Total No. of Questions : 4]

SEAT No. :

P3629

[Total No. of Pages : 1

[5146] - 101
M.Pharmacy
Advanced Analytical Techniques
(2013 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Give an account of theory, instrumentation and applications of NMR spectroscopy. **[10]**

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

a) Discuss fragmentation patterns in mass spectroscopy.
b) Write about Nuclear Overhauser effect
c) Describe the factors affecting IR vibration frequencies.
d) Differential Scanning Calorimetry.

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

a) GC—MS technique
b) Applications of Thermo Gravimetric Analysis
c) Scanning electron microscopy
d) Supercritical fluid chromatography

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

Mol wt =69

UV = No λ max above 200 μm

IR = 2941 cm^{-1}, 2273 cm^{-1}, 460 cm^{-1}

NMR = δ 2.72 (septet, 4.28 sq, J=6.7), δ 1.33 (doublet, 25.8 sq. J=6.7)

OR

Write about basic principles, instrumentation and applications of UV spectroscopy. **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3630

[Total No. of Pages : 1

[5146] - 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.***

Q1) What is the objective of research? Describe patent oriented research. **[10]**

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

a) Explain the Chi square test (X^2)

b) Give an account of sources for survey of literature

c) Describe various grants scheme of AICTE and UGC.

d) Describe in detail cost analysis of research project.

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

a) Experimental design

b) Descriptive data analysis (DTA)

c) Techniques of documentation.

d) ANOVA

Q4) Give an account of sources for survey of literature **[10]**

OR

What is documentation? Give importance and types of documentation.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3631

[Total No. of Pages : 1

[5146] - 103
M.Pharmacy
Advanced Pharmaceutics - I
(2013 Pattern) (Semester - I) (Credit System)

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

Instructions to the candidates:

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

Q1) Define preformulation. Discuss the solid state characterization in preformulation studies. **[10]**

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

a) Explain quality control tests of tablets

b) Evaluation of microspheres

c) Directly compressible vehicles

d) Solubility & pKa

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

a) Thermal characterization of polymers

b) Different methods of optimization with suitable examples

c) Concept & objectives of stability of pharmaceuticals

d) Air suspension technique of microencapsulation

Q4) What is need of dissolution testing? Explain in detail the different dissolution models. **[10]**

OR

Discuss validation of pharmaceutical process with one case study.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3632

[Total No. of Pages : 1

[5146] - 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 diagram wherever necessary***

Q1) What is resolution of recemic mixture? Discuss the methods for resolution of recemic mixtures **[10]**

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

a) Explain importance of environment protection in synthetic chemistry

b) Explain Allylic Bromination

c) Explain Biginelli Reaction

d) Explain Sterospecificity and Steroselectivity with suitable examples

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

a) Green Chemistry and its Applications

b) Pinacol-Pinacolone rearrangement

c) Hydrogenation

d) Use of diazomethane and peracids in synthesis

Q4) What is synthone approach of designing drug synthesis. Develop synthetic route for Ibuprofen or Terfenadine using synthone approach. **[10]**

OR

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

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3633

[Total No. of Pages : 1

[5146] - 105
M.Pharmacy
Advanced Pharmacology - I
(2013 Pattern) (Semester - I)

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 labeled diagrams wherever necessary.***

Q1) What is importance of preclinical screening? Add a note on its disadvantages. **[10]**

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

a) How will you screen diesretic activity of any agent using invivo model?

b) Describe biassay of insulin.

c) Enlist various toxicity studies; and describe any one.

d) Explain various uses of animal cell lines.

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

a) Array technology

b) Knockout animals

c) Proforma-B

d) Invitro evaluation of antioxidants

Q4) Enlist various guidelines available for care and handling of animals. Explain any one guideline. **[10]**

OR

Discuss invitro and invivo evaluation of anti ulcer agent.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. : ____

P3634

[Total No. of Pages : 1

[5146] - 106
M.Pharmacy
Advanced Pharmacognosy
(2013 Pattern) (Semester - I) (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 biosynthesis of benzoic acid from C_6C_3 compounds. **[10]**

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

a) Explain in detail cyclization through diels-Alder reaction.

b) Explain in detail role of allelopathic and phytoanticipin compounds.

c) Explain limitations of ethnobotanical approach to drug discovery.

d) Explain in detail sample preparation in HTS.

