

Total No. of Questions : 4]

SEAT No. :

**P3966**

[Total No. of Pages : 2

**[5246]-101**

**M. Pharmacy (Semester - I)**

**ADVANCED ANALYTICAL TECHNIQUES**

**(2013 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidate :*

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

**Q1) What is 'spin-spin' coupling in NMR? [10]**

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

- a) Discuss factors affecting the  $\lambda$  max in UV spectrum.
- b) What are handling techniques for solid samples in IR?
- c) Discuss in detail about any two pumps used in HPLC.
- d) Explain the principle of HPTLC and distinguish between HPLC and HPTLC.

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

- a) Hooke's Law
- b) Magnetic Anisotropy
- c) Principle and instrumentation of thermogravimetric analysis.
- d) Michelson's interferometer

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

**Q4)** What are the methods used for simplification of complex NMR spectra.[10]

OR

Elucidate the structure of compound from the following data.

An organic compound with molecular mass 104 gave the following spectral information.

i) UV : Transparent below 210 nm.

ii) IR : The medium bands formed are :

3125-2857  $\text{cm}^{-1}$  and 1449 $\text{cm}^{-1}$

The strong band is formed at 1718 $\text{cm}^{-1}$

The weak bands are formed at 2695 $\text{cm}^{-1}$  and 2625 $\text{cm}^{-1}$

iii) NMR :- 0.95  $\tau$  singlet (5.4 squares)

5.87  $\tau$  singlet (11.2 squares)

6.34  $\tau$  quartet (J = 7.1 cps. 10.6 squares)

8.73  $\tau$  Triplet (J = 7.1 cps. 16.2 squares)



Total No. of Questions : 4]

SEAT No. :

P3967

[Total No. of Pages : 1

[5246]-102

**M. Pharmacy (Semester - I)**  
**RESEARCH METHODOLOGY**  
**(2013 Pattern) (Credit System)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidate :*

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

**Q1)** What is technical writing? Explain in brief about research report and thesis writing. **[10]**

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

- a) Explain about selecting a problem and preparing a research proposal.
- b) Explain about methods of literature survey.
- c) Describe the format of model for oral presentation
- d) Describe about funding schemes of AICTE.

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

- a) Continuous variables and discrete variables
- b) Factorial design
- c) Chi square ( $\chi^2$ ) test
- d) Statistical measures

**Q4)** What is oral presentation? Explain importance of posture, gesture, eye contact, and facial expression in oral presentation. **[10]**

OR

Describe the use of t test and standard deviation in evaluation of data.



Total No. of Questions : 4]

SEAT No. :

**P3968**

[Total No. of Pages : 1

**[5246]-103**

**M. Pharmacy (Semester - I)**  
**ADVANCED PHARMACEUTICS-I**  
**(2013 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidate :*

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

**Q1)** Give significance of Preformulation studies. What preformulation studies are conducted for solid oral dosage forms? Explain with relevant examples.

**[10]**

**Q2)** Solve any three

**[15]**

- a) Write a note on rheology of polymers
- b) What are excipients? Discuss the selection criteria for excipients.
- c) Describe spray drying and spray congealing methods of microencapsulation.
- d) Justify "Quality is built into a product and not inspected in"

**Q3)** Write short notes on any three

**[15]**

- a) Validation of mixing process
- b) Diffusion and dissolution
- c) Cyclodextrins
- d) Hixson -Crowell and Higuchi model of Dissolution

**Q4)** Classify optimization methods. Describe briefly the importance of experimental design. Also add a note on contour plots.

**[10]**

OR

What are Accelerated, intermediate and long term stability studies. How is the shelf life prediction done on the basis of accelerated stability studies?



Total No. of Questions : 4]

SEAT No. :

P3969

[Total No. of Pages : 1

[5246]-104

M. Pharmacy (Semester - I)

ADVANCED PHARMACEUTICAL CHEMISTRY

(2013 Pattern)

Time : 3 Hours]

[Max. Marks : 50

Instructions to the candidate :

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

**Q1)** Define isomers, enantiomers and tautomers. Explain the concept of asymmetric synthesis with examples. Discuss the methods for resolution of racemic mixtures. [10]

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

- a) Ionic liquids have a number of advantages over volatile organic solvents. Justify the statement giving suitable examples.
- b) Explain any two multi component reactions in detail.
- c) Enlist the various name reactions dealing with oxidation of organic compounds. Explain any one including mechanism, stereochemistry and applications.
- d) Write a note on supported reagents and catalysts in Green chemistry.

