Total No. of Questions : 4]

SEAT No. : ____

P4009

[Total No. of Pages : 1

[5453]-101
M.Pharmacy
ADVANCED ANALYTICAL TECHNIQUES
(2013 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Explain theory, instrumentation and applications of differential thermal analysis. **[10]**

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

a) Compare proton NMR with C-13 NMR.
b) Explain two sample injection systems in HPLC.
c) Discuss rules for calculation of λmax in UV.
d) Discuss columns used in Gas chromatography.

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

a) Coupling constant in NMR.
b) Attenuated Total Reflectance
c) Golay cell
d) Fragmentation pattern for aldehydes and alkyl benzenes

Q4) a) Enumerate various methods of estimation of two drugs in a mixture by UV spectroscopy. Elaborate any two methods. **[10]**

OR

b) Elucidate the structure of compound from the following data. An organic compound with molecular mass 112 gave the following spectral information :

i) The compound is transparent in the UV spectrum.
ii) IR : The medium bands formed are :
2941 cm^{-1} and 1464 cm^{-1}
iii) NMR : Singlet at 8.48τ

Total No. of Questions : 4]

SEAT No. :

P4010

[Total No. of Pages : 1

[5453]-102
M. Pharmacy (Semester - I)
RESEARCH METHODOLOGY
(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) Explain basic principle and different types of experimental design. Add a note on "Factorial Design". **[10]**

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

a) Explain objectives and types of research.

b) Describe about instructions to authors for IJPS journal.

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

d) Give the statistical significance of coefficient of correlation.

Q3) Write short notes on (ANY THREE) : **[15]**

a) Sources of procurement of research grants.

b) Continuous variables and discrete variables

c) Chi square (χ^2) test

d) Thesis writing

Q4) Explain techniques and importance of documentation. Add a note on "Uses of computer packages in documentation". **[10]**

OR

Describe in detail cost analysis of the project with reference to cost incurred on raw materials, procedure, instrumentations and clinical trials.

Total No. of Questions : 4]

SEAT No. :

P4011

[Total No. of Pages : 1

[5453]-103
M. Pharmacy (Semester - I)
ADVANCED PHARMACEUTICS - I
(2013 Pattern)

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 indicate full marks.***

Q1) Explain various methods of microencapsulation. How are microcapsules evaluated? **[10]**

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

a) Discuss briefly the application and importance of DSC and XRD in preformulation studies.

b) Classify polymers and describe Biodegradable polymers.

c) Explain various degradation pathways that Active pharmaceutical ingredients undergo.

d) Describe Ion exchange resins.

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

a) Statistical Quality Control

b) Model independent method for dissolution

c) Importance of molecular weight and rheology of polymers

d) Accelerated stability studies and shelf life

Q4) Describe briefly the role of optimization studies in formulation Development. Explain in detail the Simplex method of optimization. **[10]**

OR

Define excipients. Explain the following with respect to excipients :

a) Cyclodextrins as novel Excipients

b) Co-processed excipients

Total No. of Questions : 4]

SEAT No. :

P4012

[Total No. of Pages : 1

[5453]-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) Use of Green chemistry procedures can solve many environmental pollution related issues. Justify the statement giving suitable examples. **[10]**

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

a) Discuss any two rearrangements in details that involve carbon to nitrogen migration.

b) What is Sharpless oxidation? Discuss the applications with suitable eaxmples.

c) Discuss the rules of disconnection in synthon approach with 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) wagner-Meerwein rearrangement.

c) Resolution of racemic mixtures.

d) Transforms in synthon approach.

Q4) Discuss in detail any three methods used for reducing organic compounds with special emphasis on selectivity, stereochemistry etc. **[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. :

P4013

[Total No. of Pages : 1

[5453]-105
M. Pharmacy
ADVANCED PHARMACOLOGY
Preclinical Evaluation of Drugs
(2013 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Define Inflammation. Explain in brief *in vivo* methods for screeing of acute, subacute and chronic inflammation. **[10]**

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

a) Write the composition and functions of IAEC.

b) Explain the screening methods for ant-anxiety drugs.

c) Write *in vitro* methods for the screening of antioxidants.

d) Explain the screening methods for antihistaminics.

