Total No. of Questions :4]

SEAT No. :

P4121

[Total No. of Pages : 1

[5346]-101
M. Pharmacy
ADVANCED ANALYTICAL TECHNIQUES
(2013 Pattern) (Semester-I)

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

Instructions to the candidates:

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

Q1) Explain why Infra-Red spectrum of a molecule is called "a fingerprint" **[10]**

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

a) Explain tandem mass spectrometry.

b) What are advantages of FTIR over dispersive IR?

c) Explain the effect of "solvent polarity" on the λ max with suitable example.

d) Explain in brief interfaces used in GC-MS.

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

a) Woodward Fieser Rules

b) Diffuse Reflectance Technique

c) 2D NMR

d) Supercritical fluid chromatography

Q4) Elucidate the structure of compound from the following data. A compound with molecular weight 116 gave the following spectral information : **[10]**

i) UV : 283 nm, ε_{max} 22

ii) IR : 3000-2500 cm^{-1} (b). 1715cm^{-1} (s), 1342 cm^{-1} (w)

iii) NMR : 7.88 τ Singlet (3H). 7.40 τ Triplet (2H), 7.75 τ Triplet (2H) and –1.1 τ Singlet (1H).

OR

Explain in detail principle of HPLC. Give an account of columns, pumps and detectors used in HPLC.

ⓘⓘⓘⓘ

Total No. of Questions :4]

SEAT No. : ____

P4122

[Total No. of Pages :1

[5346] - 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) What is documentation? Give the importance of documentation. Add a note on "Uses of computer packages in documentation". **[10]**

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

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

b) Explain in brief about types of research paper.

c) Differentiate between basic research and patent oriented research.

d) Explain in brief about cost analysis of the project.

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

a) DST as research organization in India.

b) Continuous variables and discrete variables.

c) Statistical measures.

d) Chi square (x^2) test.

Q4) Explain basic principle and different types of experimental design. Add a note on "Factorial Design". **[10]**

OR

Explain in detail parametric and non parametric tests of statistics.

Total No. of Questions : 4]

SEAT No. :

P4123

[Total No. of Pages :1

[5346]-103
M. Pharmacy
131 : ADVANCED PHARMACEUTICS -I
(2013 Pattern) (Semester-I)

[Time :3Hours] *[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) What is the role of preformulation studies? How does the preformulation differ for a tablet from a suspension. **[10]**

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

a) Define and differentiate Quality control and Quality Assurance.

b) Explain validation using any one unit process in the manufacture of solid dosage forms.

c) What is microencapsulation? Describe briefly their applications and evaluation.

d) Describe various degradation pathways of drugs citing proper examples.

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

a) Biodegradable polymers.

b) Preformulation of biotechnological products.

c) Langeragian method of optimization.

d) Surfactants and micelles.

Q4) How are excipients standardized? Write a note on drug-excipient, excipient-package and excipient-excipient interaction. **[10]**

OR

What is dissolution? Explain its importance. Also add a note on model dependent and model independent methods of dissolution.

☆ ☆ ☆

Total No. of Questions :4]

SEAT No. : ____

P4124

[Total No. of Pages :2

[5346] - 104

M. Pharmacy

133 - Advanced Pharmaceutical Chemistry

(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) 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]**

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

a) Discuss any two rearrangements reactions involving carboxylic acids or its derivatives as the starting material.

b) What is Clemmensen reduction reaction? Discuss the applications with suitable examples.

c) Discuss the principles of Green chemistry.

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

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

a) Microwave assisted reactions.

b) Baeyer-villiger oxidation.

c) Define racemic mixture. Write a note on epimerization and mutarotation with examples.

d) Supercritical fluids and water as solvent in green chemistry.

P.T.O.

Q4) Define the term "Molecular rearrangement". 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]**

OR

Give the organizational structure of Central Pollution Control Board of India. Discuss the functions of the same.

