Total No. of Questions : 4]

SEAT No. :

P3600

[Total No. of Pages : 2

[4750] - 101

M.Pharmacy (Semester - I)

ADVANCED ANALYTICAL TECHNIQUES

(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) Give theory and various fragmentation patterns in Mass spectroscopy. **[10]**

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

a) Discuss Woodward-fieser rules for calculating UV absorption in Dienes.

b) Explain IR spectra for functional groups like-COOH and C-O-C.

c) Write principle of thermogravimetric analysis.

d) Give an account of GCMS technique.

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

a) Scanning Electron Microscopy.

b) Applications of UPLC techniques.

c) Sampling Techniques in IR Spectroscopy.

d) Discuss about factors affecting Chemical Shift.

P.T.O.

Q4) Elucidate the 158 **[10]**

UV = 225nm, ε_{max} 50

IR = 3077-2857 cm^{-1}, 1828 cm^{-1}, 1757 cm^{-1}, 1457 cm^{-1}

NMR = 7.30τ septate (6.4 squares) and 8.80τ doublet (37.2 squares)

OR

Give an account of theory, steps and applications of HPTLC.

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

P3601 **[Total No. of Pages : 1**

[4750] - 102
M.Pharmacy (Semester - I)
RESEARCH METHODOLOGY
(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) What is research tool? Explain various research tools in detail. **[10]**

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

a) Statistical significance of coefficient of correlation.

b) Funding schemes of AICTE.

c) Basic principle of experimental design.

d) Comparison of one way and two ways ANOVA.

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

a) Techniques of Documentation.

b) 'Instruction Authors' of IJPS journal.

c) Sources for procurement of research grants.

d) Application of linear regression of standard curves in drug analysis.

Q4) Describe the use of t test and standard deviation in evaluation of data. **[10]**

OR

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

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

P3602 **[Total No. of Pages : 2**

[4750] - 103

M.Pharm. (Semester - I)

ADVANCED PHARMACEUTICS

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Explain the concept of Preformulation studies. Describe preformulation parameters for biotechnological products. **[10]**

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

a) Define microencapsulation. Explain in short release kinetics of drug from microcapsules.

b) Explain various biodegradation pathways of drug.

c) Discuss principles of quality assurance.

d) Explain applications of biodegradable polymers in medicine.

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

a) Standardization of excipients

b) Determination of shelf life.

c) Explain various super disintegrating agents used in pharmacy.

d) Importance of in vitro dissolution studies.

P.T.O.

Q4) Discuss applications of polymers in Pharmacy. Add a note on Characterization of polymers. **[10]**

OR

Describe various optimization techniques. Explain in detail factorial design approach.

Total No. of Questions : 4]

SEAT No. :

P3603

[Total No. of Pages : 2

[4750] - 104

M. Pharmacy (Semester - I)

ADVANCED PHARMACEUTICAL CHEMISTRY

(Spl. Pharmaceutical Chemistry)

(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) What is solid phase synthesis? Explain the mechanism of protection deprotection and coupling reaction in solid phase chemistry. **[10]**

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

a) What are chiral drug? Explain asymmetric synthesis of any two drugs.

b) Explain Grignard Reaction

c) Discuss the mechanism, stereochemistry and applications of Wagner-Meerwein - Rearrangement

d) Advantages of Green chemistry

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

a) Water as solvent

b) Hydrogenation

c) Pinacol-Pinacolone rearrangement

d) Wolff Rearrangement

P.T.O.

Q4) What is recemic mixtures. Explain different methods of resolution of recemic mixtures. **[10]**

OR

Explain use of diazomethane and peracids in synthesis

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Total No. of Questions : 4]

SEAT No. :

P3604

[Total No. of Pages : 1

[4750] - 105

M. Pharmacy (Semester - I)

ADVANCED PHARMACOLOGY - I

(Preclinical Evaluation of Drugs)

(2013 Pattern)

Time :03 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 labeled diagrams wherever necessary.***

Q1) Discuss the requirements of animal house and maintenance of records as per the guidelines of CPCSEA. **[10]**

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

a) Screening of antifertility agents.

b) Screening of muscle relaxants.

c) Explain any two methods of for evaluation of antihypertensives.

d) Screening of peripheral analgesic activity.