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

a) Proforma-B for animal experimentation as per CPCSEA guidelines.

b) *In vivo* screening methods for muscle coordination.

c) Stem cell research and its application.

d) Transgenic and Knockout animals in research.

Q4) Discuss in brief the preclinical screening methods for antihpyertensive drugs. **[10]**

OR

Defien depression. Write in details the preclinical screening methods for antidepressant drugs.

Total No. of Questions : 4]

SEAT No. :

P4014

[Total No. of Pages : 1

[5453]-106
M. Pharmacy (Semester - I)
ADVANCED PHARMACOGNOSY - I
(2013 Pattern)

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) Explain the construction mechanism of secondary metabolites. **[10]**

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

a) Needs and types of defenses in autotrophs.

b) Explain Ephedrine.

c) Explain HTS.

d) Explain types of Herbal formulations

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

a) Explain Sample preparations.

b) Dereplication.

c) Selection strategies for HTS.

d) Explain Vasicine.

Q4) Explain the process of identification of plants for targeted sets. **[10]**

OR

Explain Dereplication and isolation of bioactive compounds.

Total No. of Questions : 4]

SEAT No. :

P4015

[Total No. of Pages : 1

[5453]-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) Define Quality Assurance, describe the functions and responsibilities of Quality Assurance in Pharmaceutical Industry. **[10]**

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

a) Elaborate the Batch Production Control Record (BPCR)

b) Elaborate various aspects of material management.

c) Explain the cGMp requirements with respect to building and premises for sterile manufacturing.

d) Explain the GMP guidelines related to Analytical Outsourcing.

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

a) Prevention of Mix-ups and Cross contamination

b) IPQC

c) HVAC system

d) Site master plan

Q4) Elaborate 'CAPA-Emerging concept in QA of drugs'. **[10]**

OR

Explain the principle of Quality Audit, add a note on preparations required for FDA Inspection of manufacturing site.

Total No. of Questions : 4]

SEAT No. :

P4016

[Total No. of Pages : 1

[5453]-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) What is DRA? Give the types of regulatory networks with examples. Add a note on CDSCO and its function. **[10]**

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

a) Explain in detail about Abbreviated New Drug Application.

b) Discuss about the CTD Formats of dossiers.

c) Write in detail about the responsibilities of sponsor and investigator as per schedule Y.

d) Give the details about Hatch Waxman act and orange book.

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

a) Indian GMP certification

b) Patent infringement and Doctrine of Equivalents

c) BE studies

d) Contract and loan license manufacturing

Q4) Discuss in detail about the technical sections of NDA. **[10]**

OR

Explain the development of IP law in India. Add a brief note on role of IP in Pharma industry growth.

Total No. of Questions : 4]

SEAT No. :

P4017

[Total No. of Pages : 1

[5453]-203
M. Pharmacy (Semester - II)
NOVEL DRUG DELIVERY SYSTEMS
(2013 Pattern) (Credit)

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) ***Black figures to the right indicate full marks.***

Q1) Explain in detail transdermal drug delivery systems with a special emphasis on penetration enhancers. **[10]**

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

a) Write in detail about various theories of mucoadhesion.

b) Explain various approaches used to develop colon targeted drug delivery systems.

c) Explain in detail how the drug properties influence the design and performance of sustained drug delivery systems.

d) Which are the different implantable drug delivery systems? Brief about any one of them.

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

a) Brain targeted drug delivery

b) Characterization and applications of dendrimers

c) Liposomes

d) Regulatory considerations for NDDS for regulated markets.

Q4) Elaborate on the formulations challenges for protein and peptide. **[10]**

OR

Discuss in detail ocular delivery mechanisms and development of ocular controlled release systems.

Total No. of Questions : 4]

SEAT No. :

P4018

[Total No. of Pages : 1

[5453]-204

M. Pharmacy (Pharmaceutical Chemistry)

ADVANCED MEDICINAL CHEMISTRY

(2013 Pattern) (Semester - II) (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) Classify adrenergic agents. Explain its MOA and SAR. **[10]**

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

a) Write synthetic scheme with reaction mechanism of Cetrizine.

b) Highlight chemistry and SAR of benzodiazepines.

c) Explain antiamoebic agents.

d) Comment on antimalarial aminoquinolines.