Total No. of Questions :4]

SEAT No. :

P4125

[Total No. of Pages :2

[5346] - 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) ***Figure to right indicates full marks.***
3) ***Draw well labeled diagrams whenever necessary.***

Q1) Write in brief the physical facilities required as per CPCSEA Guidelines for animal house. Explain the composition and function of IAEC. **[10]**

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

a) Explain Elevated Plus maze and water maze test.

b) Enlist the in vivo and in vitro screening methods for antiulcer drugs. Explain any two methods.

c) Explain the types of ELISA with advantages and disadvantages.

d) Define muscle relaxants. Write any three methods for screening of muscle relaxants.

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

a) Patch Clamp technique and its applications.

b) Screening of antidepressants.

c) Explain the screening methods for anticonvulsant drugs.

d) Screening of central analgesic activity.

Q4) a) Define Bioassay, write its principles and explain the official bioassay of Digitalis and Insulin. **[10]**

OR

b) Discuss in brief the preclinical screening methods for antihypertensive drugs.

Total No. of Questions :4]

SEAT No. : ____

P4126

[Total No. of Pages :1

[5346] - 106

M. Pharmacy

ADVANCED PHARMACOGNOSY - I

(2013 Pattern) (Credit system) (Semester - I)

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

Instructions to the candidates:

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

Q1) Explain building blocks of secondary metabolites derived from primary metabolites **[10]**

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

a) Explain genetic manipulation of acetate pathway.

b) Explain primary and secondary metabolites.

c) Explain Ecological functions of plants secondary metabolites.

d) Explain Empherically and rational approaches of drug discovery.

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

a) Curcumine.

b) Types of herbal formulations.

c) Biological assays.

d) Isolation of active compounds.

Q4) Elaborate natural products that make them appropriate in new drug discovery.

OR **[10]**

Elaborate the difficulties and remedies that occur in herbal formulations.

Total No. of Questions :4]

SEAT No. :

P4127

[Total No. of Pages :2

[5346] - 107

M.Pharmacy

ADVANCED QUALITY ASSURANCE TECHNIQUES (cGMP AND DOCUMENTATION)

(2013 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Discuss cGMP requirements regarding premises, sanitation, personnel and manufacturing of sterile preparations. **[10]**

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

a) Discuss the regulatory guidelines related to equipment identification and equipment log.

b) Describe the importance of internal audit and the procedural steps involved in it.

c) Explain the cGMP requirements with respect to labels and printed materials.

d) Explain the importance of yield calculation at various stages in manufacturing.

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

a) Components of GMP

b) IPQC.

c) Handling of rejected materials.

d) Standard Operating Procedure.

P.T.O.

Q4) Explain the hazard and risk analysis in pharmaceutical products. **[10]**

OR

Explain the good practices related to prevention of Mix-ups and Cross Contamination in production of Pharmaceuticals.

Total No. of Questions :4]

SEAT No. :

P4128

[Total No. of Pages : 1

[5346]-201
M.Pharmacy
201: DRUG REGULATORY AFFAIRS
(2013 Pattern) (Semester-II)

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

Instructions to the candidates:

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

Q1) Explain the different sections of NDA. **[10]**

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

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

b) Explain the provisions related to Schedule M and Y.

c) Explain the Indian Patent Act 1970.

d) Explain the patent system in Europe.

e) Explain the Water systems in pharmaceutical plant.

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

a) Trademark filing procedure.

b) GATT.

c) IP laws in pharma industry.

d) Guidelines of GMP audit inspection.

e) HVAC systems in pharmaceutical piant.

Q4) Elaborate the following "Quality Assurance is a part of GMP". **[10]**

OR

Explain provisions of the act for loan license manufacturing and import of pharmaceuticals.

Total No. of Questions :4]

SEAT No. : ____

P4129

[Total No. of Pages :1

[5346] - 202

M.Pharmacy

202 : FORMULATIONS AND DEVELOPMENT

(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 well labeled diagrams wherever necessary.***

Q1) Explain in detail various approaches for taste masking. **[10]**

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

a) Factors affecting CMC and micellar size thermodynamics.

b) Concept of Quality by Design.

c) Niosomes.

d) Propellants.

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

a) Self Emulsified Drug Delivery Systems.

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

c) Specialized dose dispensers in veterinary dosage forms.

d) Metered Dose Inhalers.