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

a) Safety assessment tests.

b) Alternatives to animal studies.

c) Bioassay of Insulin.

d) Screening of antitussives.

Q4) Discuss the preclinical evaluation of anticonvulsants agents. **[10]**

OR

Discuss the preclinical evaluation of local anesthetics.

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

P3605

[Total No. of Pages : 1

[4750] - 106
M.Pharmacy (Semester - I)
ADVANCED PHARMACOGNOSY
(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) Elaborate a detail account of Biosynthetic pathway for Benzoic acid from C_6C_3 compunds. **[10]**

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

a) Explain oxidative cleavage of aromatic rings.

b) Explain ethnobotanical approach to drug discovery.

c) Explain Ecological functions of plant secondary metabolites.

d) Explain sample preparation for HTS.

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

a) Extender groups other than malonate in Aromatic polyketides.

b) General biosynthetic pathway for unsaturated fatty acids.

c) D - Tubocurarine.

d) Herbal shampoo.

Q4) Elaborate a detail account for biosynthetic pathway for Isoflavonoids. **[10]**

OR

Explain empirical and Rational approaches of drug discovery.

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

P3606

[Total No. of Pages : 1

[4750] - 107
M.Pharmacy (Semester - I)
ADVANCED QUALITY ASSURANCE TECHNIQUES - I (cGMP & DOCUMENTATION)
(2013 Pattern)

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

Instructions to the candidates:

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

Q1) What are the measures suggested for controlling contamination in clean rooms? **[10]**

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

a) Discuss 'PAT: Principles and Tools"

b) Write note on Expiration dating

c) Why are the reference (reserve) samples maintained?

d) State the contents of SOP on handling of the rejected materials.

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

a) Plant Security

b) HVAC system

c) Site Master File

d) Product Recalls

Q4) What are the requirements of Organization and personnel as per USFDA? **[10]**

OR

Discuss modes of outsourcing in Pharma manufacture.

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

P3607 **[Total No. of Pages : 1**

[4750]-108

M. Pharmacy (Semester - I)

Traditional System of Medicine and Ayurvedic Formulations

(2013 Pattern) (Credit System)

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

Instructions to the candidates:

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

c) Explain the principles of Ayurvedic system of medicine

d) Give an account of diagnosis and treatment of Unani system of medicine.

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

a) Rasayana

b) Taila

c) Guggulu

d) Bhasmas

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

OR

Explain the evaluation and standardization of Ayurvedic cosmetic formulations.

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Total No. of Questions : 4]

SEAT No. :

P3608

[Total No. of Pages : 2

[4750] - 109

M. Pharmacy (Semester - I & II)

BIOPHARMACEUTICS AND PHARMACOKINETICS

(2013 Pattern) (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.***
3) ***All questions are compulsory.***

Q1) What are pharmacokinetic models ? Write in detail on compartment modeling. Explain applications of compartment modeling. **[10]**

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

a) Why manufacturer is happy with Level A-IVIVC for new dosage form ?

b) What is the need of indivisualization of therapy if drug exhibits non linear kinetics ?

c) When drug displacement interactions are clinically non significant ?

d) Explain importance of bioequivalence study.

P.T.O.

Q3) Write short notes on any Three - **[15]**

a) Method to improve dissolution of poorly soluble hydrophobic drug.

b) Three compartment model.

c) Area under the curve.

d) In vitro models for determination of permeability.

Q4) Discuss physiological transporter systems and their significance. Add a note on PGP-transporter system. **[10]**

OR

Discuss various in vitro dissolutions testing models (designs).

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Total No. of Questions : 4]

SEAT No. : [ ]

P3609

[Total No. of Pages : 2

[4750] - 110

M. Pharmacy (Semester - I & II)

COSMETICOLOGY

(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Explain preservatives used in cosmetic formulations and their assessment. **[10]**

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

a) Discuss regulatory requirements for cosmetic products.

b) Describe composition of nail lacquers.

c) Describe various types of creams.

d) Give account of evaluation tests of shampoos.