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

a) Structural modification of Anthraquinones.

b) Biosynthesis of Isoflavonoids.

c) Taxol

d) Herbal creams

Q4) Elaborate a detail account for biosynthetic pathway for phenylpropenes with suitable example. **[10]**

OR

Explain the properties of natural products which makes them suitable in new drug discovery. **[10]**

✦✦✦✦

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

P3635 **[Total No. of Pages : 1**

[5146] - 107
M.Pharmacy
Advanced Quality Assurance Techniques
(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) Define Good Manufacturing Practices (GMP). Discuss the regulatory guidelines about GMP. **[10]**

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

a) Discuss the regulatory guidelines related to personnel qualification and training.

b) Enlist the documents related to Materials Management in pharmaceutical industry. Elaborate the Standard Operating Procedure (SOP) on receipt and storage of raw materials.

c) Discuss the outsourcing of analytical operations.

d) Describe the importance and contents of Standard Operating Procedure (SOP).

Q3) Answer any three of following. **[15]**

a) Comment on the designing of the water and steam system for manufacturing of sterile products.

b) Discuss the significance ofCorrective Action Preventive Action (CAPA)

c) Classify the reference standards. Explain any one technique used for characterization of reference standards.

d) Discuss the components of Quality Management System.

Q4) Discuss the measures for controlling mix-ups and cross contamination during pharmaceutical manufacturing. **[10]**

OR

Define “Change Control”. Explain and design a document for Change Control.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3636

[Total No. of Pages : 1

[5146] - 201
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) ***Black figures to the right indicate full marks.***

Q1) Explain provisions in Indian patent Act 1970, also write the procedure for patent application. **[10]**

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

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

b) Explain the different sections of NDA.

c) Write case study of Haldi plant under intellectual property rights and patent.

d) Explain the water system in pharmaceutical plant.

e) Explain the trademark filing procedure

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

a) Patent System in Europe

b) Loan license manufacturing

c) GATT

d) Provisions in schedule M and Y.

e) CTD and eCTD

Q4) Explain the WHO guidelines related to premises, sanitation & hygiene in pharmaceutical plant. **[10]**

OR

Explain the guidelines of GMP audit inspection.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. : ____

P3637

[Total No. of Pages : 1

[5146] - 202
M.Pharmacy
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 well labeled diagrams wherever necessary.***

Q1) Discuss in detail regulatory perspective of selection and evaluation of Pharmaceutical packaging materials for Novel drug delivery Systems **[10]**

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

a) ICH Q8 (R2) Guidelines for pharmaceutical development.

b) Pharmaceutical aspects of solubilisation in nonaqueous systems.

c) Concept of Quality by Design

d) Mouth dissolving formulation

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

a) Specialized dose dispensers in veterinary dosage forms

b) Quality assurance for aerosol

c) Semisolids based on Liposome

d) Metered Dose Inhalers

Q4) Explain in detail Self Micro Emulsified Drug Delivery Systems **[10]**

OR

Discuss in detail on Nutraceuticals.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3639

[Total No. of Pages : 1

[5146] - 204

M.Pharmacy (Pharmaceutical Chemistry)

Advanced Medicinal Chemistry

(2013 Pattern) (Semester - II) (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) Classify steroids with suitable example. Discuss SAR of anti inflammatory steroids. **[10]**

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

a) Discuss antiamoebic agents.

b) Comment on antihistaminics.

c) Explain HMG-CoA reductase inhibitors.

d) Write synthetic scheme and reaction mechanism for synthesis of risperidone.

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

a) Biomolecules.

b) Solid support synthesis.

c) Microbial conversion of steroids.

d) Cardiotonic agents.