Q4) Discuss in detail on Nutraceuticals. **[10]**

OR

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

Total No. of Questions :4]

SEAT No. :

P4130

[Total No. of Pages :2

[5346] - 203

M. Pharmacy

NOVEL DRUG DELIVERY SYSTEMS

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

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 approaches used to develop Gastro-retentive drug delivery system. **[10]**

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

a) Write in detail about the types of mucoadhesive polymers. Add a note on factors affecting mucoadhesion.

b) How drug properties influences the design of sustained released systems.

c) What are different ways to develop transdermal drug delivery systems.

d) Discuss formulation of Long acting contraceptives.

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

a) Techniques for stabilization of proteins and peptides.

b) Challenges in ocular drug delivery.

c) The regulatory considerations during the filing for the approval of ANDA for NDDS.

d) Polymers used for preparation of microparticles and applications.

P.T.O.

Q4) Elaborate on monoclonal antibodies as site specific drug delivery. **[10]**

OR

Explain application of ternary phase diagrams in the formulation of microemulsions. Write a note on the stability and application of microemulsions. **[10]**

Total No. of Questions :4]

SEAT No. :

P4131

[Total No. of Pages :2

[5346] - 204

M. Pharamacy

PHARMACEUTICAL CHEMISTRY

Advanced Medicinal Chemistry

(2013 Pattern) (Semester - II) (Credit System) (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) Describe opiodal receptors along with its agonists and antagonists. **[10]**

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

a) Write synthetic scheme with reaction mechanism of Linezolid.

b) Highlight chemistry and SAR of barbiturates.

c) Explain target sites for antimalarial drug development.

d) Write about microbial conversion of steroids.

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

a) Antiamoebic agents.

b) Solid phase synthesis of peptides.

c) Monoclonal antibodies.

d) CNS depressants.

P.T.O.

Q4) Describe cholinergic and anticholinergic agents. **[10]**

OR

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

♦ ♦ ♦

Total No. of Questions : 4]

SEAT No. :

P4290

[Total No. of Pages : 1

[5346]-205
M.PHARMACY (Semester - II)
DRUG DESIGN
(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Define qsar. Enlist different qsar models. Write advantages of qsar in drug design. Explain hansch qsar model. **[10]**

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

a) 3 Dimensional qsar.
b) Roles of proteomics in drug design.
c) Force fields.
d) Genetic algorithm.

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

a) Receptor based de novo design.
b) Bioprecursor prodrugs.
c) Molecular dynamics.
d) Molecular mechanics.

Q4) What is structure based drug design? Explain the methodology and Applications of molecular docking in drug design. **[10]**

OR

"Drug metabolic studies play significant role in drug design" justify the statement with liberal use of examples. **[10]**

▽▽▽▽

Total No. of Questions :4]

SEAT No. : [ ]

P4132

[Total No. of Pages :1

[5346] - 206

M. Pharmacy

202 : CLINICAL PHARMACOLOGY

(2013 Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) Classify antihypertensive drugs. Explain the pharmacology of drugs acting on renin angiotensin system. **[10]**

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

a) Describe the mechanism of action and adverse effects of digitalis glycosides.

b) Describe therapeutic drug monitoring.

c) Monoclonal antibodies.

d) Therapeutic utility of statins in hyperlipidemia

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

a) Poly (ADP - Ribose) polymerase.

b) Renal dialysis.

c) Phases of clinical trials.

d) Proton pump inhibitors.

Q4) Give a detailed account on oral hypoglycemic agents.

OR

Explain in detail clinical practice guidelines of arthritis. **[10]**

Total No. of Questions :4]

SEAT No. :

P4133

[Total No. of Pages :2

[5346] - 207

M. Pharmacy

204 : MOLECULAR PHARMACOLOGY

(Spl. Pharmacology)

(2013 Pattern) (Semester - II) (Credit System) (M - III - 4)

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) What are various techniques used in molecular pharmacology? Explain the Radioimmuno assay. **[10]**

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

a) Explain the therapeutic applications of antioxidants.

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

c) Write note on Endothelin derived vascular substances.

d) Write a note on Neuropeptide modulators.

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

a) Gene therapy.

b) Chloride channels and their modulators.

c) Cytokines

d) Phosphodiestrase enzymes & their inhibitors.

P.T.O.