P.T.O.

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

a) Antiperspirants and deodorants.

b) Evaluation of lipsticks.

c) Preservatives used in skin preparation.

d) Measurement of SPF.

Q4) Briefly describe various skin products and give protocol for sensitivity testing. **[10]**

OR

What are components of sunrays responsible for skin damage ? Describe formulation and Evaluation parameters for sunscreens.

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

P3610 **[Total No. of Pages : 1**

[4750]-111
M.Pharmacy
STERILE PRODUCTS FORMULATION AND TECHNOLOGY
(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 indicate full marks.***

Q1) Explain formulation and manufacturing process for small volume parenterals. **[10]**

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

a) Explain the role of the pH and tonicity adjustment in parenterals.
b) Drug-Excipient compatibility testing in Preformulation of parenterals.
c) Plastic as packaging component.
d) Classify the different methods of preparation of liposomes and Discuss any one.

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

a) HVAC system
b) Ocuserts
c) BFS and FFS technology
d) Parenteral devices

Q4) Discuss in detail overview of GMP Guideline for manufacturing of parenteral product. **[10]**

OR

Mechanism and validation of Autoclave sterilization.

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

P3611 **[Total No. of Pages : 1**

[4750]-112

M.Pharmacy (Semester - I)

QUALITY ASSURANCE TECHNIQUES IN HERBAL PRODUCTS

(2013 Pattern) (Theory)

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

Instructions to the candidates:

1) ***Question no. one is compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

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

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

a) Elaborate equipment-URS and qualifications.
b) Discuss about Packaging development.
c) Write in detail about outsourcing.
d) What are the analytical method development guidelines for herbal formulations.

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

a) Quality Audits
b) Pharmacovigilance for herbal products
c) Cleaning validation
d) Quality control and standardization of medicinal plant

Q4) Enlist various parameters recommended by WHO for evaluation of herbal drugs. **[10]**

OR

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

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

P3612 **[Total No. of Pages : 1**

[4750]-113
M.Pharmacy
FERMENTATION 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 indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

Q1) Explain in detail the applications of microbes in food process operations and production. **[10]**

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

a) What is upstream process? Explain the importance of inoculum development in fermentation.

b) Explain different techniques used for strain improvement.

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

d) What is biorector? Explain any one continuous biorector.

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

a) Production of bioethanol.

b) Immobilization of enzymes.

c) Recombinant protein

d) Importance of sterilization in fermentation.

Q4) How will you measure growth of industrial useful microbes. **[10]**

OR

Explain different factors affecting microbial growth. Explain growth kinetics.

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Total No. of Questions : 4]

SEAT No. : ____

P3613

[Total No. of Pages : 1

[4750]-114
M.Pharmacy (Semester - I & II)
PROJECT 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) Explain the importance of project management; give suitable cases from pharmaceutical projects for manufacturing on small scale. **[10]**

Q2) Write comments on (Attempt any three) : **[15]**

a) Role of project Manager
b) Schedule of project
c) Project planning process
d) Reporting of project objective during execution of project.

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

a) Optimum utilization of resources and execution of project
b) Significance of effective communication by team leader.
c) Management of conflict of interest
d) Project team development

Q4) What is the importance of project evaluation and review technique (PERT) in project management; also explain the concept of critical path method (CPM). **[10]**

OR

How to evaluate/determine/manage the project performance with special reference to team decision.

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

P3614 **[Total No. of Pages : 1**

[4750]-115
M.Pharmacy (Semester - I & II)
PHARMACEUTICAL ADMINISTRATION
(2013 Pattern) (Credit System)

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

Instructions to the candidates:

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

Q1) Explain the process of planning; give types and steps involved in planning. **[10]**

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

a) Explain the process of Decision making.

b) What is departmentalization?

c) Explain the manager development process and training.

d) Discuss the MBO.

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

a) Formal and informal organisation.

b) Leading-a human factor in developing.

c) Production and operation management.

d) Functions of management.

Q4) Definition of staffing. Give systems approach to human resource management. Describe the performance appraisal as staffing function. **[10]**

OR

Give the details of overall control. Explain preventive control, and direct control of the performance.

