition.

c) Peritoneal Dialysis Fluid.

d) Resealed Erythrocytes.

***Q4)*** Explain precautions, problems, hazards and complications associated with parenteral drug administration. **[10]**

OR

Describe in detail process selection and process specification in sterilization of parenterals.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

P4706

[Total No. of Pages : 1

# [4950] - 216

## M.Pharmacy

## ACTIVE PHARMACEUTICAL INGREDIENTS (APIS) MANUFACTURING TECHNOLOGY

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Write about manufacturing methods along with flow charts for sulphamethoxazole and Adrenaline. **[10]**

***Q2)*** Attempt any three questions from following. **[15]**

a) Write about chromatographic techniques in API manufacturing.

b) Give an account of radiation hazards and its detection.

c) Discuss animation reaction process for API synthesis.

d) Pharmaceutical intermediates.

***Q3)*** Write short notes on (Any two). **[15]**

a) Fluidized Bed Dryers

b) Foot and leg protection law

c) Detection and sampling

d) Industrial noise

***Q4)*** Discuss about personal protection, eye protection and types of eye protection equipments. **[10]**

OR

Write a detail account of technology involved in manufacturing of pharmaceuticals.

✦✦✦✦

Total No. of Questions : 04]

SEAT No. :

P4707

[Total No. of Pages : 1

# [4950] - 217

## M.Pharmacy

## CHEMISTRY OF MEDICINAL AND NATURAL PRODUCTS

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labelled diagrams wherever necessary.***

***Q1)*** Write in detail various methods for extraction of essential oils. **[10]**

***Q2)*** Solve the following (ANY THREE) **[3 × 5 = 15]**

a) Write biosynthetic pathway for Atropine.

b) What are Purine alkaloids, give method for extraction of caffine.

c) Give the classification and chemistry of carbohydrates.

d) Explain role of secondary metabolites in plants.

***Q3)*** Short notes (ANY THREE): **[3 × 5 = 15]**

a) Methods of extraction of Alkalods.

b) Biogenesis of Ornithine derived alkaloids.

c) Role of flavonoids.

d) Analysis of Diosgenine.

***Q4)*** Define and classify Glycosides. Give method for extraction and isolation of Anthraquinone Glycosides. **[10]**

OR

Write in detail chemistry of plant pigments and their roll in plants.

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Total No. of Questions : 04]

SEAT No. :

P4708

[Total No. of Pages : 1

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## M.Pharmacy

## TRADITIONAL SYSTEM OF MEDICINE AND AYURVEDIC FORMULATIONS

### (2013 Pattern) (Semester-I) (Credit System)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right side indicate full marks.***
3) ***Draw well labeled diagrams must be drawn wherever necessary.***

***Q1)*** Explain Unani system of medicine. Give the theory and basic concept and add a brief note on diagnosis and treatment of Unani system of medicine. **[10]**

***Q2)*** Answer the following (any three) **[15]**

a) Explain the theory and basic concept of Homeopathic system of medicine.
b) Explain the preparation and evaluation methods of Bhasmas.
c) Explain the principles of Ayurvedic system of medicine.
d) Give and account of diagnosis and treatment of chinese system of medicine.

***Q3)*** Write short notes (any three): **[15]**

a) Kwatha
b) Churna
c) Ghruta
d) Taila

***Q4)*** Enlist five drugs used in Ayurvedic medicine and Unani medicines and give their comparative account. **[10]**

OR

Define standardization and explain the importance of Physical and Chemical and microscopical methods standardization of Ayurvedic dosage forms.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P4709

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## M.Pharmacy

## MEDICINAL PLANT BIOTECHNOLOGY

## (2013 Pattern)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Draw well labeled diagrams wherever necessary.***
3) ***Enter the question number clearly in the margin of the answer book beside each of your answer***
4) ***Figures to the right indicate full marks.***

***Q1)*** What are Edible vaccines? What are possible advantages and disadvantages of Edible vaccines? What are strategies for the production of candidate vaccine antigens in plant tissue? **[10]**

***Q2)*** Solve any three **[3 × 5 = 15]**

a) What are Somaclonal variations? What are types of Somaclonal variations? What are benefits and disadvantages of somaclonal variation?

b) What is PCR? What is its principle & Basic set up?

c) What are plant growth regulators? Write classification of plant growth regulators.

d) What you mean by Genetic code? What are its salient features?

e) What are advantages & disadvantages of micropropogation?