Q4) Explain concept of chronopharmacology and their clinical implication in drug therapy. **[10]**

OR

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

Total No. of Questions :4]

SEAT No. : ____

P4134

[Total No. of Pages :2

[5346] - 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 indicates 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 counter current extraction technique.
c) Enlist various methods of extraction of essential oils with special note on expression Method.
d) Discuss the extraction, isolation and purification of Glycyrrhizinic acid.

Q3) Solve any Three **[15]**

a) Give structural elucidation of Morphin.
b) Comment on Quantitative analysis of Phyllanthin in Phyllanthus species 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.

P.T.O.

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 physical, chromatographic and spectroscopic methods of characterization of Quercetin.

Total No. of Questions :4]

SEAT No. :

P4135

[Total No. of Pages :2

[5346] - 209

M. Pharmacy

204 : 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.***
3) ***Do not write on question paper.***

Q1) Discuss the export potential, national and international market strategies for herbal products. **[10]**

Q2) Attempt any Three of following **[15]**

a) Comment on stability testing for herbal formulations.

b) Describe herb-drug interactions with suitable examples.

c) Write a note on shelf life of herbal preparations.

d) Write a note on technical and funding assistance schemes for herbal products.

Q3) Solve Any Three of following. **[15]**

a) Explain how to get a license for manufacture of AYUSH drugs.

b) Discuss GMP for Indian systems of medicine.

c) Write WHO guidelines for pharmacovigilance of herbal preparations.

d) Explain about any two leading manufacturers of herbal products in India.

P.T.O.

Q4) Discuss the various ICH guidelines for production and sale of herbal products. **[10]**

OR

Explain about Indian and International patent laws for natural products. **[10]**

Total No. of Questions :4]

SEAT No. : ____

P4136

[Total No. of Pages :1

[5346] - 210

M. PHARMACY

M-V-3 202 : PHARMACEUTICAL VALIDATION

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

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

Instructions to the candidates:

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

Q1) Discuss analytical method validation in detail by ICH guideline. **[10]**

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

a) Write about Validation Master plan.

b) Process validation of coated tablets.

c) Vendor certification.

d) Validation of capsule.

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

a) Discuss merits and demerits of validation.

b) Discuss factor to be consider for designing of cleaning method.

c) Discuss validation of HPLC.

d) Give an account of different water treatment.

Q4) Explain process validation of Liquid Orals. **[10]**

OR

How Calibration Master Plan (C. M. P.) help to establish an effective calibration control programme.

Total No. of Questions :4]

SEAT No. :

P4137

[Total No. of Pages :2

[5346] - 211

M. Pharmacy

204 : QUALITY PLANNING AND ANALYSIS

(2013 Pattern) (Semester - II) (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) Discuss the importance of "Manufacturing Planning for Quality". **[10]**

Q2) Answer Any Three of the following. **[15]**

a) Discuss steps in structuring an audit program.

b) Explain the terms "measured capability" and "Inherent capability" of a process.

c) Discuss two sources contributing to process variation.

d) What are different types of sampling risks?

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

a) Self control.

b) Resistance to change.

c) Internal and external customers.

d) Automated manufacturing.

P.T.O.

Q4) Discuss theories of motivation. **[10]**

OR

Elaborate meaning of "Quality" and state financial effects of quality.

Total No. of Questions : 04]

SEAT No. :

P4138

[Total No. of Pages : 2

[5346] - 212

M. Pharmacy.

QUALITY CONTROL & ASSURANCE OF PHARMACEUTICALS

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

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

Instructions to the candidates:

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

Q1) Discuss process validation in detail. **[10]**

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

a) Quality culture.

b) Hygiene of personnel of pharmaceutical manufacturing.

c) IPQC in Tablets manufacturing.

d) Define SOP? Give its significance.

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

a) Mix-ups and cross contamination.

b) Validation of DT test apparatus.

c) Change control.

d) Quality control of biological products.

P.T.O.

Q4) Discuss GMP aspects of sterile products. **[10]**

OR

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

Total No. of Questions :04]

SEAT No. :

P4139

[Total No. of Pages :2

[5346] - 213

M. Pharmacy

PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

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

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

Instructions to the candidates:

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

Q1) Write importance of effluent treatment and discuss in detail design of effluent treatment plant. **[10]**

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

a) Write on design and operational facilities for sterile powder ready for reconstitution.

b) Explain Design and layout for Liquid orals.

c) Write on Support services for security office, vehicle parking, canteen and cooking.

d) Discuss on design of water as utility services.