Q3) Write short notes on (ANY THREE) : **[15]**

a) Cardiotonic drugs.

b) Oral hypoglycemic agents.

c) Histamine receptors and its ligands

d) CNS stimulants

Q4) Classify steroids with suitable example. Comment on Microbial conversion of steroids. **[10]**

OR

Write detail account of biomolecules with their significance.

Total No. of Questions : 4]

SEAT No. :

P4019

[Total No. of Pages : 1

[5453]-205
M. Pharmacy
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) Justify the statement with liberal use of examples "enzyme inhibition is one of the best tools in Drug Design". **[10]**

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

a) Roles of genomics in drug design.

b) 3 Dimensional CoMFA QSAR model

c) Write a note on craig plot.

d) Drug Design based on antagonism.

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

a) Write significance of metabolic studies in drug design.

b) Significance of prodrug designing.

c) Write a short note on bioprecursor drugs.

d) Write a note on cluster analysis.

Q4) What is qsar? Explain the hansch linear model and free wilson model? Explain the methodology and applications of drug design using qsar with examples.**[10]**

OR

"Metabolomics, genomics and proteomics play significant role in drug design". Justify the statement giving sufficient number examples and discuss in details receptor based de novo design.

Total No. of Questions : 4]

SEAT No. : ____

P4020

[Total No. of Pages : 1

[5453]-206
M. Pharmacy
CLINICAL PHARMACOLOGY
(2013 Pattern) (Semester - 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 neat labelled diagrams wherever necessary.***

Q1) Explain pharmacotherapy and good clinical practices in the management of malaria. **[10]**

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

a) Describe therapeutic drug monitoring.

b) Explain management of hyperlipidemia.

c) Describe Pharmacology of Calcium channel blockers.

d) Explain pharmacotherapy of asthma.

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

a) Phases of clinical research.

b) Monoclonal antibodies.

c) Adverse drug reactions and its monitoring.

d) Antifungal drugs.

Q4) Give a detailed account on management of Rheumatoid arthritis. **[10]**

OR

Explain Pharmacotherapy of Peptic ulcer.

Total No. of Questions : 4]

SEAT No. :

P4021

[Total No. of Pages : 1

[5453]-207

M. Pharmacy (Semester - II) (Spl. Pharmacology)

MOLECULAR PHARMACOLOGY

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

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

a) Write a note on low molecular weight heparins.

b) Explain concepts of chronopharmacology with reference to drug therapy

c) Explain the role of COX-2 modulators in inflammation.

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

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

a) Sodium channel and its modulators

b) GABA receptors & modulators

c) Role of Caspases in Apoptosis

d) Glutamate receptors & modulators

Q4) What are reactive oxygen intermediates? Add a note on therapeutic implications of Antioxidants. **[10]**

OR

Discuss the implications of Human Genome Mapping in Drug Research.

Total No. of Questions : 4]

SEAT No. :

P4022

[Total No. of Pages : 1

[5453]-208
M. Pharmacy
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.*

Q1) Discuss in detail the WHO parameters used in standardization of herbal drugs. **[10]**

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

a) Write a note on flash column chromatography with its applications.

b) Write a note on microwave - assisted extraction technique.

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

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

Q3) Solve any three : **[15]**

a) Write note on sources of variation in chemical make - up of plant derived drugs.

b) Comment on Quantitative analysis of curcumin by HPTLC.

c) Discuss the screening of hepatoprotective herbal drugs.

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

Q4) Solve any One **[10]**

a) What is supercritical fluid extraction technique? Discuss its advantages over conventional techniques. Add a note on SCF extraction of Capsaicinoids.