***Q3)*** Short notes (Any three) **[3 × 5 = 15]**

a) Cellulose & Hemicellulose of plant cell wall

b) Structure of RNA

c) Benefits of In-situ conservation & drawbacks of Ex-situ conservation?

d) Genetically modified crops & Applications of Transgenic plants.

e) Enzyme reactors

***P.T.O.***

***Q4)*** What is mutation? Write brief note on mutation caused by impact on protein sequence. **[10]**

OR

What is electroporation? Explain Gene electrotransfer.

Total No. of Questions : 04]

SEAT No. :

P4710

[Total No. of Pages : 1

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## M.Pharmacy

## NATURAL PRODUCT MANAGEMENT

## (2013 Pattern) (Semester-I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Focus on the basic needs for the establishment of herbal extraction unit. **[10]**

***Q2)*** Solve the following (any three) **[15]**

a) Explain about various schemes for development medicinal plants in India.

b) Explain management of labour & machine for medicinal plant farming.

c) Highlight on trading of nutraceuticals in national & International market.

d) Write about the legal requirements for import & export of natural cosmaceuticals.

***Q3)*** Write short notes on (any three) **[15]**

a) Preparation of cocoa butter.

b) Trading of preoritized medicinal plants.

c) Co-ordination among collectors & growers for marketing of natural products.

d) Techniques for marketing of herbal raw material.

***Q4)*** Write an elaborative note on IPR of Herbs & Herbal Products **[10]**

OR

Write detail note on Import and Export of Herbs **[10]**

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Total No. of Questions : 4]

SEAT No. :

P4711

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## M.Pharmacy

## QUALITY ASSURANCE TECHNIQUES IN HERBAL PRODUCTS

## (2013 Pattern) (Theory)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Explain Quality Management System. Discuss in detail regulatory aspects and processing methods for herbal medicines. **[10]**

***Q2)*** Attempt any three questions of following: **[15]**

a) Elaborate cleaning validation

b) Discuss URS and Equipment qualifications

c) What are the analytical methods development guidelines for herbal formulations.

d) Explain Quality Audit

***Q3)*** Write short note on (any three): **[15]**

a) Global regulatory bodies for herbal drugs

b) Pharmacovigilance for herbal products

c) Evaluation of crude drug and herbal formulation

d) Safety issues related to herbal products

***Q4)*** Discuss in detail regulatory aspects and processing methods for herbal medicines. **[10]**

OR

State the term standardization. Write its importance in herbal drug industry.

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Total No. of Questions : 4]

SEAT No. :

**P4712**

[Total No. of Pages : 1

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## M.Pharmacy

## TOXICOLOGY

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams whenever necessary.***

***Q1)*** Define $LD_{50}$ and explain in brief about determination of $LD_{50}$ as per OECD guidelines. **[10]**

***Q2)*** Solve the following (any three) **[15]**

a) Explain the allergic and idiosyncrasy reaction to xenobiotics.

b) Discuss the management of toxicity reaction in humans.

c) Write the procedure and applications of PCR.

d) Define habituation, addiction, hypersensitivity, tolerance and potentiation.

***Q3)*** Write short notes (any three) **[15]**

a) Toxicokinetics.

b) Ocular toxicity.

c) Mechanisms of male and female reproductive toxicity.

d) Immunochemical techniques.

***Q4)*** Write the principles of GLP as per OECD guidelines for conducting preclinical toxicity studies. **[10]**

OR

Define toxicology. Explain preclinical toxicological requirements for biological and biotechnological products.

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Total No. of Questions : 04]

SEAT No. :

P4713

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## M.Pharmacy

## SAFETY PHARMACOLOGY

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Explain in brief the principles, scope and importance of safety pharmacology. **[10]**

***Q2)*** Solve the following (any three) : **[15]**

a) Explain the Draize test for ocular toxicity studies.

b) Write the applications of *in vitro* techniques for drug safety assessment.

c) Write the process of reporting adverse event in clinical trials.

d) Explain the Guinea pig sensitization assay for dermatological products.