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

a) Revised Factory Act.

b) Design of administrative block and training center in plant support services.

c) Layout and operational facilities for Tablet.

d) Design and layout for Ointment.

P.T.O.

Q4) Discuss in detail design and operation of Q.C. Laboratory. **[10]**

OR

Explain in detail cGMP regulatory requirement of Pharma facilities. **[10]**

Total No. of Questions :04]

SEAT No. :

P4140

[Total No. of Pages :2

[5346] - 214

M. Pharmacy

BIOPHARMACEUTICS AND PHARMACOKINETICS

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

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

Instructions to the candidates:

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

Q1) Describe the different theories of drug dissolution. State the Noyes Whitney Equation and explain all the terms of the stated equation. **[10]**

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

a) What are distribution based drug-drug interactions? Which pharmacokinetics parameters do they affect and why?

b) In general, drug companies avoid development of drugs that exhibit non-linear kinetics. Give your opinion on why this may be the case.

c) Describe the film theory for absorption of drugs. What are its assumptions?

d) Briefly discuss the causes and effects of nonlinearity.

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

a) Compendial dissolution testing methods.

b) Absorption based non-linear kinetics and its pharmacokinetic consequences.

c) Carrier mediated transport.

d) Methods to improve dissolution of poorly soluble hydrophobic drugs.

P.T.O.

Q4) Derive and describe Michaelis Menten equation for determination of Km and Vmax for drugs undergoing nonlinear pharmacokinetics. **[10]**

OR

Describe in detail time and dose dependent pharmacokinetics of drugs and its implications in the clinical use and dosage regiment design of such drugs.

Total No. of Questions :04]

SEAT No. :

P4141

[Total No. of Pages : 2

[5346] - 215

M. Pharmacy

STERILE PRODUCTS FORMULATION & TECHNOLOGY

(2013 Pattern) (Semester - I & II)

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

Instructions to the candidates:

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

Q1) What are the limitations in ophthalmic drug delivery systems? Write a note on Ocular Inserts. **[10]**

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

a) Explain the validation protocols for membrane filters.

b) Explain the resealed erythrocytes as drug delivery system.

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

d) Explain the possible hazards associated with parenteral therapy.

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

a) Manufacturing of freeze dried sterile product.

b) Elastomeric rubbers as packaging material for sterile products.

c) Industrial autoclaving.

d) Vehicles for sterile products.

P.T.O.

Q4) Explain the different sources of contaminations in sterile products, write in details about the Air quality in parenteral production areas. **[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 :4]

SEAT No. :

P4142

[Total No. of Pages :2

[5346] - 216

M. Pharmacy

215 : ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)

Manufacturing Technology

(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) Discuss about unit process and manufacturing technology of pharmaceuticals. **[10]**

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

a) Write about Industrial noise.

b) Discuss about Alkylation process with examples.

c) Comment on Pharmaceutical intermediates and heavy chemicals.

d) Write an account of Environmental protection laws.

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

a) Applications of biochemical process in synthesis.

b) Atmospheric contaminants.

c) Scale up techniques & flow charts in API manufacturing.

d) Acylation process for API manufacturing.

P.T.O.

Q4) Discuss about manufacturing process of following drugs with process and instrumentation diagram (any two). **[10]**

a) Ciprofloxacin

b) Rifampicin

c) Pentothal sodium

OR

What do you mean by radiation hazards? Discuss about radiation detection and measurements in detail. **[10]**

Total No. of Questions : 4]

SEAT No. :

P4291

[Total No. of Pages : 1

[5346]-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 right indicate full marks***

Q1) Define and classify Alkaloids. Explain in detail the methods of isolation and extraction of alkaloids with suitable example. **[10]**

Q2) Answer any three

a) Give the Structure elucidation of Solasodine. **[15]**

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

c) Explain chemistry of Caffeine.

d) Write down the chemical tests for Ephedrine and Piperine.