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

P3615

[Total No. of Pages : 1

[4750] - 201
M. Pharmacy (Semester - II)
(M.2.1) DRUG REGULATORY AFFAIRS
(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 provisions of the act for Loan license manufacturing and import of pharmaceuticals. **[10]**

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

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

b) Explain the guidelines of GMP audit inspection.

c) Explain the role of IP laws in pharma industry.

d) Explain the Trademark filing procedure.

e) HVAC systems in pharmaceutical plant

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

a) Patent system in Europe.

b) GATT.

c) Indian patent Act 1970.

d) Schedule M and Y

e) Water systems in pharmaceutical plant

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

OR

Explain the different sections of NDA.

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Total No. of Questions : 4]

SEAT No. : ____

P3616

[Total No. of Pages : 2

[4750] - 202

M. Pharmacy (Semester - II)

ADVANCED MEDICINAL CHEMISTRY (M-II-3)

(Pharmaceutical Chemistry)

(2013 Pattern) (Theory)

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

Instructions to the candidates:

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

Q1) Explain the role of microorganisms in microbial production of antibiotics with suitable examples. **[10]**

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

a) Add a note on human insulin.

b) What are the different types of receptors? Explain the Cholinergic receptors.

c) Write a brief note on scope and application of Gene therapy.

d) Explain Enzyme immobilization techniques.

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

a) Drugs used in Neurodegenerative disorders.

b) Anti-mycobacterials.

c) Solid phase synthesis of peptide and polypeptide.

d) Anti-inflammatory Steroids and receptors for steroidal drugs including SAR.

P.T.O.

Q4) Write Synthetic routes giving detail mechanism of following drugs describing reaction conditions : (Any Two) **[10]**

a) Ziprasidone

b) Linezolid

c) Ethinyl estradiol

OR

Add a detail note on monoclonal antibodies.

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

P3617 **[Total No. of Pages : 1**

[4750] - 203
M.Pharm (Semester - II)
CLINICAL PHARMACOLOGY
(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Explain clinical practice guidelines and management of congestive heart failure. **[10]**

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

a) Role of tissue transplantation in immunopharmacology.

b) Clinical practice guidelines for hyperlipidemia.

c) Give an account on drug- food interactions.

d) Monitoring of adverse drug reactions.

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

a) ACE inhibitors

b) Poly (ADP- Ribose) Polymerase

c) Phases of clinical trials

d) Antileprotic agents

Q4) Explain in detail pharmacotherapy of hypertension. **[10]**

OR

Give a detailed account on management of diabetes mellitus

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Total No. of Questions : 4]

SEAT No. :

P3618

[Total No. of Pages : 2

[4750] - 204

M. Pharmacy (Semester - II)

(Special Pharmacognosy)

PHYTOCHEMISTRY AND PHYTOPHARMACEUTICALS

(2013 Pattern)

Time :03 Hours] *[Max. Marks :50*

Instructions to the candidates:

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

Q1) Explain the role of chromatographic technique in isolation and purification of phytopharmaceuticals. Quote at least two examples to support your answer. **[10]**

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

a) Describe extraction and isolation of quercetin.

b) Comment on pharmacological importance of Taxol. Explain why a demand for newer techniques for extraction of Taxol prevails in Pharma industry.

c) Give structural elucidation of morphine by spectroscopic data.

d) Enlist various methods for extraction of essential oils with special note on enfluerage method.

Q3) Solve any three questions from the following. **[15]**

a) Write a note on counter current extraction along with its applications.

b) Describe the role of WHO in quality control of herbs.

c) Write a note on Curcumin as an important phytopharmaceutical.

d) Give principle and procedure for determination of Bitterness value.

P.T.O.

Q4) What are the advantages of supercritical fluid extraction technique. Explain with appropriate examples. Highlight on extraction of resveratrol. **[10]**

OR

Describe in details In - Vitro and In - Vivo methods for screening of Hepatoprotective Drugs.