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

- a) Pinacol-Pinacolone rearrangement.
- b) Free radical reactions.
- c) Wittig reaction.
- d) Beckmann rearrangement.

**Q4)** What are the objectives of effluent treatment? Explain the various methods used for treatment of industrial effluents. [10]

OR

Which are the various transforms used in synthon approach? Discuss the rules of disconnection in synthon approach with examples.



Total No. of Questions : 4]

SEAT No. :

P3970

[Total No. of Pages : 1

[5246]-105

**M. Pharmacy (Semester - I)**  
**ADVANCED PHARMACOLOGY**  
**Preclinical Evaluation of Drugs**  
**(2013 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates :*

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

**Q1)** Discuss in brief about objective, composition, functions of IAEC as per CPCSEA guidelines. Write a note on proforma-B animal experimentation. **[10]**

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

- a) Discuss LIPSCHITZ test and saluretic activity in rats.
- b) Write preclinical screening methods for hypoglycemic activity.
- c) Write the methods for screening of peripheral analgesic activity.
- d) Discuss any two screening methods for hypertension.

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

- a) Screening of muscle relaxants.
- b) Transgenic and Knockout animals in research.
- c) Preclinical methods for screening of anti-ulcers activity.
- d) Types of ELISA with advantages and disadvantages.

**Q4)** Explain in brief various in vivo screening methods for inflammation. **[10]**

OR

Define depression. Write the various methods used for the screening of antidepressant drugs.



Total No. of Questions : 4]

SEAT No. :

P3971

[Total No. of Pages : 1

[5246]-106

**M. Pharmacy (Semester - I)**  
**ADVANCED PHARMACOGNOSY**  
**(2013 Pattern) (Credit System)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidate :*

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

**Q1)** Briefly describe biogenetic pathway for flavonoids and flavolignans. **[10]**

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

- a) Explain polyketids pathways for anthraquinones.
- b) Explain difficulties for formulations of herbal formulations and remedies.
- c) Explain modern drug discovery with Taxol.
- d) Describe ethnobotanical approach for drug discovery.

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

- a) Withania Alkaloids
- b) Biogenesis of coumarins
- c) Herbal syrups
- d) Nutraceutical powders/ granules

**Q4)** Elaborate rational use of secondary metabolites as medicinal compounds. **[10]**

OR

Explain in detail HIS with selection strategies, sample preparation and test with recent case studies.



Total No. of Questions : 4]

SEAT No. :

P3972

[Total No. of Pages : 1

[5246]-107

M. Pharmacy (Semester - I)

**ADVANCED QUALITY ASSURANCE TECHNIQUES**

**(CGMP AND DOCUMENTATION)**

**(2013 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidate :*

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

**Q1)** Explain the principle of Quality Audit, add a note on preparations required for FDA Inspection of manufacturing site. **[10]**

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

- a) Discuss the regulatory guidelines related to equipment identification and equipment log.
- b) Elaborate various aspects of material management.
- c) Explain the cGMP requirements with respect to labels and printed materials.
- d) Explain the GMP guidelines related to recalled and returned products.

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

- a) Batch production records
- b) IPQC
- c) HVAC system
- d) Standard Operating Procedure

**Q4)** Discuss cGMP requirements regarding building, premises, sanitation and hygiene for pharmaceutical products. **[10]**

OR

Explain the hazard and risk analysis in pharmaceutical products.





Total No. of Questions : 4]

SEAT No. :

P3974

[Total No. of Pages : 2

**[5246]-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 details study of ICH Q8 (R2) Guidelines for pharmaceutical development. **[10]**

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

- a) Concept of Quality by Design
- b) Factors affecting phase behaviour
- c) Regulatory perspective of pharmaceutical packaging material for Novel drug delivery Systems.
- d) Semisolid based on Liposomes

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

- a) Approaches for taste masking
- b) Self emulsified drug delivery systems
- c) Nutraceuticals
- d) Metered Dose Inhalers

**P.T.O.**

**Q4)** Discuss role of propellants in inhalation aerosols. Add a note on quality assurance of Aerosol formulation. **[10]**

OR

Discuss Specialized dose dispensers in veterinary dosage forms and explain formulation strategy for administration of veterinary dosage forms via drinking water. **[10]**