***Q3)*** Write short notes on (any three) : **[15]**

a) Statistics in Pharmaceutical safety assessment.

b) Study design for acute toxicity studies.

c) Risk benefits assessment in clinical trials.

d) Carcinogenicity.

***Q4)*** Explain the regulatory requirements of ICH for new drug safety assessment. **[10]**

OR

Write in detail about the study design and importance of reproductive toxicity studies.

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Total No. of Questions : 04]

SEAT No. :

P4714

[Total No. of Pages : 1

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## M.Pharmacy

## CLINICAL TRIALS

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labelled diagram wherever necessary.***

***Q1)*** Discuss in brief the role of institutional review board and informed consent in ethical conduct of clinical trials. **[10]**

***Q2)*** Solve any three **:** **[15]**

a) Explain ethical guidelines of declaration of Helsinki.

b) Write the process for filling NDA.

c) Explain various elements of clinical trial design.

d) Discuss the blinded and Randomization Study.

***Q3)*** Write short notes on (any three) : **[15]**

a) Role and responsibilities of CRO.

b) Patient recruitment in clinical trials.

c) Investigater Brochure.

d) Investigational New Drug (IND) process.

***Q4)*** Define clinical research. Discuss in brief various types and phases of clinical trials. **[10]**

OR

Discuss the role of FDA in new drug development process.

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Total No. of Questions : 04]

SEAT No. :

P4715

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## M.Pharmacy

## CLINICAL PHARMACOKINETICS AND PHARMACODYNAMICS

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** What is non linearity in kinetics? How is it detected? Explain the methods for determination of $V_{max}$ and $K_m$. **[10]**

***Q2)*** Answer the following (any three) : **[15]**

a) Explain the implications of drug metabolism on drug response.

b) Explain the applications of Wagner-Nelson method.

c) Explain the need of individualization with respect to drug interactions.

d) Explain the Blood placental Barrier.

***Q3)*** Write a note on following (any three) : **[15]**

a) Mean residence time.

b) Therapeutic window.

c) Area Under Curve.

d) Factors affecting bioavailability of drug from dosage form.

***Q4)*** Discuss the kinetics following one compartment given as intravenous bolus dose of a drug. **[10]**

OR

Write a exhaustive note on Clearance of drug.

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Total No. of Questions : 4]

SEAT No. :

P4716

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## M.Pharmacy

## CLINICAL IMMUNOLOGY & ENZYMOLOGY

## (2013 Pattern) (Semester - I)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** What is graft rejection? Enlist its different types and describe in detail the mechanism of graft rejection. **[10]**

***Q2)*** Solve any three**.** **[15]**

a) Write an account on humoral autoantibodies.

b) Give a detail account on adaptive immunity.

c) Define immunity. Elaborate on its different types.

d) Give a detail account on anaphylactic reaction.

***Q3)*** Write short notes (any three) : **[15]**

a) Congenital immunodeficiency

b) Enzyme kinetics

c) Major Histocompatibility complex

d) Acquired immunodeficiency

***Q4)*** What is autoimmunity? Describe the mechanisms of autoimmunity. **[10]**

OR

Give a detail account on monoclonal antibodies. Elaborate their applications in diagnosis and immunotherapy.

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Total No. of Questions : 4]

SEAT No. :

P4717

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## M.Pharmacy

## INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT

## (2013 Pattern) (Semester - I & II)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Explain in detail pilot scale-up and design for capsules and semisolid preparations. **[10]**

***Q2)*** Answer any three. **[15]**

a) Discuss automation in pharmaceutical industry.

b) Explain the safety monitoring and preventive system for industrial hazards due to chemicals and pharmaceuticals.

c) What are the requirements related to the sale of drugs as per the Drugs and Cosmetics Act?

d) Discuss the engineering aspects of electronic parts of a pharmaceutical machinery.

***Q3)*** Write short notes (any three) : **[15]**

a) Material handling for various pharmaceutical products.

b) Vendor development capacity assessment of inventory management.

c) Statistical design and applied optimization methods.

d) Quality assurance and process control.