Q4) Give details of drugs used in neurodegenerative disorders. **[10]**

OR

Give details of opiodal receptors its agonists and antagonists **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3640

[Total No. of Pages : 1

[5146] - 205
M.Pharmacy
(Pharmaceutical Chemistry)
Drug Design
(2013 Pattern) (Credit System) (Semester - II)

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

Instructions to the candidates:

1) ***Attempt all the questions. Internal choices are given.***
2) ***Figures to the right indicate full marks.***

Q1) Explain in detail the applicaiton of prodrug concept to overcome pharmacokinetic barriers in drug design. **[10]**

Q2) Explain, with suitable examples, the appropriate physicochemical parameters that influence drug design in following points (Any three) **[15]**

a) Influence on drug absorption

b) Influence on distribution

c) Influence on metabolism

d) Influence on Excretion.

Q3) Give detail account of importance of studying OSAR in drug design. Illustrate the phenomenon of toplis tree and cluster analysis. **[10]**

Q4) Explain the following (Any Three) **[15]**

a) Explain drug design of NSAID

b) Drug design based on enzyme inhibition

c) Analog approach of drug design

d) Explain the utility of study of metabolic reactions in drug design. Add a note on development of benzodiazepine class of drugs based on metabolic studies.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3641

[Total No. of Pages : 1

[5146] - 206
M.Pharmacy (Semester - II)
Clinical Pharmacology
(2013 Pattern)

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

Instructions to the candidates:

1) ***Figure to the right indicates full marks.***
2) ***Draw well labeled diagrams wherever necessary.***

Q1) Explain clinical practice guidelines and management of hyperlipidemia. **[10]**

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

a) Describe the role of nitrates in angina pectoris

b) Give an account of different types of adverse drug reactions

c) Explain the pharmacology of antiasthmatic agents

d) Write about rational use of antibiotics

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

a) Post transplantation drug dose adjustment in renal failure

b) Chronic obstructive pulmonary diseases

c) Digitalis glycosides

d) Reverse transcriptase inhibitors

Q4) Define clinical pharmacology. Describe phases of clinical trials. Add a note on informed consent. **[10]**

OR

Classify antihypertensive drugs. Explain the pharmacology of vasodilators.**[10]**

✦ ✦ ✦ ✦

Total No. of Questions : 4]

SEAT No. :

P3642

[Total No. of Pages : 1

[5146] - 207

M.Pharmacy (Spl. Pharmacology)

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 lebeled diagrams wherever necessary.***

Q1) Define Immunopharmacology and explain cellular cytotoxicity. **[10]**

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

a) Explain the therapeutic applications of antioxidants.

b) Discuss the recent advances in drugs acting on cholinergic receptors.

c) What are monoclonal antibodies? Explain their clinical significance.

d) Write a note on Neuropeptide modulators.

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

a) Phophodiesterase enzyme.

b) Atrial natriuretic peptide.

c) Cytokines

d) Sodium channel and it's modulators.

Q4) Discuss the implications of Human Genome Mapping in Drug research. **[10]**

OR

Define and classify receptors. Explain the cellular signaling systems. **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3643

[Total No. of Pages : 1

[5146] - 208

M.Pharmacy (Semester - II)

Phytochemistry and Phytopharmaceuticals

(2013 Pattern) (Theory)

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

Instructions to the candidates:

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

Q1) Explain the conventional methods used in the standardization of herbal drugs with their limitations. Add a note on new approaches in standardization of herbal drugs. **[10]**

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

a) Write a note on supercritical fluid extraction with its applications.

b) Discuss the role of HPLC in separation and standardization of phytoconstituents.

c) Enlist various methods of extraction of essential oils with special note on enfluerage method

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

Q3) Solve (Any three) **[15]**

a) Give structural elucidation of Ergometrine.

b) Comment on Quantitative analysis of andrographolide in Andrographis paniculata by HPTLC

c) Discuss the screening of anti-diabetic 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 invivo and invitro screening methods of anti-inflammatory drugs with suitable examples.

b) Discuss the parameters for selecting appropriate extraction method. Add a note on steps in extraction process.