Total No. of Questions : 4]

SEAT No. :

**P3975**

[Total No. of Pages : 2

**[5246]-203**

**M. Pharmacy (Semester - II)**  
**NOVEL DRUG DELIVERY SYSTEMS**  
**(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 :abeled diagrams wherever necessary.*

**Q1)** Explain the effect of drug properties and routes of administration on the design of sustained and controlled release system. **[10]**

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

- a) Write an account on transdermal permeation enhancers.
- b) Explain the factors affecting nasal absorption of drugs.
- c) What are the regulatory requirements for controlled drug delivery systems?
- d) Write a note on biowavers for bioequivalence studies
- e) Describe the different in vitro, ex-vivo and in vivo methods for evaluation of mucosal drug delivery systems.

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

- a) Niosomes
- b) Drug targeting to brain
- c) Preparation methods for nanosuspensions
- d) Issues and challenges in ocular drug delivery
- e) Analysis of proteins and peptides

**P.T.O.**

**Q4)** Enlist various methods for preparation of microparticles. Describe about characterization and applications of microparticles. **[10]**

OR

Explain various approaches for colon targeting.



Total No. of Questions : 4]

SEAT No. :

**P3976**

[Total No. of Pages : 1

**[5246]-204**

**M. Pharmacy (Pharmaceutical Chemistry)  
ADVANCED MEDICAL 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)** What is enzyme immobilization? Explain enzyme immobilization techniques. **[10]**

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

- a) Highlight GABA receptor and its ligands
- b) Comment on histamine receptors and its ligands.
- c) Explain target sites for antimalarial drug development.
- d) Write synthetic scheme and reaction mechanism for synthesis of Alprazolam.

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

- a) RTIs
- b) Monoclonal antibodies.
- c) Oral hypoglycemic agents
- d) CNS depressants

**Q4)** Describe biomolecules and their significance. **[10]**

OR

Write in detail about Anti-mycobacterial agents.



Total No. of Questions : 4]

SEAT No. :

P3977

[Total No. of Pages : 1

[5246]-205

M. Pharmacy (Semester - II)

DRUG DESIGN (M-II-4)

(2013 Pattern)

Time : 2 Hours]

[Max. Marks : 50

Instructions to the candidate :

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

**Q1)** What is Bioisoterism? Write applications of bioisosterism in designing of drug molecules [10]

**Q2)** Attempt any Three questions out of Four [15]

- a) Write a note on Cluster analysis.
- b) Drug design based on antagonism
- c) Write significance of Metabolism study in drug design.
- d) Write in short about bioprecursor prodrugs.

**Q3)** Attempt any Three questions out of Four [15]

- a) Write in brief about Topliss tree approach
- b) Antagonism concept in drug design.
- c) Write in short on CoMFA
- d) Write a note on Craig plot

**Q4)** What are prodrugs? Discuss designing of drug molecule based on metabolism studies with suitable examples. [10]

OR

Explain The concepts of enzyme inhibition were proved to be excellent tools in the process of drug design with suitable examples. [10]



Total No. of Questions : 4]

SEAT No. :

P3978

[Total No. of Pages : 1

[5246]-206

**M. Pharmacy (Semester - II)**  
**CLINICAL PHARMACOLOGY**  
**(2013 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidate :*

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

**Q1)** Give a detailed account on management of diabetes mellitus. **[10]**

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

- a) Describe the pharmacology of calcium channel blockers.
- b) Describe different types of adverse drug reactions.
- c) Elaborate on different phases of clinical trials.
- d) Explain clinical practice guidelines of malaria.

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

- a) Reverse transcriptase inhibitors **[5]**
- b) Chronic obstructive pulmonary disease **[5]**
- c) Drug- food interactions **[5]**
- d) Poly (ADP- Ribose) Polymerase **[5]**

**Q4)** Classify antihypertensive drugs. Explain the therapeutic utility of thiazide diuretics in hypertension. **[10]**

OR

Give a detailed account on class I antiarrhythmic agents. **[10]**



Total No. of Questions : 4]

SEAT No. :

P3979

[Total No. of Pages : 1

[5246] - 207

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

**MOLECULAR PHARMACOLOGY**

**(2013 Pattern) (Credit System)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates :*

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

**Q1)** Explain the process of Apoptosis with its clinical implications. **[10]**

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

- a) Write a note on Calcium and calcium binding proteins
- b) Explain the concept of Human Genome Mapping.
- c) What are monoclonal antibodies? Explain their clinical significance.
- d) Explain the therapeutic applications of antioxidants.