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

Total No. of Questions : 4]

SEAT No. :

P4023

[Total No. of Pages : 1

[5453]-209
M. Pharmacy (Semester - II)
INDUSTRIAL PHARMACOGNOSY
(2013 Pattern) (Credit System)

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 question paper.***

Q1) Define Patent? Explain about Indian and International patent laws as applicable to natural products/traditional Indian drugs. **[10]**

Q2) Attempt Any Three of following **[3 × 5 = 15]**

a) Write about various factors affecting the stability of herbal formulations

b) Explain plant breeder's right with suitable examples.

c) Write about any two leading manufacturers of herbal drugs in India.

d) Explain about WHO guidelines for safety monitoring of herbal medicines.

Q3) Solve Any Three of following **[3 × 5 = 15]**

a) Write a note on Traditional Knowledge Digital Library

b) Explain about top Indian herbs/value added herbal products exported from India.

c) Write a note on industry oriented R & D institutions as applicable to herbal products.

d) Explain about various ethical issues for herbal products.

Q4) Explain in detail WHO guidelines for the production of phytomedicines **[10]**

OR

Define Pharmacovigilance? Elaborate pharmacokinetic and pharmacodynamic interactions of herbal preparations with suitable examples.

Total No. of Questions : 4]

SEAT No. :

P4024

[Total No. of Pages : 1

[5453]-210
F. Y. M. Pharmacy (Semester - II) (Theory)
PHARMACEUTICAL VALIDATION
(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 in detail about analytical method validation by FDA guideline **[10]**

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

a) Validation of Compressed air

b) Validation of HPLC

c) Give an account of different water treatment

d) write about Validation master plan

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

a) Validation of HVAC system

b) Validation of Coated tablets

c) Vendor certification

d) Discuss User Requirement Specification (U.R.S.) for dry powder mixer

Q4) Justify how process validation build Quality product. **[10]**

OR

Explain in details calibration master plan.

Total No. of Questions : 4]

SEAT No. :

P4025

[Total No. of Pages : 1

[5453]-211
M. Pharmacy (Semester - II)
QUALITY PLANNING AND ANALYSIS
(2013 Pattern) (Credit)

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 the causes of poor quality and provide remedies for improving quality **[10]**

Q2) Attempt Any Three questions from the following **[15]**

a) Discuss criteria for self inspection

b) State advantages of statistical control.

c) State the factors considered while deciding how much inspection is necessary.

d) Discuss the potential stages for conducting product audit.

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

a) Audit reporting

b) Inspection planning

c) Types of sampling plans

d) Statistical control charts-General

Q4) Explain the universal process of juran trilogy for "Managing the quality" **[10]**

OR

Comment on "Organizing for Quality in manufacturing operations"

Total No. of Questions : 4]

SEAT No. :

P4026

[Total No. of Pages : 1

[5453]-212
M. Pharmacy (Semester - I)
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) ***Draw well labeled diagrams wherever necessary.***

Q1) Describe in details various stages of equipment qualification **[10]**

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

a) Explain master validation plan used in typical pharmaceutical organization

b) Provide you view on sources of contamination and contamination control

c) Give in detail contents of SOP on SOP

d) Discuss post manufacturing materials management issues

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

a) Revalidation

b) Quality control of sterile pharmaceuticals

c) Cleaning validation

d) QA audit questionnaire for production dept.

Q4) What are the process validation methods? Describe in detail prospective process validation **[10]**

OR

Describe in detail procedures and documentation in relation to release of finished products and handling of rejected products.

Total No. of Questions : 4]

SEAT No. :

P4027

[Total No. of Pages : 1

[5453]-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 for sterile powder ready for reconstitution. **[10]**

Q2) Attempt ANY THREE from following : **[3 × 5 = 15]**

a) Write importance of effluent treatment.

b) Discuss security office, vehicle parking and scrap yards design in plant support services.

c) Explain operational facilities with services and utilities for Capsule.

d) Describe design of compressed air and other gases.

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

a) Design of effluent treatment plant

b) cGMP regulatory requirement of Pharma facilities

c) Design and operation of Q.C. Laboratory.

d) Design and operational facilities for Ointment

Q4) Discuss the design, layout and operational facilities with services and utilities for Tablet. **[10]**

OR

Enlist utility services in Pharmaceutical Industry. Explain in detail design of water and steam system.

