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

P5450 **[Total No. of Pages : 2**

[5553]-101

M.Pharmacy (Semester - I)

ADVANCED ANALYTICAL TECHNIQUES

(2013 Pattern) (Credit System)

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

Instructions to the candidates:

1) ***Question No. 1 is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw Neat Labelled diagram wherever necessary.***

Q1) Discuss in details about rules of fragmentation in mass spectrometry. Explain with example fragmentation of alcohols. **[10]**

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

a) Discuss about instrumentation of DTA.

b) Explain system suitability parameters for HPLC.

c) Write a note on MALDI.

d) Write principle, instrumentation and applications of super critical fluid chromatography.

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

a) Thermogravimetric Analysis

b) Travelling Electron Microscopy

c) Differential Scanning Calorimetry

d) Gas-liquid chromatography

P.T.O.

Q4) Suggest suitable structural formula for following spectroscopic data

Molecular formula : $C_8H_{10}O$ **[10]**

δppm 2.2 (s, 1H):

2.7 (t,J=6.5 Hz,2H):

3.68 (t,J + 7Hz,2H):

7.2(m,5H)

OR

Write in detail about the pumps and detectors in HPLC

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

P5451 **[Total No. of Pages : 1**

[5553]-102

M.Pharmacy (Semester - I)

RESEARCH METHODOLGY

(2013 Pattern) (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) What is experimental design? Enlist various types of research design. Add a note on "Factorial Design". **[10]**

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

a) Explain about methods of literature survey.

b) Give the importance of communication skill in oral presentation.

c) Describe about various funding schemes of AICTE.

d) Give the statistical significance of coefficient of correlation.

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

a) Statistical measures

b) Techniques of documentation

c) Bioavailability/Bioequivalence studies

d) Types of research.

Q4) a) Explain in detail parametric and non parametric tests of statistics. **[10]**

OR

b) Describe in brief research report and thesis writing.

● ● ●

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

P5452 **[Total No. of Pages : 1**

[5553]-103

M. Pharmacy (Semester - I)

ADVANCED PHARMACEUTICS

(2013 Pattern) (Credit System)

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

Instructions to the candidates:

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

Q1) Write in detail the concept and objectives of stability of pharmaceuticals. **[10]**

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

a) How expiry of dosage forms is calculated?

b) Write short note on biodegradable and bioerodible polymers

c) Write note on solid state characterization of API and Excipients.

d) Give factors affecting selection of excipients.

Q3) Write short notes on (Any Three) : **[15]**

a) Validation of mixing process

b) Solubility and dissolution

c) Quality control and Quality Assurance

d) Co-processed Excipients

Q4) Write significance of carrying out Preformulation Study. Explain with suitable examples preformulation studies conducted for solid oral dosage forms. **[10]**

OR

Define optimization. Describe importance of experimental design in formulation development.

● ● ●

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

P5453 **[Total No. of Pages : 1**

[5553]-104

M. Pharmacy (Semester - I)

ADVANCED PHARMACEUTICAL CHEMISTRY

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Enlist the various types of molecular rearrangements. Discuss any one rearrangement involving migration to electron deficient nitrogen and one involving migration to electron deficient carbon in detail. **[10]**

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

a) Discuss the principles of Green chemistry.

b) Define configurational and conformational isomerism. Explain configurational isomerism with examples.

c) What are the advantages of Ionic liquids over volatile organic solvents? Justify giving suitable examples.

d) Give the advantages and disadvantages of multicomponent synthesis. Explain any two reactions in detail.

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

a) Migratory aptitude of group.

b) Clemmensen reduction.

c) Microwave assisted reactions.

d) Use of diazomethane and peracids in synthesis.

Q4) Give the various types of synthon approach for synthesis of organic compounds. Explain the disconnection rules and transforms using the examples of retrosynthesis of at least two drugs. **[10]**

OR

What are the sources of industrial effluents? Classify and discuss the treatment process for industrial effluents.