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

- a) Nitric oxide and endothelin modulators.
- b) Adrenoreceptors
- c) Neurosteroids and their modulators
- d) RT-PCR

**Q4)** Discuss the recent advances in drugs acting on angiotensin receptors. **[10]**

OR

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

▽▽▽▽



Total No. of Questions : 4]

SEAT No. :

P3980

[Total No. of Pages : 1

[5246] - 208

M.Pharmacy (Semester - II) (Theory)

**PHYTOCHEMISTRY AND PHYTOPHARMACEUTICALS**  
**(2013 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates :*

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

**Q1)** Discuss in detail the invivo and invitro screening methods of anti-inflammatory drugs with suitable examples. **[10]**

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

- a) Give principle and applications of column chromatography.
- b) Discuss the new approaches in standardization of herbal drugs.
- c) Enlist various methods of extraction of essential oils with special note on modern methods of essential oil extraction.
- d) Discuss the extraction, isolation and purification of Piperine.

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

- a) Give structural elucidation of Nicotine.
- b) Comment on Quantitative analysis of bacosides in Bacopa species by HPTLC.
- c) Discuss the screening methods for anti-asthmatic herbal drugs.
- d) Discuss the role of fractional liberation in isolation of chemical constituents from herbal extracts.

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

- a) Discuss in detail the WHO parameters used in standardization of herbal drugs.
- b) Discuss the advantages of supercritical fluid extraction technique with suitable examples. Add a note on extraction of Capsaicinoids.



Total No. of Questions : 4]

SEAT No. :

**P3981**

[Total No. of Pages : 1

**[5246] - 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.*

**Q1)** Enumerate briefly the WHO guidelines for the regulation of herbal drugs in India. **[10]**

**Q2)** Explain the global regulatory status of herbal medicine. **[10]**

**Q3)** Elaborate the demand of important plants used in indigenous systems of medicine and in modern medicine. **[10]**

OR

Explain the export potential of Herbal medicinal product from India.

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

- a) Shelf life of herbal products
- b) Natural Product- Strength & Weakness
- c) Ways leading to causes toxicity of herbal drugs
- d) Patent laws & amendments
- e) Herbal drug interaction of commonly used herbs

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P3982

[Total No. of Pages : 1

[5246] - 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 where necessary.*

**Q1)** Define validation. Describe in detail concept of IQ, OQ, PQ. **[10]**

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

- a) Validation of autoclave
- b) Validation of dissolution test apparatus
- c) Validation of fluid bed dryer
- d) Describe validation master plan

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

- a) Validation of dry powder mixer
- b) Enlist & explain the steps for stability indicating HPLC method
- c) State the protocol for validation of blister strip packing machine
- d) Validation of pure steam

**Q4)** Explain validation of HVAC system. **[10]**

OR

Describe in detail vendor certification.



Total No. of Questions : 4]

SEAT No. :

P3983

[Total No. of Pages : 1

[5246] - 211

M.Pharmacy (Semester - II)

QUALITY PLANNING AND ANALYSIS

(2013 Pattern) (Credit System)

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates :*

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

**Q1)** Discuss "Theories of Motivation". **[10]**

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

- a) What are the categories of quality related costs?
- b) What are different issues included in "Review of product design" prior to release to operations?
- c) Write note on "Technology & Culture".
- d) What is the location of control stations for measurement of actual performance?

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

- a) Statistical control charts in general.
- b) Characteristics of good acceptance plan.
- c) Human relations in auditing.
- d) Seriousness classification.

**Q4)** Explain the role of process capability study in the process control. **[10]**

OR

Discuss in detail, concept of Quality Audit.



Total No. of Questions : 4]

SEAT No. :

P3984

[Total No. of Pages : 1

[5246] - 212

**M.Pharmacy (Semester - I & II) Common (Elective) (Theory)**

**QUALITY CONTROL & ASSURANCE OF  
PHARMACEUTICALS**

**(2013 Pattern) (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)** What is Master production and control record? Give its contents. **[10]**

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

- a) Describe sources of contamination & their control
- b) Components of QA
- c) Types of pharmaceutical plant audits
- d) Define SOP? Give its significance.