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

P3619

[Total No. of Pages : 1

[4750] - 205
M. Pharmacy (Semester - II)
PHARMACEUTICAL VALIDATION
(Spl. Quality Assurance Techniques)
(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 analytical method validation in detail. **[10]**

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

a) Write about harmonisation of GMP and validation.

b) Describe validation of dissolution test apparatus.

c) Write in brief about vendor selection & qualification process.

d) Write about Calibration Master Plan.

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

a) Equipment cleaning method validation.

b) Process validation and its types.

c) Validation of water system for pharmaceutical use.

d) Computer system validation.

Q4) Explain OQ and PQ for Tablet compression Machine. **[10]**

OR

Explain Validation of HVAC System.

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

P3620

[Total No. of Pages : 1

[4750] - 206
M.Pharmacy (Semester - II)
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 role of propellants in inhalation aerosols. Add a note on quality assurance of Aerosol formulation. **[10]**

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

a) Discuss formulation of Self emulsified drug delivery systems.

b) Discuss regulatory perspective of selection of pharmaceutical packaging materials for novel drug delivery systems.

c) Discuss on penetration enhancers in semisolid formulation.

d) Explain formulation strategy to administer veterinary dosage forms via drinking water.

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

a) Quality by Design.

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

c) Quality assurance of Aerosol formulation.

d) Specialized dose dispensers in veterinary dosage forms.

Q4) Explain in detail formulation of mouth dissolving tablets. **[10]**

OR

Discuss in detail concept of Nutraceuticals.

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Total No. of Questions : 5] **SEAT No. :**

P3621 **[Total No. of Pages : 1**

[4750] - 207
M. Pharmacy (Semester - II)
DRUG DESIGN
(Spl. Pharmaceutical Chemistry)
(2013 Pattern)

Time : 2 Hours] ***[Max. Marks : 50***

Instructions to the candidates:

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

Q1) What is QSAR? Give advantages and disadvantages of QSAR. Explain Free Wilson analysis. **[10]**

Q2) Attempt any three questions out of four (3/4) : **[15]**

a) Role of Proteomics in drug discovery.

b) Analog approach for drug design with suitable examples.

c) Role of drug design in drug discovery.

d) Drug design based on Enzyme inhibition.

Q3) Attempt any three questions out of four (3/4) : **[15]**

a) Pharmacophore modeling.

b) Cluster analysis.

c) Significance of Metabolism study in drug design.

d) Three dimensional QSAR.

Q4) Drug design based on antagonism. **[10]**

OR

Q5) What are prodrugs? Explain in brief about designing of drug molecule based on metabolism studies with suitable examples. **[10]**

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

P3622 **[Total No. of Pages : 1**

[4750] - 208
M. Pharmacy (Semester - II)
MOLECULAR PHARMACOLOGY
(Spl. Pharmacology)
(2013 Pattern) (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) Explain the process of Apoptosis with its clinical implications. **[10]**

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

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

b) Write a note on neurosteroids and their modulators.

c) Explain the concept of Human Genome Mapping.

d) Discuss implications of chronopharmacology in drug therapy.

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

a) Sodium channel and it's modulators.

b) Glutamate receptors.

c) Phophodiesterase enzyme.

d) Immunostaining techniques in molecular pharmacology.

Q4) Define Immunopharmacology with emphasis on antibody mediated immunity? Add note on monoclonal antibodies. **[10]**

OR

Discuss the recent advances in drugs acting on angiotensin receptors.

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

P3623 **[Total No. of Pages : 1**

[4750] - 209
M. Pharmacy (Semester - II)
NOVEL DRUG DELIVERY SYSTEM
(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) Explain drug transport mechanism across skin and describe technologies for developing transdermal drug delivery system. **[10]**

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

a) Explain design considerations in ocular drug delivery.

b) Describe strategies to enhance bioavailability of BCS class II drugs.

c) Formulation of microemulsions.

d) Describe formulation considerations in vaginal drug delivery.

e) Describe structure classification and preparation methods of niosomes.

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

a) Active and passive drug targeting.

b) Microbial approach for colon targeting.

c) Transdermal permeation enhancers.

d) Analysis of proteins and peptides.

e) Describe preparation and properties of dendrimers.