Total No. of Questions : 4]

SEAT No. :

P4028

[Total No. of Pages : 1

[5453]-214

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

BIOPHARMACEUTICS AND PHARMACOKINETICS

(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) ***Neat diagrams must be drawn wherever necessary.***

Q1) Classify transporters. Write a note on P-glycoprotein and its importance in the GI tract and in the blood brain barrier and how their they can be modulated to alter drug pharmacokinetics. **[10]**

Q2) Answer any three: **[3 × 5 =15]**

a) What are the drug binding sites in blood? Give examples.

b) How are the vitro methods used to predict bioavailability of drugs? Give their advantages and limitations.

c) What are some in vitro methods used for assessment of metabolism. Give their advantages and limitations.

d) Explain importance of Bio-equivalence study.

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

a) Experimental dissolution methods.

b) IVIVC.

c) AUC determination by Trapezoidal Rule.

d) Compartmental Models and their advantages and limitaions.

Q4) Give Noyes-Whitney equation. Explain the effect of the various parameters on dissolution rate. **[10]**

OR

Describe various methods for estimation of number of binding sites (kinetics for protein binding)

Total No. of Questions : 04]

SEAT No. :

P4029

[Total No. of Pages : 1

[5453]-215
M.Pharmacy (Common for Semester - I&II)
STERILE PRODUCTS FORMULATION & 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.***

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 validation protocols for sterilization by heat.
b) Explain the liposomes as drug delivery system.
c) Explain the maintenance of tonicity in sterile products.
d) Explain the possible hazards associated with parenteral therapy.

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

a) Manufacturing of sterile suspensions.
b) Glass as packaging material for sterile products.
c) FFS and BFS technology.
d) Vehicles for sterile products.

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

OR

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

○○○

Total No. of Questions : 04]

SEAT No. :

P4030

[Total No. of Pages : 1

[5453]-216
M.Pharmacy (Common for Semester - I&II)
ACTIVE PHARMACEUTICAL INGREDIENTS (APIS) MANUFACTURING TECHNOLOGY
(2013 Pattern) (Credit)

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) Give an account of basic terminologies used in chemical and pharmaceutical industries. Explain biochemical process with at least two examples. **[10]**

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

a) Discuss Nitration process involved in drug synthesis.
b) Write about Flow charts & equipments in API manufacturing process.
c) Give an account of reaction kinetics in synthesis of APIs.
d) Batch manufacturing process.

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

a) Industrial centrifuges in manufacturing process.
b) Unit process & scale up techniques in synthesis.
c) Chromatographic techniques used in the manufacturing process of API.
d) Radiation hazards and its control.

Q4) a) Write an account of laws related to foot & leg protection. **[10]**

OR

b) Describe in detail manufacturing process of following drugs with process and instrumentation diagram (any two)
   i) Adrenaline
   ii) Benzocaine
   iii) Rifampicin

○○○

Total No. of Questions : 04]

SEAT No. :

P4031

[Total No. of Pages : 1

[5453]-217
M.Pharmacy (Semester - I)
CHEMISTRY OF MEDICINAL NATURAL PRODUCTS
(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) Define and classify Glycosides. Explain in detail the methods of isolation and extraction of alkaloids with suitable example. **[10]**

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

a) Give the structure elucidation of solasodine.

b) Add a brief note on chemistry and properties of Carbohydrates.

c) Explain chemistry of Atropine.

d) Write down the chemical tests for Caffeine and piperine.

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

a) Biosynthetic pathways in plants.

b) Structure elucidation of Morphine by physical methods.

c) Primary and secondary metabolites.

d) Chemical tests for solasodine and Diosgenin.

Q4) Answer any one of the following: **[10]**

a) Define Terpenoids. Give their properties and explain its chemistry.

b) Explain in detail structure elucidation of Ephedrine by chemical and physical methods.