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3644

[Total No. of Pages : 1

[5146] - 209

M.Pharmacy

Industrial Pharmacognosy

(2013 Pattern) (Semester - II) (Credit System)

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

Instructions to the candidates:

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

Q1) Enumerate briefly the WHO guidelines on safety monitoring of herbal drugs in pharmacovigillance systems. **[10]**

Q2) Describe the comprehensive account on commercialization worldwide and domestic trade of natural products in India. **[10]**

Q3) Explain the patent law and its recent amendments as applicable to herbal products. **[10]**

OR

Elaborate the worldwide regulatory status for the regulation of herbal drugs **[10]**

Q4) Write notes on- (Any four) **[20]**

a) Stabilization & Stability testing of herbal formulation

b) GMP for Indian System of Medicine

c) Bottlenecks of plant Based drug industry

d) Quality by Design (QBD)

e) Herbal drug toxicity

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3645

[Total No. of Pages : 1

[5146] - 210

M.Pharmacy (Semester - II)

Pharmaceutical Validation

(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.***
3) ***Draw well labelled diagrams wherever necessary.***

Q1) Expain in detail HVAC system validation **[10]**

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

a) Describe sampling techniques in cleaning validation

b) Explain the concept of URS

c) Give an account of different water treatment systems

d) Justify process validation as a quality assurance tool

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

a) Equipment qualification of tablet compression machine

b) Validation of compressed air

c) Validation of dry heat sterilization tunnel

d) Explain the concept of design qualification

Q4) Discuss framework for Computer Systems Validation. **[10]**

OR

Explain principles of Analytical Method Validation

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3646

[Total No. of Pages : 1

[5146] - 211
M.Pharmacy
Quality Planning and Analysis
(2013 Pattern) (Credit System) (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 labelled diagrams wherever necessary.***

Q1) Explain features of automated manufacturing. **[10]**

Q2) Answer Any three **[15]**

a) What can be the techniques used to overcome resistance to change?

b) What is universal sequence of steps in control process?

c) What is the importance of providing evidence of management leadership in quality?

d) What are the principles to identify quality control subjects?

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

a) Advantage of decreased process variability.

b) Conformance for specification and fitness for use

c) Double sampling plan

d) Concept of quality assurance

Q4) Discuss in detail, 'effect of measurement error on acceptance decision. **[10]**

OR

Discuss the construction of operating characteristic curve **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3647

[Total No. of Pages : 1

[5146] - 212

M.Pharmacy (Semester - I & II)

Quality Control & Assurance of Pharmaceuticals

(2013 Pattern) (Credit System) (Elective) (Theory)

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

Instructions to the candidates:

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

Q1) Discuss GMP aspects of sterile products. **[10]**

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

a) Define SOP? Give its significance

b) Describe sources of contamination & their control.

c) Components of QA

d) Types of pharmaceutical plant audits

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

a) Cleaning validation

b) Quality culture

c) Specifications

d) DMF

Q4) Explain the concept of material management. **[10]**

OR

Define validation. Explain validation of pharmaceutical HVAC system. **[10]**

✦ ✦ ✦ ✦

Total No. of Questions : 4]

SEAT No. :

P3648

[Total No. of Pages : 1

[5146] - 213
M.Pharmacy
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 labelled diagrams wherever necessary.***

Q1) Discuss the design, layout and operational facilities for sterile powder ready for reconstitution. **[10]**

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

a) Design, layout and operational facilities for Tablet

b) Designing of Administrative block and training centre

c) Design of water stream as Pharmaceutical plant utility services

d) Designing of plant support services

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

a) Design of Q.C. Laboratory

b) Design, layout and operational facilities for Dry Syrup

c) Design of Compressed air and other gases as Pharmaceutical plant utility services

d) Design, layout and operational facilities for Capsule

Q4) Discuss in detail revised schedule M and Factory Act **[10]**

OR

Discuss in detail Design of effluent treatment plant **[10]**

✦✦✦✦

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

P3649 **[Total No. of Pages : 1**

[5146] - 214
M.Pharmacy
Biopharmaceutics and Pharmacokinetics
(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) 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 **[15]**

a) Describe various techniques for developing a correlation between in vivo and in vitro data.

b) Explain absolute and relative bioavailability. Discuss the trapezoidal rule to determine area under the curve.

c) Describe the salient features of various pharmacokinetic models? Enlist various pharmacokinetic parameters that can be determined by these models?

d) How can dosage forms be designed for transportation through placental barrier?