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

- a) Revalidation
- b) Quality culture
- c) Change control
- d) GMP requirements of equipments of sterile products

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

OR

Explain validation of pharmaceutical HVAC system.

▽▽▽▽

Total No. of Questions : 4]

SEAT No. :

P3985

[Total No. of Pages : 1

[5246] - 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 in detail revised schedule M and Factory Act. **[10]**

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

- a) Discuss layout and operational facilities for Ointment.
- b) Write on design of compressed air as utility service.
- c) Explain design and operational facilities for sterile powder ready for reconstitution.
- d) Write on fuel storage and medical services in plant support services.

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

- a) Layout and operational facilities for Dry syrup
- b) Administrative block and training center in plant support services
- c) Design and Layout for Liquid Orals
- d) Design of water as utility services

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

OR

Define effluent, write its complications and describe in detail design of effluent treatment plant.



Total No. of Questions : 4]

SEAT No. :

P3986

[Total No. of Pages : 1

[5246] - 214

M.Pharmacy (Semester - I & II)

BIOPHARMACEUTICS AND PHARMACOKINETICS

(2013 Pattern) (Credit System)

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 in detail time and dose dependent pharmacokinetics of drugs and its implications in the clinical use and dosage regiment design of such drugs. [10]

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

- a) How do perfusion rate and organ size affect distribution of drugs?
- b) What are the properties of the drug that affect its permeation across the cell membrane?
- c) Explain significance and factors affecting to protein binding study.
- d) What is the importance of Level A IVIVC for new dosage forms

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

- a) Compartmental Models and their advantages and limitations
- b) Area under the curve
- c) Protocol for bioavailability studies of conventional dosage forms
- d) In vitro models for determinations of permeability

**Q4)** What are the physiological barriers to distribution of drugs? Explain the difficulties encountered in targeting drugs to the brain. How are these overcome? [10]

OR

Discuss plasma concentration time profile. If drug is given as I.V. infusion through one compartmental model, derive equation for it's determination of plasma concentration.



Total No. of Questions : 4]

SEAT No. :

P3987

[Total No. of Pages : 1

[5246] - 215

M.Pharmacy (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 physico-chemical, formulation considerations in small volume parenterals. **[10]**

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

- a) Explain the design concept of filling area in sterile product manufacturing unit.
- b) Explain the liposomes as drug delivery system.
- c) What are different parenteral irrigating solutions? Explain the fundamentals for peritoneal dialysis solutions.
- 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) Glass as packaging material for sterile products.
- c) Industrial autoclaving.
- d) FFS and BFS technology.

**Q4)** Explain the GMP requirements related to premises, sanitation, hygiene and personnel in sterile manufacturing units. **[10]**

OR

What are the limitations in ophthalmic drug delivery systems? Write a note on ocular inserts.





Total No. of Questions : 4]

SEAT No. :

P3988

[Total No. of Pages : 2

[5246] - 216

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

**ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)**

**MANUFACTURING TECHNOLOGY**

**(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)** Write about pharmaceutical intermediates. Discuss about Fluidized bed dryers in manufacturing process. **[10]**

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

- a) Discuss unit process for oxidation reactions with suitable examples.
- b) Explain the terms Fine chemicals & Heavy chemicals with examples.
- c) Write about eye protection equipments.
- d) Give an account of Finger & Arm protection in API manufacturing.

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

- a) Chemical mixtures.
- b) Esterification process in manufacturing of APIs.
- c) Stoichiometry in drug synthesis.
- d) Catalysts used in API manufacturing.

*P.T.O.*

**Q4)** Give an account of manufacturing process of following drugs with process and instrumentation diagram (any two) **[10]**

- i) Aspirin
- ii) Adrenaline
- iii) Sulphamethoxazole

OR

Write with suitable examples regarding biochemical process in API manufacturing.



Total No. of Questions : 4]

SEAT No. :

P3989

[Total No. of Pages : 1

[5246] - 217

M.Pharmacy (Semester - I & II)

CHEMISTRY OF MEDICINAL NATURAL PRODUCTS

(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)** Define Glycosides. Write Chemistry and biogenesis of Diosgenine. [10]

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

- a) Write chemical properties of Alkaloids.
- b) Define Terpenoids, write chemistry of it.
- c) Mention biosynthesis of Tryptophan derived Alkaloids.
- d) Focus on methods of analysis of Diosgenine.