● ● ●

Total No. of Questions : 4]

SEAT No. :

P5454

[Total No. of Pages : 1

[5553]-105

M. Pharmacy (Semester - I)

ADVANCED PHARMACOLOGY - I

(Preclinical Evaluation of Drugs)

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Discuss the preclinical evaluation methods of anti-ulcer drugs. **[10]**

Q2) Solve the following (Any Three) : **[15]**

a) Screening of antifertility agents.

b) Discuss in detail Form B.

c) Screening of anxiolytic agents.

d) Describe two preclinical screening methods of nootropics.

Q3) Write a short notes (Any Three) : **[15]**

a) Describe two preclinical screening methods of peripheral analgesics.

b) Patch clamp technique.

c) Discuss the applications of proteomics.

d) Screening of anti-thyroid agents.

Q4) Discuss the preclinical screening methods of antihypertensive agents. **[10]**

OR

Discuss the preclinical screening methods of anti-inflammatory agents.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5455

[Total No. of Pages : 1

[5553]-106

M. Pharmacy (Semester - I)

ADVANCED PHARMACOGNOSY

(2013 Pattern) (Credit System)

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

Instructions to the candidates:

1) ***Question No.1 is compulsory.***
2) ***Neat diagrams must be drawn wherever necessary.***
3) ***Figures to the right indicate full marks.***

Q1) Elaborate a detail account of biosynthetic pathway for cinnamic acid. **[10]**

Q2) Answer the following (Any three) **[3 × 5 = 15]**

a) Explain in detail the Building blocks for secondary metabolites derived from Primary metabolites.

b) Explain in detail the Ethnobotanical Approach for drug discovery.

c) Explain the difficulties produce in preparation of Herbal formulations.

d) Explain the selection strategies for HTS.

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

a) Phenolic oxidative coupling.

b) Biosynthesis of Flavonolignans.

c) Phytoalexin.

d) Vinca Alkaloids.

Q4) Explain the characteristics of natural products that makes them appropriate material in discovering new drugs. **[10]**

OR

Elaborate a detail account of biosynthetic pathway for coumarins.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5456

[Total No. of Pages : 1

[5553]-107

M. Pharmacy (Semester - I)

ADVANCED QUALITY ASSURANCE TECHNIQUES (cGMP and Documentation)

(2013 Pattern)

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 material management in pharmaceutical industry. **[10]**

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

a) cGMP guidelines for equipment

b) Site master file

c) Manufacturing outsourcing

d) Change control

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

a) HACCP

b) Sanitation in sterile manufacturing facility

c) Drug product salvaging

d) Personnel in sterile manufacturing area

Q4) Discuss the process of handling market complaints. **[10]**

OR

Explain various "Plant level Documents".

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5457

[Total No. of Pages : 1

[5553]-201

First Year M. Pharmacy (Semester - II)

DRUG REGULATORY AFFAIRS

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Discuss the different types of intellectual properties that can be protected under IPR. Explain the procedure for obtaining patent in India. **[10]**

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

a) Write in detail about IND, its types and contents of IND applications.

b) Explain organization of common technical document. Brief each module of CTD.

c) Discuss the provisions of the Act for loan license manufacturing.

d) What is PCT? Give the procedure for application under PCT.

Q3) Short notes (Any three) **[15]**

a) Haldi and Neem case

b) Drug regulatory authority in India

c) ICH guidelines for stability testing

d) Trademark and copyright filing

Q4) Write in detail about the Technical sections of NDA. **[10]**

OR

Explain in detail BE studies and discuss norms for US submission.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5458

[Total No. of Pages : 1

[5553]-202

M. Pharmacy (Semester - II)

202 : FORMULATIONS AND DEVELOPMENT

(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 neat and labeled diagrams wherever necessary.***

Q1) Discuss in detail mouth dissolving formulations. **[10]**

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

a) Classify Nutraceuticals. Discuss in brief formulation of Nutraceuticals.

b) Discuss in brief components of aerosol formulation.

c) Explain Self micro emulsifying drug delivery systems.

d) Discuss in brief various approaches for taste masking of formulations.

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

a) Niosomes.

b) Quality Assurance of Aerosol formulation.

c) Metered Dose inhalers.

d) Explain the concept of 'Quality by Design'.