Q4) Write an account of various evaluation methods for various mucoadhesive systems. **[10]**

OR

Describe various approaches to formulate parenteral long acting formulations.

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Total No. of Questions : 4]

SEAT No. :

P3624

[Total No. of Pages : 1

[4750] - 210

M. Pharmacy (Semester - II)

INDUSTRIAL PHARMACOGNOSY

(2013 Pattern)

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

Instructions to the candidates:

1) ***Attempt all questions.***

2) ***Figures to the right indicates full marks.***

Q1) What are requirements for of National drug safety monitoring system in order to widen scope of herbal medicines? **[10]**

Q2) Discuss in brief methods of stabilization of Herbal formulations. Give the parameters for stability of herbal medicine. **[10]**

Q3) Global regulatory status of Herbal drugs. **[15]**

OR

What are different types of Patents? Explain in brief process involved in grant of patent within purview of Indian Patent Act.

Q4) Write notes on (Any three) **[15]**

a) Commercialization of Natural product in india.

b) Objectives of WHO guidelines on safety monitoring of herbal drugs in pharmacovigiliance system.

c) Conditions of licences for manufacturing of Ayurvedic and Unani drugs.

d) Potential for Herbal-Drug interaction.

Total No. of Questions : 4]

SEAT No. : ____

P3625

[Total No. of Pages : 1

[4750] - 211

M.Pharm. (Semester - II)

QUALITY PLANNING AND ANALYSIS

(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" and discuss its two dimensions. **[10]**

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

a) What are the steps of "Improve phase" in six sigma concept?

b) Comment on 'Overall review of manufacturing planning".

c) Enlist examples of quality measurement in manufacturing operations.

d) Explain application of PRE-control.

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

a) Error-Proofing the process.

b) Process Capability.

c) Quality Indexes for Acceptance Sampling Plans.

d) Self control.

Q4) Discuss disposition of non - conforming product. **[10]**

OR

Discuss principles of Quality Audit Program.

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

P3626 [Total No. of Pages : 1

[4750]-212

M. Pharmacy (Semester - I & II)

ACTIVE PHARMACEUTICAL INGREDIENTS (APIS) MANUFACTURING TECHNOLOGY (Theory)

(2013 Pattern) (Credit System)

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

Instructions to the candidates:

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

Q1) Discuss in detail about Alkylation and Esterification process of manufacturing. **[10]**

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

a) Write about Fine and Heavy Chemicals in industry.

b) Discuss Environment Protection laws.

c) Chromatographic techniques in manufacturing technology.

d) Discuss about effects of Sound and Ultrasound.

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

a) Amination process in industry

b) Types of Eye protection equipments.

c) Fluidized bed dryers

d) Radiation hazards

Q4) Describe in detail manufacturing process of Aspirin and Ciprofloxacin. **[10]**

OR

Give detail about intermediates and fine chemicals in API manufacturing.

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

P3627 **[Total No. of Pages : 1**

[4750]-213

M. Pharmacy (Semester - I & II)

SAFETY 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.***

Q1) Define safety pharmacology. Explain the scope, importance and principles of safety pharmacology. **[10]**

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

a) Discuss various studies for reproductive toxicity testing.

b) Explain the guinea pig sensitization assays for dermatological products.

c) Write in details about principles of safety evaluation of drugs.

d) Explain OECD guidelines for acute oral toxicity.

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

a) Risk benefit assessment in clinical trial.

b) Ames test for mutagenicity.

c) Ocular toxicity testing.

d) Statistic in pharmaceutical safety assessments.

Q4) Discuss about the study design and importance of carcinogenicity studies.**[10]**

OR

Define pharmacovigilance. Write about data collection and reporting in pharmacovigilance.

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

P3628 **[Total No. of Pages : 1**

[4750]-214

M. Pharmacy (Semester - I & II)

CHEMISTRY OF MEDICINAL NATURAL PRODUCTS

(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) Give chemical classification of alkaloids. Write in detail chemistry of alkaloids. **[10]**

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

a) Give the biosynthetic pathway for Atropine.

b) Mention the structural elucidation of Diosgenine.

c) Define and classify Terpenoids, Add on Extraction of Essential oils.

d) Give the general methods of extraction of Glycosides.