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

a) Factors affecting distribution of drugs

b) Protein binding

c) In vitro and in vivo models for prediction of absorption and permeability.

d) Causes and detection of non-linearity in pharmacokinetics

Q4) What is dose dependent pharmacokinetics? Describe any one method to determine V_{max} and km. **[10]**

OR

How can urinary excretion data be used to calculate elimination rate constant(K)? Describe any one equation to calculate K. **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3650

[Total No. of Pages : 1

[5146] - 215
M.Pharmacy
Sterile Products Formulation & Technology
(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.***

Q1) Explain physiological and formulation parameters in designing of LVP's. **[10]**

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

a) Explain in brief formulation and manufacturing considerations in ophthalmic suspensions.

b) Explain in brief formulation of Liposomes.

c) Describe the sterile plastic devices with their materials.

d) Give the layout of parenteral facility

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

a) Glass containers as a packaging material.

b) Total Parenteral nutrition

c) BFS technology.

d) Dried forms of SVP's

Q4) Describe process, selection and specification of sterilization method for parenterals **[10]**

OR

Explain the preformulation studies of proteins and peptides for parenteral dosage forms. **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3651

[Total No. of Pages : 1

[5146] - 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 number one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

Q1) Discuss in detail technology involved in manufacturing of pharmaceuticals. **[10]**

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

a) Write about various chromatographic techniques used in the manufacturing process of API.

b) Discuss about alkylation reaction process in the manufacturing

c) Give an account of Industrial noise and noise measuring instruments.

d) Write about Foot and leg protection law.

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

a) Intermediates in API synthesis

b) Oxidation and reduction process in manufacturing.

c) Biochemical process in synthesis

d) Eye protection equipments.

Q4) Describe in detail manufacturing process of following drugs with process and instrumentation diagram (any two) **[10]**

i) Sulphamethaoxazole

ii) Adrenaline

iii Ciprofoxacin

OR

Explain in detail about health hazards giving emphasis on bioethics and biosafety. **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. : ____

P3652

[Total No. of Pages : 1

[5146] - 217
M.Pharmacy
Chemistry of Medicinal Natural Products
(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 labelled diagrams wherever necessary.***

Q1) Explain general metabolic pathways for secondary metabolites in plants. **[10]**

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

a) Write physical and chemical properties of purine Alkaloids.

b) Write significance of secondary metabolites in plants.

c) Give methods of isolation of maize and potato starch

d) Give method for isolation of Euginol from Clove buds.

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

a) Methods of extraction of glycosides.

b) Physicochemical properties of steroids.

c) Monosaccharides and disaccharides.

d) Analytical evaluation of Solasodine.

Q4) Highlight on spectral data to prove structure of Ephidrin. **[10]**

OR

Explain role of Flavonoids in plants and their uses in animals with examples **[10]**

✦✦✦✦

Total No. of Questions : 4]

SEAT No. :

P3653

[Total No. of Pages : 1

[5146] - 218

M.Pharmacy (Semester - I)

Traditional System of Medicine and Ayurvedic Formulations (2008 & 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) 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 Churna

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) Panchakarma

b) Bhasmas

c) Ghruta

d) Taila

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

OR

Explain the importance of Physical and Chemical and microscopical methods standardization of Ayurvedic dosage forms **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3655

[Total No. of Pages : 1

[5146] - 220
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) Explain the use and importance of Land, Labour and machine for farming. **[10]**

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

a) Discuss about agricultural marketing.

b) Explain the quality control of prioritize medicinal species.

c) Discuss the trading of Nutraceuticals.

d) Discuss various schemes for medicinal plant cultivation.

Q3) Write Short Notes on. (any three) **[15]**

a) Patenting of herbal products.

b) Trading of phytoconstituents.

c) cooperation between collectors and growers.

d) Research in farm management.

Q4) Write on the establishment of an extraction unit. **[10]**

OR

Discuss about import and export of herbal cosmetics. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3656

[Total No. of Pages : 1

[5146] - 221
M.Pharmacy
Quality Assurance Techniques in Herbal Products
(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 lebeled diagrams wherever necessary.***

Q1) Explain different components of Quality Assurance. Write GMP Requirements for herbal medicinal products. **[10]**

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

a) Elaborate Stability guidelines for studies related to herbal extracts

b) Enlist types of packages. Write note on quality evaluation of packages.

c) Write significance and discuss components of equipment qualifications.

d) Write note on compendial methods for evaluation of crude drug.