Q4) Discuss in detail Veterinary dosage forms. **[10]**

OR

Explain in detail formulation and evaluation of liposomes.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5459

[Total No. of Pages : 1

[5553]-203

M. Pharmacy (Semester - II)

NOVEL DRUG DELIVERY SYSTEMS

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Discuss in detail the influence of drug properties on the design and performance of sustained drug delivery systems. **[10]**

Q2) Attempt Any Three. **[15]**

a) Write in detail about the mechanism of mucoadhesion.

b) Explain the approaches used to develop pulsatile drug delivery systems.

c) Discuss penetration enhancement through stratum corneum modification.

d) What are the different strategies to enhance bioavailability?

Q3) Short notes (Any Three). **[15]**

a) Advantages and disadvantages of proteins and peptides as therapeutic agents and their methods of analysis.

b) Regulatory consideration in controlled release.

c) Various approaches for design and development of targeted ophthalmic drug delivery systems.

d) Niosomes.

Q4) Elaborate on drug delivery to brain. **[10]**

OR

Describe various types of nanoparticles.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5460

[Total No. of Pages : 1

[5553]-204

M. Pharmacy (Pharmaceutical Chemistry) (Semester - II)

ADVANCED MEDICINAL CHEMISTRY

(2013 Pattern) (Theory) (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) Write in detail about Anti-mycobacterial agents. **[10]**

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

a) Write synthetic scheme with reaction mechanism of Gefitinib.

b) Explain aryloxypropanolamines..

c) Highlight 4-aminoquinolines and 8-aminoquinolines as antimalarials.

d) Highlight GABA receptor and its ligands.

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

a) Reverse Transcriptase Inhibitors.

b) Alkylating agents..

c) Human Insulin: A breakthrough in drug therapy.

d) Applications of Interleukins.

Q4) Write in detail about drug used in treatment of Alzheimer's disease. **[10]**

OR

What is enzyme immobilization? Comment on enzyme immobilization techniques

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5461

[Total No. of Pages : 1

[5553]-205

M. Pharmacy (Semester - II)

DRUG DESIGN

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Define qsar. Enlist Different Drug Design techniques. Write Advantages of structure based Drug Design. Explain in details molecular docking Methodology. **[10]**

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

a) 3 dimensional Qsar.

b) Roles of genomics in Drug Design.

c) Energy Minimization Methods.

d) Monte carlo simulations.

Q3) Attempt any three questions. **[15]**

a) Drug Metabolism Drug Design.

b) Significance of Prodrug Designing.

c) Artificial Intelligence Methods.

d) Analog Based Approach.

Q4) What is receptor based Drug Design Approach? Explain the Methodology and Applications of Molecular Docking in Drug Design. **[10]**

OR

"Fragment Based Drug Design play significant role in Drug Design" justify the statement giving sufficient number examples and discuss in details virtual screening techniques.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5462

[Total No. of Pages : 1

[5553]-206

M. Pharmacy (Semester - II)

CLINICAL PHARMACOLOGY

(2013 Pattern)

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

Instructions to the candidates:

1) ***Question No. 1 is compulsory.***
2) ***Figures to right indicate full marks.***
3) ***Draw well labeled diagrams whenever necessary.***

Q1) Define metabolic disorders Classify ant-diabetic drugs. Explain in brief the pharmacology of pioglitazone. **[10]**

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

a) Write the mechanism of action and clinical uses of H_2 receptor antagonist in the treatment of ulcer.

b) Explain the role of ACEI in hypertension.

c) Write the treatment of Diarrhoea.

d) Write drug interaction during drug metabolism with example.

Q3) Write note on (Any Three) **[15]**

a) Define TDM. Write criterion for TDM.

b) Write different principles of toxicology.

c) Write physiological functions of caspases.

d) Discuss the treatment of gout.

Q4) a) Define clinical research. Explain the types and various phases of clinical research. **[10]**

OR

b) Define Angina pectoris. Discuss the pharmacology of organic nitrates in the management of anginal pain.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5463

[Total No. of Pages : 1

[5553]-207

M. Pharmacy (Semester - II)

MOLECULAR PHARMACOLOGY

(Specialization Pharmacology)

(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 labelled diagrams wherever necessary.***

Q1) Explain the concept of chronopharmacology and its clinical implications in drug therapy. **[10]**

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

a) Write a note on cyclic nucleotides.

b) Explain COX-2 regulators and their role in inflammation.

c) Explain the therapeutic implications of antioxidants.

d) Discuss in detail modulators of dopamine receptors.