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

a) Biosynthetic pathways in plants

b) Structure elucidation of Atropine 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 Morphine by chemical and physical methods.

Total No. of Questions :4]

SEAT No. :

P4143

[Total No. of Pages :2

[5346] - 218

M. Pharmacy

119 : TRADITIONAL SYSTEMS OF MEDICINE AND AYURVEDIC FORMULATIONS

(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 Ayurvedic system of medicine. Give the theory and basic concept and add a brief note on Diagnosis and treatment of Ayurvedic system of medicine. **[10]**

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

a) Explain the preparation and evaluation methods of Churna.

b) Explain the theory and basic concept of Unani system of medicine.

c) Give an account of diagnosis and treatment of Chinese system of medicine.

d) Explain the role and importance of serial dilution in homeopathic system of medicine.

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

a) Arka.

b) Taila.

c) Arishta.

d) Gutika.

P.T.O.

Q4) Explain the evaluation and standardization of Ayurvedic cosmetic formulations. **[10]**

OR

Explain in detail modern drug discovery using Ethnopharmacognosy.

Total No. of Questions : 4]

SEAT No. :

P4292

[Total No. of Pages : 2

[5346]-219

M. Pharmacy(Common for Semester I & II)

MEDICINAL PLANT BIOTECHNOLOGY

(2013 Pattern) (Credit system) (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) Elaborate a detail account of recombinant DNA Technology along with it's principles, tools, process and applications. **[10]**

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

a) Describe, how chemodemes and mutation is helping to improve quality of crops along with suitable example.

b) What is suspension culture? Explain advantages and disadvantages of suspension culture.

c) Explain in vitro method of germplasm conservation.

d) Write an overview of localization of transferred gene in genetically modified plants.

e) Describe, how plant develops resistance to physiological stress through genetic transformation.

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

a) Physical maps using in-situ hybridization.

b) Immobilization of enzymes and it's application.

c) Structure and complexity of genome.

d) Biotransformation.

e) Chemical mediated gene transfer.

P.T.O.

Q4) Explain principle, working of bioreactor. Describe different types of bioreactors along with it's advantages, disadvantages and applications. **[10]**

OR

Elaborate a detail account of papain & bromelain along with their applications.

Total No. of Questions : 4]

SEAT No. :

P4293

[Total No. of Pages : 1

[5346]-220

M. Pharmacy

PHARMACOGNOSY

Natural Products Management (11)

(2013 Pattern) (Credit system) (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) Elaborate the management and utility of resources in medicinal plants farming **[10]**

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

a) Farm planning & Budgeting.
b) Method to obtain oil from oil seeds.
c) Indian Government Schemes for development of Medicinal plants.
d) Cultivation of prioritized medicinal plants.

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

a) Establishment of Extraction unit.
b) Quality parameters for cultivation and conservation of medicinal plants.
c) Preparation of Cocoa.
d) Research in farm management.

Q4) Discuss the national and international trading of medicinal plants. **[10]**

OR

Enumerate the process for patenting of herbal products. **[10]**

Total No. of Questions : 04]

SEAT No. :

P4144

[Total No. of Pages : 2

[5346] - 221

M. Pharmacy.

QUALITY ASSURANCE TECHNIQUES IN HERBAL PRODUCTS

(2013 Pattern) (Semester - I & II) (Common - elective)

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

Instructions to the candidates:

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

Q1) Explain in detail various factors are taken into account for creating herbal product manufacturing facility. **[10]**

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

a) Explain in brief standardization of herbal products with reference to cGMP guidelines.

b) Explain in brief Quality control and standardization of Neutraceuticals.

c) Describe in detail Advancement in packaging.

d) Pharmacovigilance for herbal product and its importance.

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

a) Quality Audits.

b) Compendial methods for evaluation of crude drugs.

c) Stability issues guidelines for studies related to herbal formulations.

d) Cleaning and sanitization of plant and equipments.

P.T.O.

Q4) Discuss in detail equipment URS and qualification along with its importance and significance. **[10]**

OR

Explain in detail Analytical methods development guidelines for Herbal formulations and modern herbal formulations.