○○○

Total No. of Questions : 04]

SEAT No. :

P4032

[Total No. of Pages : 1

[5453]-218
M.Pharmacy (Common for Semester - I)
TRADITIONAL SYSTEM OF MEDICINE AND AYURVEDIC FORMULATIONS
(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 labeled diagrams wherever necessary.***

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

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

a) Explain the preparation and evaluation methods of Vati.
b) Give an account of diagnosis and treatment of Chinese System of medicine.
c) Discuss in brief about the Ayurvedic cosmetics.
d) Explain the theory and basic concept of Unani system of medicine.

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

a) Rasa.
b) Taila.
c) Avleha.
d) Gutika.

Q4) Explain the evaluation and standardization of Ayurvedic dosage form. **[10]**

OR

Explain in detail modern drug discovery using Ethnopharmacognosy.

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Total No. of Questions : 04]

SEAT No. :

P4033

[Total No. of Pages : 1

[5453]-219
M.Pharmacy
MEDICINAL PLANT BIOTECHNOLOGY
(2013 Pattern) (Credit System) (Common for Semester - I&II) (Elective)

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

Instructions to the candidates:

1) ***Neat diagrams must be drawn wherever necessary.***
2) ***Figures to the right indicate full marks.***

Q1) What is hairy root culture? Explain process and applications of hairy root culture along with suitable examples. **[10]**

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

a) Explain somaclonal variation and its applications.
b) What are regulated stages of gene expression.
c) Compare and contrast between point mutation and spontaneous mutation.
d) Describe various steps in micropropagation.
e) Explain process of liposomes for gene transfer.

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

a) In situ conservation.
b) Edible vaccine.
c) PCR in gene mapping.
d) Isolation and purification of enzymes.
e) Techniques of Haploid culture.

Q4) What is gene mapping? Write a detail note on process and applications of molecular maps. **[10]**

OR

Compare and contrast between DNA & RNA, write a note on DNA replication.

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Total No. of Questions : 04]

SEAT No. :

P4034

[Total No. of Pages : 1

[5453]-220
M.Pharmacy (Common for Semester - I&II)
NATURAL PRODUCTS MANAGEMENT
(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) Enumerate the requirement for cultivation and quality control of prioritized medicinal plants. **[10]**

Q2) Short notes on the following (any three) **[15]**

a) Appraisal of resources in medicinal plants farming.
b) Extraction oil from Oil seeds.
c) Research in Farm Management.
d) Highlight Indian Government policies in development of medicinal plants.

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

a) Trading of Herbs.
b) IPR of Natural Medicinal product.
c) Mechanization of natural product market.
d) Management of labour and machines in medicinal plants farming.

Q4) Elaborate the interrelationship between demand and supply material in market. **[10]**

OR

Discuss the requirement for storage, transport and marketing of natural products.

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Total No. of Questions : 04]

SEAT No. :

P4035

[Total No. of Pages : 1

[5453]-221
M.Pharmacy (Common for Semester - I&II)
QUALITY ASSURANCE TECHNIQUES IN HERBAL PRODUCTS
(2013 Pattern) (Elective)

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) Explain in detail standardization of herbal products with reference to WHO and cGMP guidelines. **[10]**

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

a) Provide information on regulatory bodies like USFDA & MHRA for quality management.

b) Explain in brief quality control and standardization of Herbal cosmetics.

c) Provide information on analytical method development guidelines for isolated compounds of natural origin.

d) Explain in brief quality evaluation as applicable to packages.

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

a) Outsourcing with reference to quality management.

b) Stability issues guidelines for studies related to natural products.

c) Safety issues related to herbal products.

d) Cleaning validation.

Q4) Explain in detail EMEA guidelines for herbal products along with it's significance. **[10]**

OR

Explain in detail study of compendial methods for evaluation of crude drugs and herbal formulation.

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Total No. of Questions : 04]

SEAT No. :

P4036

[Total No. of Pages : 1

[5453]-222
M.Pharmacy (Common For Semester - I&II)
TOXICOLOGY
(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 well labeled diagrams wherever necessary.***

Q1) Explain in detail about oral repeat dose toxicity studies as per OECD guidelines. **[10]**

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

a) Explain molecular changes to Xenobiotics.

b) Explain the term Regulatory toxicology.

c) Explain in detail industrial Application of Toxicology.

d) Write in detail on the Southern Blotting Technique.