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

a) Cholinergic receptors.

b) Monoclonal antibodies and their importance.

c) Calcium channel and its modulators.

d) Cell cultures techniques in molecular biology.

Q4) Explain the concept of Human Genome Mapping and its potential application in drug research. **[10]**

OR

Discuss the recent advances in drug acting on adrenoreceptors.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5464

[Total No. of Pages : 1

[5553]-208

M. Pharmacy (Semester - II)

PHYTOCHEMISTRY AND PHYTOPHARMACEUTICALS

(2013 Pattern)

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 is supercritical fluid extraction technique? Discuss its advantages over conventional techniques. Add a note on SCF extraction of Flavonoids. **[10]**

Q2) Solve Any Three : **[15]**

a) Write a note on microwave assisted extraction technique.

b) Write note on RP- column chromatography with suitable example.

c) Enlist various methods of extraction of essential oils with special note on modern methods of essential oil extraction.

d) Discuss the extraction, isolation and purification of Ergometrine.

Q3) Solve Any Three : **[15]**

a) Write note on Froth - floatation technique.

b) Comment on Quantitative analysis of bacosides in Bacopa species by HPTLC.

c) Discuss the screening methods for anti-asthmatic herbal drugs.

d) Discuss the role of fractional liberation in isolation of chemical constituents from herbal extracts.

Q4) Solve Any One : **[10]**

a) Discuss in detail the WHO parameters used in standardization of herbal drugs.

b) Discuss the physical, chromatographic and spectroscopic methods of characterization of Glycerrhizinic acid.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5466

[Total No. of Pages : 1

[5553]-210

M. Pharmacy (First Year) (Semester - II)

M-V-3 PHARMACEUTICAL VALIDATION (Theory)

(2013 Pattern) (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) Discuss analytical method validation in detail by USP guideline. **[10]**

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

a) Vender certification

b) Validation of Autoclaves

c) Computer system validation

d) Validation of capsule

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

a) Validation of HVAC system

b) Validation of Compressed air

c) Validation of UV/Visible spectrophotometers

d) Cleaning method validation

Q4) Explain process validation of tablet by dry granulation. **[10]**

OR

Discuss various stages to be performed for validation of computer system.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5467

[Total No. of Pages : 1

[5553]-211

M. Pharmacy (Semester - II)

QUALITY PLANNING AND ANALYSIS

(2013 Pattern) (Credit System)

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

Instructions to the candidates:

1) ***Question number 1 is compulsory.***
2) ***Figures to the right indicate full marks.***

Q1) Explain with suitable examples. The seriousness classification of quality characteristics. **[10]**

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

a) Explain the terms "Limiting Quality level" and "Indifference Quality level for a sampling plan.

b) What are sporadic and chronic quality problems?

c) Explain the categories of Quality cost.

d) Discuss "Creating and managing awareness of Quality".

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

a) Quality culture

b) Process Audit checklist

c) Automated Inspection

d) Human relations in auditing

Q4) How to establish the means of "measuring actual performance" of a quality level? **[10]**

OR

Discuss five essential principles for successful quality audit program.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P5468

[Total No. of Pages : 1

[5553]-212

M. Pharmacy (Semester - I & II)

QUALITY CONTROL AND ASSURANCE OF PHARMACEUTICALS

(2013 Pattern) (Theory)

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 concept of quality control and assurance. **[10]**

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

a) IPQC testing

b) Change control

c) Recall of products

d) cGMP guidelines for equipment

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

a) Validation Master plan

b) Internal audit

c) Guidelines for building and facilities

d) MPCR

Q4) Discuss material management. **[10]**

OR

Explain quality control of biological products.