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

a) Cleaning validation

b) Pharmacovigilance for herbal products

c) Analytical methods development guidelines for herbal extracts

d) Outsourcing

Q4) Elaborate Quality control and standardization of medicinal plant and plant based products. **[10]**

OR

Enlist various important facilities and discuss their relevance in building construction to provide suitable atmosphere for herbal product manufacturing. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3657

[Total No. of Pages : 1

[5146] - 222
M.Pharmacy
Toxicology
(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 lebeled diagrams whenever necessary.***

Q1) Explain the single dose and repeat dose toxicity studies as per OECD guidelines. **[10]**

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

a) Define tachyphylaxis, idiosyncrasy, habituation, tolerance and antagonism.

b) Explain the methods for allergenicity testing

c) Draw a flow chart for development of preclinical toxicity.

d) Write in details about toxic agents.

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

a) Management of toxicity reactions in human.

b) Management of Mutagenicity.

c) Cell culture techniques.

d) Safety analysis in preclinical toxicology.

Q4) Explain about preclinical toxicological requirements for biological products. **[10]**

OR

Discuss in detail the study design and management of reproduction toxicity. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3658

[Total No. of Pages : 1

[5146] - 223
M.Pharmacy
Safety Pharmacology
(2013 Pattern) (Semester - I) (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) Define pharmacovigilance. Explain in detail the process for collection and reporting of pharmacovigilance data. **[10]**

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

a) Write the study design for repeat dose toxicity.

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

c) Write in detail about principle of safety evaluation of drug.

d) Explain the various tests to conduct ocular toxicity studies.

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

a) Scope and importance of safety pharmacology

b) Safety assessment of dermatological products.

c) Product safety update reports

d) Analysis of safety Pharmacological data

Q4) Define mutagenicity and discuss in detail the tests for chromosomal abrasion. **[10]**

OR

Explain the regulatory requirements of ICH for the new drug safety Assessment. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3659

[Total No. of Pages : 1

[5146] - 224
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) ***Figure to right indicate full marks.***
3) ***Draw well labeled diagram wherever necessary.***

Q1) Define clinical trials. Explain in brief about different phases of clinical trials. **[10]**

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

a) Explain the ethical principles of nuremberg code.

b) Write the special issues in therapeutic drug monitoring.

c) Discuss the criteria for investigator selection.

d) Write the contents of-investigator brochure.

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

a) Inclusion and exclusion criteria

b) Principles of ICH-GCP guidelines

c) Role and responsibilities of CRO

d) Randamization and blinded study.

Q4) Define institutional review board(IRB). Explain in brief the objectives, composition, responsibilities and process of IRB. **[10]**

OR

Discuss in brief the various elements in design of clinical trials.

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Total No. of Questions : 4]

SEAT No. : ____

P3660

[Total No. of Pages : 1

[5146] - 225
M.Pharmacy
Clinical Pharmacokinetics and Pharmacodynamics
(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 lebeled diagrams wherever necessary.***

Q1) Discuss the kinetics following one compartment given as intravenous bolus dose of a drug. **[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 hepatic failure.

d) Explain the Blood Brain Barrier.

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

a) Kinetics of drug protein binding

b) Therapeutic window

c) Area Under Curve

d) Factors affecting bioavailability of drug from dosage form.

Q4) What is non linearity in kinetics? How is it detected? Explain the methods for determination of Vmax and Km **[10]**

OR

Write a exhaustive note on Clearance of drug. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3666

[Total No. of Pages : 1

[5146] - 226
M.Pharmacy
Clinical Immunology and Enzymology
(2013 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Give a detail account on monoclonal antibodies. Elaborate their applications in diagnosis and immunotherapy. **[10]**

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

a) Give a detail account on adaptive immunity.

b) Describe the tumor immunotherapy

c) What is hybridoma? Explain its applications in immunology

d) Define immunity. Elaborate on its different types.