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

a) Regulatory Toxicology.

b) Mutagenicity.

c) Occular Toxicity.

d) Allergy and Hypersensitivity.

Q4) Write in detail about genetic toxicological testing as per ICH guidelines. **[10]**

OR

Describe in detail the method of PCR technique and its application in toxicology.

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Total No. of Questions : 04]

SEAT No. :

P4037

[Total No. of Pages : 1

[5453]-223
M.Pharmacy
SAFETY PHARMACOLOGY
(2013 Pattern) (Common for Sem - I&II) (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 diagrams wherever necessary.***

Q1) Write importance & study design for oral sub-acute toxicity testing in rodents as per OECD guidline 407. **[10]**

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

a) Discuss various studies for dermatological testing.

b) Define safety pharmacology & give its importance.

c) Discuss about mutagenicity testing.

d) Explain in detail Individual Case Safety Report (ICSR).

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

a) Risk-benefit assessment.

b) A Periodic Safety Update Report (PSUR)

c) Ames test for mutagenicity.

d) Discuss various studies for genotoxicity testing.

Q4) Define pharmacovigilance. Discuss various methods of data collection in pharmacovigilance. **[10]**

OR

Discuss in detail methods for causality Assessment.

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Total No. of Questions : 04]

SEAT No. :

P4038

[Total No. of Pages : 1

[5453]-224
M.Pharmacy (Semester - I&II)
CLINICAL TRIALS
(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.***
3) ***Draw well labeled diagrams whenever necessary.***

Q1) Define clinical research, Explain in brief about various types and phases of clinical research. **[10]**

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

a) Explain the role and responsibilities of principal investigator and Sponsor in the clinical trials.

b) Write the importance of Belmont report.

c) Discuss the types and process of blinded study.

d) Write various advantages and disadvantages of clinical trial designs.

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

a) Principles of ICH GCP guidelines.

b) Criterions and process of patient recruitment.

c) Significance and content of Inform Consent form.

d) Issues in Therapeutic drug monitoring.

Q4) a) Define Institutional Review Board (IRB). Explain the composition, responsibilities and procedure of IRB. **[10]**

OR

b) Give the detail approval process for generic drugs.

Total No. of Questions : 04]

SEAT No. :

P4039

[Total No. of Pages : 1

[5453]-225
M.Pharmacy (Semester - I)
CLINICAL PHARMACOKINETICS AND PHARMACODYNAMICS
(2013 Pattern) (Credit System)

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

Instructions to the candidates:

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

Q1) Attempt any one: **[10]**

Define area under drug plasma concentration-time curve. Discuss various methods to determine the 'Area Under Curve'.

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

a) Explain well stirred model of hepatic clearance.
b) Explain the factors affection bioavailability of drug from dosage form.
c) Write the applications of Wagner–Nelson method.
d) Explain kinetics following IV bolus dose of a drug.

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

a) Placental barrier.
b) pH partition hypothesis.
c) Renal clearance.
d) Mean residence time.

Q4) Attempt any one: **[10]**

Explain effect of plasma protein binding on therapeutic response of a drug.

OR

How metabolism of drug alters response of a drug?

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Total No. of Questions : 04]

SEAT No. :

P4040

[Total No. of Pages : 1

[5453]-226
M.Pharmacy (Semester - I)
CLINICAL IMMUNOLOGY AND ENZYMOLOGY
(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Explain in detail various techniques of immobilization of enzymes. Add a note on industrial applications of immobilized enzymes. **[10]**

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

a) Explain the diagnostic value of autoantibodies.
b) Brief the Histocompatibility complex.
c) Give a detail account on biosensor technology.
d) Elaborate on anaphylactic reaction.

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

a) Acquired immunodeficiency.
b) Tumor immunotherapy.
c) Diagnostic value of enzymes.
d) T-cell mediated hypersensitivity reaction.