▽▽▽▽

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

P5469 **[Total No. of Pages : 1**

[5553]-213
M.Pharmacy
PHARMACEUTICAL PLANT DESIGN AND OPERATIONS
(2013 Pattern) (Credit System) (Elective) (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) Discuss in detail design, layout and operational facilities with services and utilities for Tablet. **[10]**

Q2) Attempt ANY THREE from following **[15]**

a) Explain layout and operational facilities for Dry Syrup

b) Discuss design of effluent treatment plant --

c) Explain Operation of Q.C. Laboratory

d) Describe design of compressed air

Q3) Short Note (ANY THREE) **[15]**

a) Importance of effluent treatment

b) Operational facilities with services and utilities for Ointment

c) Design and operational facilities for Capsules

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

Q4) Enlist utility services in Pharmaceutical Industry. Explain design of water and steam system **[10]**

OR

Discuss in detail regulatory requirements of Pharma facilities with reference to cGMP and revised schedule M

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Total No. of Questions : 4]

SEAT No. :

P5470

[Total No. of Pages : 1

[5553]-214

M.Pharmacy

BIOPHARMACEUTICS AND PHARMACOKINETICS

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

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

Instructions to the candidates:

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

Q1) What are pharmacokinetic models? Discuss in detail compartmental modeling with advantages and applications. **[10]**

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

a) What is non linear pharmacokinetics? Explain the causes of non linearity?

b) Discuss regulatory aspects of bioavailability and bioequivalence studies.

c) Describe in-vitro and in-vivo methods for the study of drug bio-transformation

d) Write down significance and kinetics of protein binding.

Q3) Write short notes (Any Three) **[15]**

a) Bioequivalenec study designs.

b) Experimental models for predicting drug absorption.

c) Estimation of km and Vmax

d) Amoxiallin has a short half life (around 1 hour) has to be taken multiple times per day, discuss and justify the case.

Q4) Discuss in detail physiological barriers to the distribution of drug in correlation with dosage form design. **[10]**

OR

Explain film theory with respect to Noyes-whitney's dissolution rate law. Discuss various approaches to improve dissolution of poorly soluble drugs.

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Total No. of Questions : 4]

SEAT No. :

P5471

[Total No. of Pages : 1

[5553]-215

M.Pharmacy

STERILE PRODUCTS FORMULATION & 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 the different sources of contaminations in sterile products, write in details about the Air quality in parenteral production areas. **[10]**

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

a) Explain the Industrial autoclaving.

b) Explain the Vehicles for sterile products.

c) What are different parenteral irrigating solutions? Explain the fundamentals for Total Parenteral Nutrition.

d) Explain the possible complications and hazards associated with parenteral therapy.

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

a) Manufacturing of freeze dried sterile solids.

b) Elastomeric rubbers as packaging material for sterile products.

c) Liposomes.

d) Resealed erythrocytes as drug delivery system.

Q4) What are the limitations in ophthalmic drug delivery systems? Write a note on Ocular Inserts. **[10]**

OR

Explain the design concept of filling area for sterile products, add a note on gowning procedure in parenteral manufacturing areas.

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Total No. of Questions : 4]

SEAT No. :

P5472

[Total No. of Pages : 1

[5553]-216

M.Pharmacy

ACTIVE PHARMACEUTICAL INGREDIENTS (APIS) & MANUFACTURING TECHNIQUES

(2013 Pattern) (Semester - I & II) (Elective) (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) Give detailed account on environmental protection laws enforced on the pharmaceutical manufacturing units. **[10]**

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

a) Enumerate different halogenation processes utilized in manufacturing units.

b) Applications of chromotagraphic techniques in manufacturing units.

c) Draw a diagram of continuous fluid-bed vapour phase reduction of nitrobenzene.

d) Write a short account on amination by reduction using zinc as a catalyst.

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

a) Draw a well labeled diagram of fluidized-bed dryer.

b) Use of solvents in manufacturing units.

c) Handling of fine chemicals

d) Health hazards of ultra sound

Q4) Describe in detail the process involved in manufacturing sulphamethoxazole and ciprofloxacin. **[10]**

OR

Give detail explanation on health hazards and personal safety. Give methods emphasized on safety measures for human eye.

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

P5473 **[Total No. of Pages : 1**

[5553]-217
M.Pharmacy
CHEMISTRY OF MEDICINAL AND NATURAL PRODUCTS (E.1.6)
(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.***
3) ***Draw well labelled diagram whenever necessary.***

Q1) Write in detail about general method for extraction of alkaloids and elaborate chemical method for structural elucidation of Ephedrine. [10]

Q2) Solve the following. (Any Three) [15]

a) Explain method of isolation and purification of flavonoids.
b) Write about physical method for structural elucidation of Piperine.
c) Biogenesis of ornithine derived alkaloids
d) Explain method of analysis of Morphine.