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

a) Congenital immunodeficiency

b) Anaphylactic reaction

c) Fusion method of Hybridoma

d) Enzyme kinetics

Q4) What is graft rejection? Enlist its different types and describe in detail the mechanism of graft rejection. **[10]**

OR

What are the changes occurs in tumor cell surface? Describe immune responses occurring against tumor cell. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3661

[Total No. of Pages : 1

[5146] - 227
M.Pharmacy
Industrial Pharmacy and Production Management
(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) Explain in detail pilot plant scale-up and design for tablet and liquid oral preparations. **[10]**

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

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

b) Explain about the effluent testing and treatment for pharmaceutical industry.

c) Describe in detail the methods for monitoring and preventing system for industrial hazards due to accidents and mechanical equipment.

d) Explain the basic requirement for design of product and facility for parenterals.

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

a) Total quality management and productivity

b) Statistical design and applied optimization methods

c) Vendor development capacity assessment of inventory management.

d) Automation in pharmaceutical industry

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

OR

Describe the plant site selection, layout and organization of pharmaceutical industries. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3662

[Total No. of Pages : 1

[5146] - 228
M.Pharmacy
Fermentation Technology
(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) ***Neat diagrams must be drawn vherever necessary.***

Q1) What is strain improvement? Explain different techniques used for strain improvement. **[10]**

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

a) How will you screen microbial cultures from soil for production of antibiotics.

b) Write the applications of protease in food processing.

c) Explain different food components prepared by the process of fermentation.

d) Write the importance of immobilized enzymes.

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

a) Fed-batch biorector.

b) Microbial growth kinetics

c) Production of biopesticides

d) Secondary metabolites

Q4) What is recombinant protein? Explain the method of preparation of any one recombinant protein. **[10]**

OR

Explain in detail process monitoring and control parameters used in biorectors. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3663

[Total No. of Pages : 1

[5146] - 229
M.Pharmacy (Elective)
Project Management
(2013 Pattern) (Semester - I & II)

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

Instructions to the candidates:

All question are compulsory.

Q1) Explain 'Project life cycle' with reference to a typical pharmaceutical project with special emphasis on role of project manager. **[10]**

Q2) Explain the factors related to project management (Any Three) **[15]**

a) Activities considered for strategic management process.

b) Network plan of a project.

c) Risk management by a project manager.

d) Ethics and Building trust in project management

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

a) Loose ends and logic errors

b) Assessing Resources allocation

c) Project time reduction process

d) Outsourcing Advantages & limitations

Q4) Explain the concept of project constraints with special reference to technical & physical constraints involved in project management. **[10]**

OR

Explain the concept of team development with special emphasis on important stages of development of team building for a project. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3664

[Total No. of Pages : 1

[5146] - 230
M.Pharmacy
PHARMACEUTICAL ADMINISTRATION
(2013 Pattern) (Semester - I & II)

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

Instructions to the candidates:

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

Q1) Define staffing. Give system approach to human resource management and on overview of staffing function. Explain performance appraisal as a staffing function. **[10]**

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

a) Structure and process of organizing.
b) Requirements for effective control.
c) Explain the process of decision making.
d) Describe the function of management.
e) Focus on control of overall performance.

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

a) Concept of MBO.
b) Management social responsibility and ethics.
c) What is leading?
d) Managerial planning process
e) Process of Communication

Q4) How the management and administration is different? Explain about pharmaceutical administration. **[10]**

OR

Effective and positive organisation culture is important in the bussiness, justify. How will you justify the controlling is valuable in the organisation **[10]**

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Total No. of Questions : 4]

SEAT No. : [ ]

P3665

[Total No. of Pages : 1

[5146] - 231
M.Pharmacy
Cosmeticology
(Semester - I & II) (2013 Pattern) (Elective)

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) Discuss composition of Nail and give detailed account of different cosmetics for nails and its evaluation **[10]**

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

a) Discuss regulatory requirements for cosmetic products,

b) Discuss ideal properties and surfactants used in shampoos?

c) Discuss factors affecting SPF of sunscreens.

d) Discuss various components of nail lacquer and importance of ratio of solvent to diluents.

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

a) Evaluation of shampoos.

b) Packaging of cosmetics

c) Preservatives used in skin preparation

d) Antiperspirants and deodorants

Q4) Describe clinical testing protocol for shampoo products. **[10]**

OR

What are components of sunrays responsible for skin damage? Describe formulation and Evaluation parameters for sunscreens **[10]**

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