Q4) Explain in detail the methods of production and purification of monoclonal antibodies. Add a note on applications of monoclonal antibodies. **[10]**

OR

Enlist different types of lymphoproliferative disorders. Add a note on the mechanism of graft rejection. **[10]**

Total No. of Questions : 04]

SEAT No. :

P4041

[Total No. of Pages : 1

[5453]-227
M.Pharmacy (Semester - I)
INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT
(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) Discuss the need for optimization in pharmaceutical industry? Explain and classify the different optimization methods with suitable examples. **[10]**

Q2) Answer Any three. **[3×5=15]**

a) Explain briefly production planning.
b) Describe in detail the requirements related to manufacture as per the Drugs and Cosmetics Act.
c) What are the salient features of ISO 9000?
d) Explain pharmaceutical process validation.

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

a) Electrical and electronic parts in pharmaceutical industry.
b) Effluent testing and Treatment in pharmaceutical industry.
c) Computer control systems.
d) Typical automation models for solid manufacturing.

Q4) Describe in detail pilot plant scale-up and design for capsules and semisolid preparations. **[10]**

OR

Elaborate on industrial hazards due to fire, accident, mechanical and electrical equipment, chemical and pharmaceuticals. Explain the monitoring and preventive system.

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Total No. of Questions : 04]

SEAT No. :

P4042

[Total No. of Pages : 1

[5453]-228
M.Pharmacy
FERMENTATION TECHNOLOGY
(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.***
3) ***Draw well labeled diagrams wherever necessary.***

Q1) What is upstream process? Explain the importance of media optimization in fermentation. **[10]**

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

a) What is submerged fermentation?
b) Explain different techniques used for isolation of important microbes.
c) What is secondary metabolites? Explain.
d) Explain 'production of bioethanol'.

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

a) Protease in food processing.
b) Immobilized enzymes.
c) Protoplast fusion.
d) Measurement of microbial growth.

Q4) Explain in detail process monitoring and control parameters used in bioreactors. **[10]**

OR

Explain different food products prepared by process of fermentation. **[10]**

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Total No. of Questions : 04]

SEAT No. :

P4043

[Total No. of Pages : 1

[5453]-229
M.Pharmacy (Common for 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) Describe in detail how to execute the project successfully? **[10]**

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

a) How will you develop project team?
b) Explain the process of managing the conflicts.
c) How will you sources of power wisely in project management.
d) Justify - holding effective meetings is important for successful project Management.

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

a) Critical path.
b) Project scheduling.
c) Budget preparation for planning the project.
d) Estimating and sequencing the activities.

Q4) Preplanning is important for the project management. **[10]**

OR

Explain the process parameters involved in heading the project Team.

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Total No. of Questions : 04]

SEAT No. :

P4044

[Total No. of Pages : 1

[5453]-230
M.Pharmacy (Semester-I)
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 new control techniques and mention their advantage over old control technique. **[10]**

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

a) Discuss in brief Maslow's need hierarchy theory, with its merits and demerits.
b) Explain various performance appraisal methods.
c) Elaborate process of rational decision making.
d) Explain roles of rule, methods and procedure for development of policies.

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

a) Organization structure.
b) Barrier to communication.
c) Budgetary control.
d) Productivity problems.

Q4) How training is different from education. Discuss various types, methods and advantages of training. **[10]**

OR

Discuss in brief line and staff concept.

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Total No. of Questions : 04]

SEAT No. :

P4045

[Total No. of Pages : 1

[5453]-231
F.Y.M.Pharmacy (Semester-I&II)
COSMETICOLOGY
(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) Give an overview of emulsion based skin care products. Add a note on bioengineering methods used for assessing skin condition. **[10]**

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

a) Explain softening point and breaking point test of lipsticks.
b) How and why skin irritation tests are carried out for cosmetic products?
c) What are different hair products? Write quality control tests performed for analysis of shampoo.
d) Explain preservative efficacy testing method.

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

a) Regulatory requirements for cosmetic products.
b) Colouring materials in cosmetic formulations.
c) Antiperspirants and deodorants.
d) Packaging of cosmetics.

Q4) Write in detail about the vehicles used in cosmetic preparations. **[10]**

OR

Write in detail about the physiological consideration of nail in relation to cosmetic applications. Write in detail about nail care cosmetic products.

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