Q3) Write short Notes (Any Three) **[15]**

a) Chemistry of steroids
b) Plant pigments
c) Properties of carbohydrates
d) Method of analysis Solasodine

Q4) Write in detail about chemistry and properties of Terpenoids. **[10]**

OR

Write about chemistry and method of analysis of caffeine. **[10]**

⊖⊖⊖

Total No. of Questions : 4]

SEAT No. :

P5474

[Total No. of Pages : 1

[5553]-218

M.Pharmacy (Semester - I)

TRADITIONAL SYSTEM OF MEDICINE AND AYURVEDIC FORMULATIONS

(2013 Pattern) (Credit System) (Elective)

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

Instructions to the candidates:

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

Q1) Explain in detail Ayurvedic cosmetic formulations. **[10]**

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

a) Explain the preparation and evaluation methods of Avaleha

b) Add a note on Ethnopharmacognosy

c) Explain the principles of Unani system of medicine

d) Give an account of Chinese system of medicine

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

a) Taila

b) Bhasma

c) Vati

d) Rasayana

Q4) Explain in detail principles and treatment methods in Homeopathy. **[10]**

OR

Explain the methods for standardization of Ayurvedic drugs.

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

P5475 **[Total No. of Pages : 1**

[5553]-219
M.Pharmacy
MEDICINAL PLANT BIOTECHNOLOGY
(2013 Pattern) (Sem - 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) ***Neat diagrams must be drawn wherever necessary.***

Q1) Explain in details Different types of cultures in Plant tissue culture and its applications. **[10]**

Q2) Attempt Any Three **[15]**

a) Enlist the different methods of improving quality of crop with emphasis on plant breeding.

b) Explain in details about Plant growth regulators and Elicitors.

c) Explain in detail Edible Vaccines.

d) What are the uses of PCR in Gene mapping?

e) Explain in details Immobilization of Enzymes.

Q3) Write short note (Any Three) **[15]**

a) Hybridization.

b) Biotransformation.

c) Application of Transgenic plant in production of Phytopharmaceuticals

d) Techniques of DNA mediated gene transfer

e) Gene transfer by using vector of Agrobacterium.

Q4) Explain in details principle of DNA recombination technology along with its process and applications.

OR

Explain different types of enzymes? Write in details isolation and purification of enzymes.

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Total No. of Questions : 4]

SEAT No. :

P5476

[Total No. of Pages : 1

[5553]-220
M.Pharmacy
NATURAL PRODUCTS MANAGEMENT
(2013 Pattern) (Semester - I & II) (Elective)

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

Instructions to the candidates:

1) ***Question number one is compulsory.***
2) ***Figures to right indicate full marks.***
3) ***Draw well labelled diagram wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) What are types of extracts of herbal drugs? Discuss the general requirements for preparation of purified dry extract from medicinal plants. **[10]**

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

a) What is farm planning and budgeting? Describe different steps involved in it.

b) What are objectives of AYUSH?

c) What is Central Sector Scheme for "Conservation, Development and Sustainable Management" of Medicinal Plants?

d) What is agricultural marketing? Explain the processes involved in agricultural marketing.

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

a) IPR of natural products

b) Extraction of oil from seeds

c) Export of natural products

d) Protocols for cultivation

Q4) What are Ex-situ and in-situ methods of conservation of medicinal plants?**[10]**

OR

What are the management exercises before farm planning?

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Total No. of Questions : 4]

SEAT No. :

P5477

[Total No. of Pages : 1

[5553]-221
M.Pharmacy
QUALITY ASSURANCE TECHNIQUES IN HERBAL PRODUCTS
(2013 Pattern) (Semester - I & II) (Elective) (E.1.10) (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***
3) ***Draw well labelled diagram whenever necessary.***

Q1) Write in detail GMP requirements for herbal products and elaborates its components and objectives. **[10]**

Q2) Solve the following. (Any Three) **[15]**

a) Explain of standardization of herbal products as per cGMP.

b) Brief about compendial methods for evaluation of crude drugs and herbal formulations.

c) Explain in detail about cleaning validation methods.

d) Detail about outsourcing.