Total No. of Questions :04]

SEAT No. :

P4145

[Total No. of Pages :2

[5346] - 222

M. Pharmacy.

TOXICOLOGY

(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 indicates full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

Q1) Define Toxicology. Explain preclinical toxicological requirement for Biotechnological Product. **[10]**

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

a) Write a note on Forensic Toxicology.

b) Discuss Immunochemical Technique in Toxicology.

c) Management of Dermal Toxicity.

d) Explain Research and Academic Application of Toxicology.

Q3) Write Short Notes (**Any Three**): **[15]**

a) Maximum Tolerated Dose.

b) Toxicokinetic.

c) Idiosyncrasy.

d) Difference between cDNA and Genomic Libraries.

P.T.O.

Q4) Write in detail about study design and management of Reproductive Toxicity. **[10]**

OR

Discuss in detail the factors influencing single dose and repeated dose toxicity studies.

Total No. of Questions :4]

SEAT No. :

P4146

[Total No. of Pages :2

[5346] - 223

M. Pharmacy

222 : SAFETY PHARMACOLOGY

(2013 Pattern) (Common for Semester - 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 labeled diagrams wherever necessary.***

Q1) Explain in detail 1.0 ECD grid line, 420 for oral acute toxicity studies in rodents. **[10]**

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

a) Discuss various studies for carcinogenicity texting.

b) Discuss importance and principle of safety pharmacology.

c) Write a note on ocular toxicity testing.

d) Write a note on Individual Case Safety Report. (ICSR)

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

a) Risk- Benefit - Assessment.

b) Reproductive toxicity testing.

c) Amer test for mutagenicity.

d) Causality Assessment.

P.T.O.

Q4) Define Pharmacovigilance. Write about data collection & Reporting in pharmacorigilance. **[10]**

OR

Discuss in detail periodic safety update report of marketed products. **[10]**

Total No. of Questions :04]

SEAT No. :

P4147

[Total No. of Pages :2

[5346] - 224

M. Pharmacy

CLINICAL TRIALS

(2013 Pattern) (Semester - I & II)

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 wherever necessary.***

Q1) Discuss in brief the objectives, compositions and functions of Institutional Review Board. Write the importance of Informed consent in ethical conduct of clinical trials. **[10]**

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

a) Explain the principles of Belmont report.

b) Write the contents of Investigators Brochure.

c) Advantages and disadvantages of clinical trial designs.

d) Discuss the blinded and randomization study.

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

a) Issues in Therapeutic drug monitoring.

b) NDA and ANDA.

c) Data monitoring and Computer applications in clinical research.

d) Principles of ICH GCP guidelines.

P.T.O.

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

OR

b) Discuss the role of various stakeholders in clinical trials.

Total No. of Questions : 04]

SEAT No. :

P4148

[Total No. of Pages : 2

[5346] - 225

M. Pharmacy.

CLINICAL PHARMACOKINETICS AND PHARMACODYNAMICS

(2013 Pattern) (Semester - I) (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) What are drug displacement interactions due to protein binding? Explain with suitable examples. **[10]**

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

a) Explain one compartment model.

b) Explain drug ionization and pH partition hypothesis.

c) Discuss various methods to determine the 'Area Under Curve'.

d) Explain the implications of multiple drug regimen in drug therapy.

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

a) Blood brain barrier.

b) Mean residence time.

c) Plasma protein binding.

d) Multiple drug regimen.

P.T.O.

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

Define clearance. Explain importance of clearance at an individual organ level.

OR

Describe Wagner Nelson method. Explain limitations of this method.

Total No. of Questions : 04]

SEAT No. :

P4149

[Total No. of Pages : 2

[5346] - 226

M. Pharmacy.

CLINICAL IMMUNOLOGY AND ENZYMOLOGY

(2013 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Describe the diagnostic and therapeutic value of enzymes with suitable examples. **[10]**

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

a) Describe the approaches to cancer immunotherapy.

b) Write on kinetics of immobilized enzymes.

c) Brief the applications of monoclonal antibodies.

d) Write an account on fusion methods of hybridoma.

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

a) Diagnostic value of autoantibodies.

b) Biosensor technology.

c) Acquired immunodeficiency.

d) Production and purification methods of monoclonal antibodies.

P.T.O.