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

a) Role secondary metabolites in plants and animals.

b) Plant pigments.

c) Disacharides.

d) Plant steroids.

Q4) Describe methods of analysis for Solasodine. **[10]**

OR

Classify Flavonoids, write down the chemistry of Flavonoids. **[10]**

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

P3629 **[Total No. of Pages : 1**

[4750]-215

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 labeled diagrams wherever necessary.***

Q1) Discuss on the modernization and mechanization of Natural product market. **[10]**

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

a) Explain planning and budgeting of Herbal farming.

b) Write on coordination between collectors and growers.

c) Highlight on trading of preoritized species in international market.

d) Write in short about various government schemes for development of medicinal plants in India.

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

a) Trading of herbs.

b) Import and export of food supplements.

c) Establishment of Herbal extraction unit.

d) IPR of Natural medicinals products.

Q4) Write down the efforts required for storage transport and marketing management of natural products. **[10]**

OR

How to organize land, labour and machine for agricultural development. **[10]**

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Total No. of Questions : 4]

SEAT No. :

P3630

[Total No. of Pages : 2

[4750] - 216

M. Pharmacy (Semester - I)

CLINICAL TRIALS

(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) Justify role of informed consent and institutional review board in ethical conduct of clinical trials. **[10]**

Q2) Solve any three -

a) Explain the importance of Computer applications in data analysis. **[5]**

b) Explain randomization and blinding. **[5]**

c) Explain role of various stakeholders of clinical trials. **[5]**

d) Explain concept and importance of ICH-GCP guidelines. **[5]**

P.T.O

Q3) Short Notes (any three):

a) Special issues in therapeutic drug mentoring. **[5]**

b) Belmont report. **[5]**

c) NDA and ANDA. **[5]**

d) Clinical trial designs. **[5]**

Q4) What is new drug development process ? Explain in detail different phases of clinical trials. **[10]**

OR

Discuss role of FDA in various countries in new drug development.

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Total No. of Questions : 4]

SEAT No. :

P3631

[Total No. of Pages : 2

[4750] - 217

M. Pharmacy (Semester - I) (Credit System)

PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

(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 design, layout and operational facilities for sterile powder ready for reconstitution. **[10]**

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

a) Discuss operation of Q.C. Laboratory.

b) Discuss operational facilities with services and utilities for Liquid orals.

c) Enlist utilities services; write its significance in Pharmaceutical Industry.

d) Write in brief about water system design.

P.T.O.

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

a) Layout and operational facilities for Ointment.

b) Design, layout and operational facilities for Capsules.

c) Support services : security office, vehicle parking, fuel storage, canteen and cooking, garden and horticulture.

d) Design of compressed air.

Q4) Define effluent, writes its complication and describe in detail effluent treatment plant. **[10]**

OR

Discuss in detail revised schedule M and Factory Act.

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

P3632 **[Total No. of Pages : 2**

[4750] - 218

M. Pharmacy

MEDICINAL PLANT BIOTECHNOLOGY

(2013 Pattern)

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

Instructions to the candidates:

1) ***Question number 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.***

Q1) 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. **[10]**

Q2) Solve Any three. **[3 × 5 = 15]**

a) What are different plant signal transduction pathways ? What are Mitogen-activated protein kinases (MAP kinases) ? What are types of MAP kinases?

b) What is an Immobilized Enzyme ? What are its commercial uses ? What are different ways by which one can immobilize an enzyme.

c) 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 ?

P.T.O

d) What are Elicitors for Production of Secondary metabolites ? What is its classification ? What are the different features of Elicitors ?

e) What are Restriction enzymes ? & Give a brief account of its types.

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

a) Gibson assembly & Its advantages.

b) Overview of Ex-citu Germplasm Conservation in Plants.

c) A microRNA.

d) Recombinant DNA molecule & Molecular cloning.

e) Papain.

Q4) a) Define Gene expression. **[10]**

b) What are Regulated stages of gene expression ?

c) Comment on concept of epigenetic regulation & its correlation with the Methylation of DNA.