Q3) Write short notes (Any Three) **[15]**

a) Pharmacovigilance for herbal products.

b) Flexible packaging.

c) Regulatory bodies ICH.

d) Sanitization of Plant and equipment.

Q4) Explain in detail stability issues guidelines for studies related to herbal formulations, extracts and isolated natural compounds. **[10]**

OR

Enlist various facilities and discuss building facilities for herbal product Manufacturing.

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Total No. of Questions : 4]

SEAT No. :

P5478

[Total No. of Pages : 1

[5553]-222
M. Pharmacy
TOXICOLOGY
(2013 Pattern) (Semester - I & II) (Elective)

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

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figure to right indicates full marks.***
3) ***Draw well labeled diagram wherever necessary.***

Q1) Discuss the principle of GLP as per OECD guidelines, for conducting preclinical toxicity studies. **[10]**

Q2) Solve the following (Any Three): **[15]**

a) Write the different mechanism of hepatic toxicity.

b) Write the factor influencing on single dose and repeat dose toxicity study.

c) Give Ames test for mutagenicity.

d) Define Toxicity and types of toxicology with example.

Q3) Write short notes (Any Three) **[15]**

a) C-DNA and Genomic libraries

b) Academic and industrial application of toxicology.

c) Renal toxicity studies

d) Cellular and sub-cellular changes due to Xenobiotics.

Q4) Explain in detail the preclinical toxicological requirement for biological products. **[10]**

OR

Discuss Neuronal and behavioral toxicity study and it's management.

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

P5479 **[Total No. of Pages : 1**

[5553]-223
M.Pharmacy
SAFETY PHARMACOLOGY
(2013 Pattern) (Semester - I & II) (Elective)

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

Instructions to the candidates:

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

Q1) Define pharmacovigilance. Explain in detail collection and reporting of pharmacovigilance data. **[10]**

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

a) Write in detail about guinea pig sensitization assay for testing dermatological products.

b) Describe ocular toxicity studies.

c) Explain the process of ADR reporting in clinical trials.

d) Give an account on oral toxicity guideline for Acute Oral Toxicity.

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

a) Product safety update reports

b) Test for mutagenicity

c) Scope of Safety Pharmacology

d) Risk benefit assessment

Q4) Explain in detail ICH S7A guidelines used for safety pharmacology studies.**[10]**

OR

Explain in detail various applications of in vitro techniques in drug safety assessment.

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Total No. of Questions : 4]

SEAT No. :

P5480

[Total No. of Pages : 1

[5553]-224

M.Pharmacy (Semester - I & II)

CLINICAL TRIALS

(2013 Pattern) (Credit System) (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 labelled diagrams wherever necessary.***
4) ***Do not write anything on the question paper except seat number.***

Q1) Define Clinical Research. Discuss the history, types and phases of clinical research. **[10]**

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

a) Write the principles of Nuremberg code

b) Discuss the designs used in Clinical trials with their advantages and disadvantages

c) Discuss the data analysis issues in clinical trials

d) Explain the various statistical tests used in clinical trials

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

a) Ethical issues in clinical trials

b) Investigators brochure

c) Data analysis issues in clinical trials

d) Principles of ICH-GCP guidelines

Q4) Discuss the roles and responsibilities of stakeholders of clinical trials. **[10]**

OR

Define informed consent. Discuss in brief the significance and contents of informed consent.

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Total No. of Questions : 4]

SEAT No. :

P5481

[Total No. of Pages : 1

[5553]-225

M.Pharmacy

CLINICAL PHARMACOKINETICS AND PHARMACODYNAMICS

(2013 Pattern) (Semester - I & II) (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) Explain the plasma concentration time curve in detail. Discuss the calculation of pharmacokinetic parameters such as therapeutic index, AUC, $AUC_{0-\infty}$ and Elimination half life **[10]**

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

a) What is mean residence time? How to calculate it? **[5]**

b) What is total clearance and renal clearance? How to calculate renal clearance? **[5]**

c) What is non-linear Pharmacokinetics? What is its significance? **[5]**

d) What is dose individualization? Discuss the influence of genetics and age in dose individualization. **[5]**