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

- a) Plant pigments.
- b) Structural elucidation of Solasodine.
- c) Flavonoids.
- d) Carbohydrates extraction.

**Q4)** Explain methods of extraction and isolation of Volatile oils. [10]

OR

Classify Alkaloids. Explain method of extraction and isolation of Opium alkaloids. [10]



Total No. of Questions : 4]

SEAT No. :

P3990

[Total No. of Pages : 1

[5246] - 218

M.Pharmacy

**TRADITIONAL SYSTEM OF MEDICINE AND  
AYURVEDIC FORMULATIONS**

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

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

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

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

- a) Churna
- b) Avaleha
- c) Ghruta
- d) Kwatha

**Q4)** Explain in detail modern drug discovery using Ethnopharmacognosy. **[10]**

OR

Explain the standardization of Ayurvedic drugs using Physical and Chemical methods.



Total No. of Questions : 4]

SEAT No. :

**P3991**

[Total No. of Pages : 2

**[5246]-219**

**M. Pharm.**

**MEDICINAL PLANT BIOTECHNOLOGY**

**(2013 Pattern)**

**(E.1.10) (Elective subject of all semesters)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates:*

- 1) Question No. 1 is compulsory.*
- 2) Draw well labeled diagram wherever necessary.*
- 3) Enter the question number clearly in the margin of the answer book beside each of your answer.*
- 4) Figures to the right indicate full marks.*

**SECTION - I**

**Q1)** Define Gene expression. What are Regulated stages of gene expression? Write a note on epigenetic regulation & its correlation with the Methylation of DNA. **[10]**

**Q2)** Solve Any three: **[3×5=15]**

- a) What are different Plant signal transduction pathways? What are Mitogenactivated protein kinases (MAP kinases)? What are types of MAP kinases?
- b) What is the Genetic code? What are its salient features? What is start codon? How Alternative start codons are different from the standard AUG codon? What is stop codon?
- c) What is the Recombinant DNA molecule? Why it is called as called 'chimeric DNA'? How recombinant DNA molecule is created by Molecular cloning? How does Molecular cloning which is the laboratory process used to create recombinant DNA differs from another process called polymerase chain reaction?
- d) What is Somatic embryogenesis? What are its applications? What are different steps required in plant regeneration via somatic embryogenesis? Enlist the Problems associated with somatic embryogenesis.
- e) Write an overview of Ex situ Germplasm Conservation in Plants.

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

**Q3) Short notes (Any three)**

**[3×5=15]**

- a) Gibson assembly & Its advantages
- b) Elicitors for Production of Secondary metabolites & its classification
- c) A microRNA
- d) Restriction enzymes & its types
- e) Edible Vaccines

**Q4) What is an Immobilized Enzyme? What are its commercial uses? What are different ways by which one can immobilize an enzyme. [10]**



Total No. of Questions : 4]

SEAT No. :

**P3992**

[Total No. of Pages : 1

**[5246]-220**

**M.Pharmacy (Semester - I & II)**  
**NATURAL PRODUCT MANAGEMENT**  
**(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 labelled diagrams wherever necessary.*

**Q1)** What is demand and supply of market? Explain the factors affecting it. [10]

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

- a) Explain planning and budgeting of Herbal farming.
- b) Write on modernization of natural product market.
- c) Explain trading of preoritized species in international market.
- d) Write in short about various government schemes for development of medicinal plants in India.

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

- a) Trading of Neutraceuticals.
- b) Import and export of food supplements.
- c) Establishment of Herbal products unit.
- d) Patent rights of herbal products.

**Q4)** Write down the significance of collective efforts of collectors and growers for management of natural products. [10]

OR

Explain management of land, labour and machine for agricultural development.



Total No. of Questions : 4]

SEAT No. :

**P3993**

[Total No. of Pages : 1

**[5246]-221**

**M.Pharmacy (Semester - I & II)**  
**QUALITY ASSURANCE TECHNIQUES IN HERBAL**  
**PRODUCTS**  
**(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)** State the term stability Testing and provide stability issue guidelines for studies related to herbal formulations along with their significance. **[10]**

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

- a) Explain elements of QA with reference to quality management.
- b) Explain in brief equipment URS and qualification.
- c) Provide information on Analytical method development guidelines for modern Herbal formulations.
- d) Provide information on storage of Herbal raw materials and Herbal products.