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

P3633 **[Total No. of Pages : 1**

[4750]-219

M.Pharmacy (Semester - I)

QUALITY CONTROL AND ASSURANCE OF PHARMACEUTICALS

(2013 Pattern)

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 labeled diagrams wherever necessary.***

Q1) Give an account of guidelines for design and implementation of pharmaceutical manufacturing. Documentation (PMD) programme. **[10]**

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

a) Describe concept and components of Quality Assurance.

b) Describe sources of contamination and methods of contamination control.

c) What is Regulatory audit? Provide audit questionnaire for stores dept.

d) Elaborate the concept of QC.

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

a) Revised schedule M

b) Quality control of biological products

c) Media fill test to validate sterile facility

d) Pharmaceutical Water system validation

Q4) Provide detailed overview of different types of documents used in sterile formulation facility. **[10]**

OR

Explain your concept of materials management with suitable examples and documents.

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

P3634 **[Total No. of Pages : 1**

[4750]-220
M.Pharmacy (Semester - I & II)
TOXICOLOGY
(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Define maximum tolerated dose and LD50.Explain in brief about determination of LD50 as per OECD guidelines. **[10]**

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

a) Explain the allergic reaction caused by xenobiotics.

b) Write about safety analysis in preclinical toxicity studies.

c) Discuss the carcinogenesis produced by environmental chemicals.

d) Write the sources and classification of toxic agents.

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

a) Teratogenic effect

b) Cell culture technique in toxicology

c) Factors influencing single and repeat dose toxicity

d) Application of forensic and clinical toxicology

Q4) Discuss in details about the analysis of toxic lung damage. **[10]**

OR

Explain the preclinical toxicological Requirements for biological products.

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

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

[4750]-221
M.Pharmacy (Semester - I & II)
Clinical Pharmacokinetics and Pharmacodynamics
(2013 Pattern)

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 labeled diagrams wherever necessary.***

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

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

a) Explain importance of clearance as pharmacokinetic parameter.

b) Describe the method for determination of Vmax and Km.

c) Discuss implications of drug protein binding in pharmacokinetics.

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

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

a) Protein drugs

b) Dose individualization

c) Apparent Volume of distribution

d) Drug ionization and P^H partition hypothesis

Q4) Define area under drug plasma concentration-time curve. Discuss various methods to determine the 'Area Under Curve'. **[10]**

OR

Describe the Wagner-Nelson method for determination of absorption rate constant. What is the limitation of this method?

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

P3636 **[Total No. of Pages : 1**

[4750]-222
M.Pharmacy (Semester - I)
CLINICAL IMMUNOLOGY & ENZYMOLOGY
(2013 Pattern)

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

Instructions to the candidates:

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

Q1) Enlist the tumor antigens and add note on immune response to tumors. **[10]**

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

a) Acquired immunodeficiency.

b) Mechanisms of autoimmunity.

c) What is hybridoma? Explain its applications in immunology.

d) Define immunity. Elaborate on its diffferent types.

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

a) Explain fusion method of hybridoma

b) Applications of monoclonal antibodies

c) Biosensor technology

d) Enzyme kinetics

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

OR

Describe the diagnostic and therapeutic value of enzymes with suitable examples.

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

P3637 **[Total No. of Pages : 1**

[4750]-223

M.Pharmacy (Semester - I)

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) Explain in detail plant site selection, layout and organization of pharmaceutical industries. **[10]**

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

a) What are Simplex and Lagrangian models?

b) Explain total quality management and productivity.

c) Elaborate on quality assurance and GMP considerations.

d) Describe the pilot plant scale up for liquid preparations.

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

a) Mechanical, electrical and electronic parts of pharmaceutical machinery, equipment

b) Material handling for various pharmaceutical products

c) Requirements related to manufacture and sale of drugs

d) Drugs and Cosmetics Act

Q4) Describe industrial hazards due to fire, accident, mechanical and electrical equipment, chemical and pharmaceuticals, monitoring and preventive system. **[10]**

OR

Give details about effluent testing and treatment : for pharmaceutical industry.

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