***Q4)*** Describe in detail the mechanical, electrical and electronic parts of pharmaceutical machinery and equipments. **[10]**

OR

Explain in detail effluent testing and treatment for the pharmaceutical industry.

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Total No. of Questions : 4]

SEAT No. :

P4718

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## M.Pharmacy

## FERMENTATION TECHNOLOGY

## (2013 Pattern) (Semester - I/II) (Elective)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Explain different techniques used for isolation and screening of industrial important microbes. **[10]**

***Q2)*** Answer the following (any three): **[15]**

a) What is Recombinant protein? Explain.

b) Explain the design and working of mechanically agitated fermenter.

c) Write the importance of optimization of fermentation media.

d) Explain different factors affecting microbial growth. Explain growth kinetics.

***Q3)*** Write a note on (any three): **[15]**

a) Fermented foods and beverages.

b) Production of Biethanol

c) Michaelis-Menten Kinetics

d) Anylase

***Q4)*** What is immobilization? Write importance of immobilized enzymes. **[10]**

OR

Explain in detail process monitoring and control parameters used in Bioreactors.

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**Total No. of Questions : 4]** **SEAT No. :**

**P4719** **[Total No. of Pages : 1**

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## M.Pharmacy

## PROJECT MANAGEMENT

## (2013 Pattern) (Semester - I & II)

***Time : 3 Hours]*** ***[Max. Marks : 50***

***Instructions to the candidates:***

1) ***Question one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** What is the importance of project evaluation and review technique (PERT) in project management; also explain the concept of critical path method (CPM) **[10]**

***Q2)*** Write comments on (Attempt any three): **[15]**

a) Role of project Manager.

b) Schedule of Project.

c) Project planning process.

d) Reporting of project objective during execution of project.

***Q3)*** Short notes (any three): **[15]**

a) Optimum utilization of resources and execution of project.

b) Significance of effective communication by team leader.

c) Management of conflict of interest.

d) Project team development.

***Q4)*** Explain the importance of project management; Give suitable cases from pharmaceutical projects for manufacturing on small scale. **[10]**

OR

How to evaluate/determine/manage the project performance with special reference to team decision.

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Total No. of Questions : 04]

SEAT No. :

P4720

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## M.Pharmacy

## PHARMACEUTICAL ADMINISTRATION

## (2013 Pattern) (Semester - I & II) (Credit System)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***

***Q1)*** Explain the concept of management and administration. Give the various functions of management. Describe the corporate social responsibility of the firm. **[10]**

***Q2)*** Answer the following (any three) **[15]**

a) Explain the process of planning in details.

b) What is decision making?

c) Give the line and staff concept of organisation.

d) Performance appraisal is a staffing function-justify.

***Q3)*** Write short notes on the following (any three) **[15]**

a) Critical control and standards.

b) Productivity problems and measurement.

c) Control of overall performance.

d) Span of control

***Q4)*** Explain human motivation theories of Abraham Maslow and Mcclelland's needs theory. **[10]**

OR

What is communication? Give the details of process of communication. Explain the barriers of communication.

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Total No. of Questions : 4]

SEAT No. :

**P4721**

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## M.Pharmacy (Semester - I & II)

## COSMETICOLOGY

## (2013 Pattern)

*Time : 3 Hours]* *[Max. Marks : 50*

***Instructions to the candidates:***

1) ***Question number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

***Q1)*** Discuss anatomy of skin and give detailed account of various skin creams with their components. **[10]**

***Q2)*** Attempt any three: **[3 × 5 = 15]**

a) Describe various rheological additives in cosmetics.

b) Describe preservative efficacy testing in cosmetics?

c) Discuss formulation factors affecting efficacy of sunscreen products.

d) Give account of evaluation tests of shampoos.

***Q3)*** Short notes (any three): **[3 × 5 = 15]**

a) Herbal cosmetics

b) Packaging of cosmetics

c) Formulation components of nail lacquers

d) Permanent hair colours

***Q4)*** Give an account of antiperspirants and their formulation. **[10]**

OR

Discuss various surface active agents used in shampoo preparations.

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