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

- a) Primary and Tertiary packages.
- b) Compendial methods for evaluation of Herbal Formulations.
- c) Standardization of Herbal products with reference to WHO guidelines.
- d) Australian guidelines for Herbal products.

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

OR

Explain in detail infrastructural development and Facility required for processing of Herbal products along with cleaning. Pulverization and processing of Herbal products.





Total No. of Questions : 4]

SEAT No. :

**P3994**

[Total No. of Pages : 1

**[5246]-222**

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

**TOXICOLOGY**

**(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)** Define Maximum Tolerable Dose. Write the principles of GLP as per OECD guidelines for preclinical toxicity testing. **[10]**

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

- a) Define idiosyncrasy, tachyphylaxis, habituation, synergism and Potentiation.
- b) Write in detail on the Northern Blotting Technique.
- c) Explain Cell Culture Techniques in toxicology.
- d) Management of Behavioral toxicity.

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

- a) Regulatory Toxicology.
- b) Management of Toxic Reaction in Human.
- c) Molecular Cloning.
- d) LD50.

**Q4)** Explain Preclinical toxicological requirement for Biological Product. **[10]**

OR

Write in detail about study design for Carcinogenicity Testing.



Total No. of Questions : 4]

SEAT No. :

**P3995**

[Total No. of Pages : 1

**[5246]-223**

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

**SAFETY PHARMACOLOGY**

**(2013 Pattern) (Credit System)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates:*

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

**Q1)** Discuss the importance and principles of safety pharmacology. **[10]**

**Q2)** Solve the following (Any 3) **[15]**

- a) Explain OECD guidelines for acute oral toxicity.
- b) Explain Risk-benefit assessment in clinical trials.
- c) Write in detail about data collection during pharmacovigilance.
- d) Write in detail about guinea pig sensitization assays for testing dermatological products.

**Q3)** Write short notes (Any 3) **[15]**

- a) Product safety update reports
- b) Regulatory requirements for safety pharmacology
- c) Analysis of safety Pharmacological data
- d) Post-marketing surveillance

**Q4)** Discuss in detail Ames test for mutagenicity. **[10]**

OR

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



Total No. of Questions : 4]

SEAT No. :

**P3996**

[Total No. of Pages : 1

**[5246]-224**  
**M. Pharmacy**  
**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 diagram wherever necessary.*

**Q1) Define clinical research. Explain the types and phases of clinical research.[10]**

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

- a) Write the composition and responsibilities of Institutional Review Board.
- b) Role and responsibilities of CRO in clinical research.
- c) Explain the ethical guidelines of Declaration of Helsinki.
- d) Discuss the criteria for selection of investigator in clinical research.

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

- a) Investigational New drug (IND) process.
- b) Inclusion and exclusion criteria.
- c) Issues in Therapeutic drug monitoring.
- d) Various elements in design of clinical trials.

**Q4) Define informed consent. Discuss in brief the significance and contents of informed consent form. [10]**

OR

Discuss the role of FDA in new drug development process.



Total No. of Questions : 4]

SEAT No. :

**P3997**

[Total No. of Pages : 1

**[5246]-225**

**M. Pharmacy**

**CLINICAL PHARMACOKINETICS AND  
PHARMACODYNAMICS**

**(2013 Pattern) (Credit System)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates:*

- 1) Question No.1 is compulsory.*
- 2) Draw neat labelled diagrams wherever necessary.*
- 3) Figures to the right indicate full marks.*

**Q1)** Describe compartment modelling with its assumptions. Add a note on one compartment model. **[10]**

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

- a) Describe the method for determination of  $V_{max}$  and  $K_m$ .
- b) Explain the implications of multiple drug regimens in drug therapy.
- c) Explain the significance of half life of drug in elimination.
- d) Explain an initiating and managing therapy as individualization.

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

- a) Wagner-Nelson method
- b) Area under curve
- c) pH partition hypothesis
- d) Hepatic clearance

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

Elaborate effect of metabolites on drug response.

OR

How plasma protein binding affects effect of a drug.



Total No. of Questions : 4]

SEAT No. :

**P3998**

[Total No. of Pages : 1

**[5246]-226**

**M. Pharmacy**

**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 diagram wherever necessary.*

**Q1)** Give a detail account on production and purification of monoclonal antibodies.  
Add a note on applications of monoclonal antibodies. **[10]**

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

- a) Explain the immune response to tumors.
- b) Describe the graft rejection reaction.
- c) Brief the applications of hybridoma in immunology.
- d) Write about humoral autoantibody.