Q4) Explain in detail the mechanisms involved in various types of hypersensitivity reactions. **[10]**

OR

Elaborate in detail the mechanism of graft rejection. Add a note on approaches to cancer immunotherapy. **[10]**

Total No. of Questions : 04]

SEAT No. :

P4150

[Total No. of Pages : 2

[5346] - 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) Give details about effluent testing and treatment : for pharmaceutical industry. **[10]**

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

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

b) How will you do plant site selection and organization for a pharmaceutical industry?

c) Elaborate on total quality management and productivity.

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

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

a) Simplex and Lagrangian models.

b) Automation of flexible manufacturing system, computer control systems.

c) Vendor development capacity assessment of inventory management.

d) Mechanical parts of pharmaceutical machinery and equipments.

P.T.O.

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

OR

Give requirements related to manufacture and sale of drugs. Drugs and Cosmetics Act.

Total No. of Questions :04]

SEAT No. :

P4151

[Total No. of Pages :2

[5346] - 228

M. Pharmacy. (Elective)

FERMENTATION TECHNOLOGY

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Explain different techniques used for strain improvement of industrial microbes. **[10]**

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

a) Explain different factors affecting microbial growth.

b) What is surface fermentation?

c) Write the applications of protease and amylase in food processing.

d) What is immobilization? Write its importance.

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

a) Recombinant protein.

b) Fermenter design and working.

c) Screening of industrial important microbes.

d) Food additives prepared by fermentation.

P.T.O.

Q4) Explain the Michaelis-Menten kinetics for enzyme catalysis. **[10]**

OR

Explain the production of bioethanol and biohydrogen by fermentation. **[10]**

Total No. of Questions : 04]

SEAT No. :

P4152

[Total No. of Pages : 1

[5346] - 229

M. Pharmacy (Elective)

PROJECT MANAGEMENT

(2013 Pattern) (Semester - I & II)

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

Instructions to the candidates : All questions are compulsory.

Q1) Illustrate the detail process of the Project planning. **[10]**

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

a) Give important of project manager.

b) Explain organizing for project management.

c) Role of project manager in the success of the project.

d) Give the role of clients and customers in project management.

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

a) Managing the conflicts during the project completion.

b) Communicating Effectively.

c) Wisely using sources of power.

d) Team decision.

Q4) Explain in detail-heading the Project Team. **[10]**

OR

Focus on executing the project effectively. **[10]**

Total No. of Questions : 04]

SEAT No. :

P4153

[Total No. of Pages : 2

[5346] - 230

M. Pharmacy.

PHARMACEUTICALADMINISTRATION

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

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

Instructions to the candidates:

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

Q1) Discuss various factors responsible for development of organisation structure. **[10]**

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

a) Explain in brief functions of management.

b) Describe various factors governing span of management.

c) Elaborate process of rational decision making.

d) Discuss effect of various environmental factors on strategy development.

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

a) Break even analysis.

b) Sources of recruitment.

c) Limitation of traditional appraisal method.

d) Priniciples of effective communication.

P.T.O.

Q4) Discuss in brief old control techniques. **[10]**

OR

How training is different from education. Discuss various types, methods and advantages of training.

Total No. of Questions :4]

SEAT No. :

P4154

[Total No. of Pages :2

[5346] - 231

F. Y. M. Pharmacy

130 : COSMETICOLOGY

(2013 Pattern) (Semester - I & II)

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 indicates full marks.***

Q1) Explain the different methods of analysis to assess the quality of the following cosmetic products. **[10]**

a) Lipsticks.

b) Hair care Products.

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

a) Safety issues regarding the use of topical non-invasive anti-aging ingredients.

b) List various cosmetic qualities required and characteristics that an ideal sunscreen products should possess.

c) Explain the Draize eye irritation test.

d) Describe emulsion based skin care products.

P.T.O.

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

a) Skin corrosion test.

b) Dental cosmetic products.

c) Assessment of preservative system for cosmetics.

d) Herbal Cosmetics.

Q4) With suitable formulation aspect discuss in detail various advances in cosmetics. **[10]**

OR

What are suntan and anti-sun burn preparations? Write a note on formulation and evaluation of suntan and anti-sun burn preparations.