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

a) Well stirred model of hepatic clearance **[5]**

b) Physiological membranes **[5]**

c) Drug plasma protein binding **[5]**

d) Wagner Nelson method **[5]**

Q4) Write a detail account of kinetics of drugs following one compartment model following I.V. bolus dose **[10]**

OR

Discuss in detail pH partition hypothesis for the drugs administered orally along with its limitations

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Total No. of Questions : 4]

SEAT No. :

P5482

[Total No. of Pages : 1

[5553]-226

M.Pharmacy

CLINICAL IMMUNOLOGY AND ENZYMOLOGY

(Semester - I & II) (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 in detail techniques of immobilisation of enzymes and their application in industry. **[10]**

Q2) Solve any three

a) Explain different types of immunity. **[5]**

b) What are monoclonal antibodies? How are they being prepared? **[5]**

c) Write the applications of immunotherapy in pharmaceutical research. **[5]**

d) Explain mechanism and prevention of graft rejection reaction. **[5]**

Q3) Short Notes (any three)

a) Immunodeficiency **[5]**

b) Therapeutic applications of enzymes **[5]**

c) Lymphoproliferative disorders **[5]**

d) Adaptive immunity **[5]**

Q4) Discuss in detail on delayed hypersensitivity reactions. **[10]**

OR

Explain mechanism of autoimmune diseases and add note on diagnostic values of autoantibodies.

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Total No. of Questions : 4]

SEAT No. :

P5483

[Total No. of Pages : 1

[5553]-227
M.Pharmacy
INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT
(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) How is optimization applied in pharmaceutical industry? Describe and classify the different optimization methods with suitable examples. **[10]**

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

a) What do you understand by material handling for various pharmaceutical products?

b) Explain Drugs and Cosmetics Act- requirement related to manufacture of drugs.

c) Elaborate on total quality management and productivity.

d) Explain in detail vendor development capacity assessment of inventory management.

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

a) Simplex and Lagrangian models

b) Safety monitoring and preventive system for industrial hazards due to chemicals and pharmaceuticals.

c) Plant site selection and organization for a pharmaceutical industry

d) Quality assurance and GMP considerations

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

OR

What are the typical models of automation for solid and liquid manufacturing?

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Total No. of Questions : 4]

SEAT No. :

P5484

[Total No. of Pages : 1

[5553]-228
M. Pharmacy (Semester - I & II)
FERMENTATION TECHNOLOGY (Elective)
(2013 Pattern)

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 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 continuous bioreactor.
c) Write the importance of optimization of fermentation media.
d) Explain different factors affecting microbial growth and metabolism.

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

a) Food ingredients prepared by fermentation.
b) Production of biopesticides.
c) Michaelis-Menten kinetics.
d) Amylase.

Q4) What is immobilization? Write the applications of immobilization of enzymes and cells. **[10]**

OR

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

Total No. of Questions : 4]

SEAT No. :

P5485

[Total No. of Pages : 1

[5553]-229
M. Pharmacy (Semester - I & II)
PROJECT MANAGEMENT
(2013 Pattern) (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) Give importance of project management. Explain role of project manager and customer in the project management. **[10]**

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

a) How will you develop the project management?
b) Focus on managing the performance.
c) Explain about managing the conflicts.
d) Justify - communicating effectively in project management.

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

a) Closing the project.
b) Reporting on the project objectives.
c) Managing the risk in project management.
d) Controlling the change in the project.

Q4) Explain the project planning process. **[10]**

OR

Describe in detail about pre-planning for project management.

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Total No. of Questions : 4]

SEAT No. :

P5486

[Total No. of Pages : 1

[5553]-230
M. Pharmacy (Semester - I & II)
PHARMACEUTICAL ADMINISTRATION
(2013 Pattern) (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) Discuss in brief criteria for selection of training method. **[10]**

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

a) Explain different types of policies.
b) Write importance of rationality in decision making.
c) Explain steps involve in selection procedure.
d) Define objectives and discuss characteristics of objectives.

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

a) Break even analysis
b) Departmentalisation.
c) Critical control prompts and standards.
d) Production problem and measurement.

Q4) "Planning is an essential management function" Elucidate. **[10]**

OR

Discuss in brief old control techniques.

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