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

- a) Therapeutic value of autoantibodies
- b) Histocompatibility complex
- c) Adaptive immunity
- d) Therapeutic applications of enzymes

**Q4)** Explain in detail various techniques of immobilization of enzymes and their industrial applications. **[10]**

OR

Enlist different types of hypersensitivity reactions and explain in detail the mechanism underlying the hypersensitivity reactions.



Total No. of Questions : 4]

SEAT No. :

**P3999**

[Total No. of Pages : 1

**[5246]-227**

**M.Pharmacy (Semester - I & II)**  
**INDUSTRIAL PHARMACY AND PRODUCTION**  
**MANAGEMENT**  
**(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)** Elaborate in detail pilot plant scale-up and design for tablet and liquid oral preparations. **[10]**

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

- a) As per the Drugs and Cosmetics Act what are the requirements related to sale of drugs?
- b) What is vendor development capacity and assessment of production rate changes?
- c) Explain what is pharmaceutical validation process for various products.
- d) Explain the safety monitoring and preventive system for industrial hazards due to chemicals and pharmaceuticals.

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

- a) Elaborate on quality assurance and GMP considerations.
- b) Statistical design and applied optimization methods.
- c) Effluent testing and treatment: for pharmaceutical industry
- d) Material handling for various pharmaceutical products.

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

OR

Explain in details the typical models of automation for solid and liquid manufacturing.



Total No. of Questions : 4]

SEAT No. :

**P4000**

[Total No. of Pages : 1

**[5246]-228**

**M.Pharmacy (Semester - I/II)**  
**FERMENTATION TECHNOLOGY**  
**(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 process monitoring and control parameters used in Bio reactors. **[10]**

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

- a) Michaelis - Menten equation & its deviations.
- b) Explain different techniques used for strain improvement.
- c) Explain various factors affecting microbial growth.
- d) Explain surface fermentation.

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

- a) Methods used for immobilization of enzymes.
- b) Fermentation media.
- c) Recombinant protein.
- d) Production of biopesticides.

**Q4)** Write different food ingredients and additives prepared by process of fermentation. **[10]**

OR

Discuss in details different techniques used for screening of industrial important microbes.



Total No. of Questions : 4]

SEAT No. :

**P4001**

[Total No. of Pages : 1

**[5246]-229**

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

**PROJECT MANAGEMENT**

**(2013 Pattern) (Elective)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instruction to the candidates:*

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

**Q1)** Explain the concept of team development with special emphasis on important stages of development of team building for a project. **[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 'Project life cycle' with reference to a typical pharmaceutical project with special emphasis on role of project manager.





Total No. of Questions : 4]

SEAT No. :

**P4002**

[Total No. of Pages : 1

**[5246]-230**

**M. Pharmacy**

**PHARMACEUTICAL ADMINISTRATION**

**(2013 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 50*

*Instructions to the candidates:*

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

**Q1)** What is Leadership? Give various styles of leadership and focus on managerial grid. **[10]**

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

- A) Performance appraisal.
- B) Departmentalization.
- C) Direct and preventive control.
- D) Functions of management.

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

- A) Management by result.
- B) Maslow's theory of motivation.
- C) Managerial training.
- D) Decision making.

**Q4)** Explain process, steps involved in planning. Focus on strategic planning. **[10]**

OR

What are principles of organizing? Give the concept of span of control and developing positive organizing culture.



Total No. of Questions : 4]

SEAT No. :

**P4003**

[Total No. of Pages : 1

**[5246]-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) *Black figures to the right indicate full marks.*

**Q1)** What are different dental cosmetic products? Describe in detail rheology of dentifrices. Add a note on evaluation test for dental products. **[10]**

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

- a) Explain in detail about the formulation and evaluation of sunscreens.
- b) Give account of evaluation tests for lipsticks.
- c) Write in detail about the formulation techniques of aerosol cosmetics.
- d) Protocol for skin sensitivity testing.

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

- a) Advances in cosmetics
- b) Evaluation of Hair care cosmetic products
- c) Various types of cosmetic creams
- d) Regulatory requirements for cosmetic products

**Q4)** Describe in detail formulation development of Herbal Cosmetics. **[10]**

OR

What are preservatives? Write a note on preservative raw material used in cosmetics. Explain identification and quantification of sodium benzoate.

