

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 = 7.30 τ septate (6.4 squares) and 8.80 τ 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.

⌚ ⌚ ⌚ ⌚

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 racemic mixtures. Explain different methods of resolution of racemic mixtures. **[10]**

OR

Explain use of diazomethane and peracids in synthesis



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.



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 compounds. **[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.



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 1 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.



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.



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 individualization 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).



Total No. of Questions : 6]

SEAT No. :

P3571

[Total No. of Pages : 2

[4750] - 11

M.Pharmacy (Semester - I)
ADVANCED ANALYTICAL TECHNIQUES
(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Question No. 1 and 4 are compulsory.*
- 2) *Attempt any one question from the remaining in Section - I and any one from the remaining question of Section - II.*
- 3) *Answer to the two sections should be written on the separate books.*
- 4) *Draw diagram whenever necessary.*
- 5) *Figures to the right indicate full marks.*

SECTION - I

Q1) a) A compound with molecular weight 116 gives following structural information

UV: 283 m μ , ϵ_{\max} 22

IR : 3000-2500, 1715, 1342 cm⁻¹

NMR : 7.88 τ Singlet (3H), 7.40 τ Triplet (2H), 7.75 τ Triplet (2H), 1.1 τ singlet (1H) Deduce the structure of the compound. **[8]**

b) Discuss various transitions in UV spectroscopy. **[8]**

c) Give applications of IR spectroscopy. **[4]**

Q2) a) Discuss in detail theory, instrumentation and applications of NMR spectroscopy. **[8]**

b) Write about Finger Print region in IR spectroscopy. **[8]**

c) Write about Emission spectroscopy. **[4]**

P.T.O.

- Q3)** a) Give an account of theory, instrumentation and applications of mass spectroscopy. [8]
b) Discuss about Chromophores in UV Spectroscopy. [8]
c) Write note on HPTLC. [4]

SECTION - II

- Q4)** a) Write about theory, instrumentation and application of HPLC. [10]
b) Discuss theory, instrumentation and application of GC-MS. [10]

- Q5)** a) Give an account of Differential Scanning Calorimetry. [10]
b) Write about Derivative Thermogravimetric analysis. [10]

- Q6)** a) Write about Ion pair Chromatography. [10]
b) Explain theory and applications of X-ray diffraction techniques. [10]



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.



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.



Total No. of Questions : 6]

SEAT No. :

P3572

[Total No. of Pages : 1

[4750] - 12
M.Pharmacy (Semester - I)
RESEARCH METHODOLOGY
(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Questions 1 and 4 are compulsory.*
- 2) *Attempt any one questions from the remaining in Section - I and any one questions from the remaining questions of Section - II.*
- 3) *Answers to the two sections should be written in separate books.*

SECTION - I

- Q1)** a) Give an account of sources for survey of literature. [10]
b) Explain process of making a research proposal. [10]
- Q2)** a) Describe the various types of research in detail. [10]
b) Explain in detail student t test. [10]
- Q3)** a) What is interpretation of data? Give the need and importance of interpretation of data. [10]
b) Discuss the different forms of questionnaire. Give its advantages and disadvantages. [10]

SECTION - II

- Q4)** a) What is a patent? Describe importance of patent in research. [10]
b) Explain the importance of poster, gesture, eye contact and expressions in oral presentation. [10]
- Q5)** Why protection is needed on intellectual property? Give the detailed account of historical development of concept of intellectual property rights. [20]
- Q6)** Write notes on any two of the following : [20]
a) Industrial project as part of industry institute interaction.
b) Trademark designs and copyrights.
c) Status of intellectual property rights in India.



Total No. of Questions : 6]

SEAT No. :

P3573

[Total No. of Pages : 2

[4750]-13

M.Pharm. (Semester - I)

ADVANCED PHARMACEUTICS

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Attempt any 2 questions from each section.*
- 2) *Draw well labeled diagram wherever necessary.*
- 3) *Figures to the right indicate full marks.*

SECTION - I

Q1) Explain in detail the importance and methodology of stability testing of pharmaceutical dosage forms. [20]

Q2) Explain different parameters studied in preformulation of a solid dosage form. Add a note on solid state characterization. [20]

Q3) Write short notes on (any two) : [20]

- a) Characterization of polymers.
- b) Co-processed excipients.
- c) Biodegradable polymers.

P.T.O.

SECTION - II

Q4) Explain the experimental design approach used in the optimization of formulations. Write a note on classification of optimization methods. [20]

Q5) Discuss the applications and evaluation of microcapsules. Explain in detail any one technique used for the preparation of microcapsules. [20]

Q6) Write short notes on (any two) : [20]

- a) Correlation and regression analysis.
- b) Importance of Dissolution.
- c) Quality assurance and quality control.



Total No. of Questions : 8]

SEAT No. :

P3574

[Total No. of Pages : 2

[4750] - 14

M. Pharmacy (Semester - I)

ADVANCED PHARMACEUTICAL CHEMISTRY

Spl. Pharmaceutical Chemistry

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Question number one and five are compulsory out of remaining attempt any 2 questions from each Section I and Section II.*
- 2) *Figures to the right indicate full marks.*
- 3) *Draw well labeled diagrams wherever necessary.*

SECTION - I

Q1) Explain Sharpless oxidation. [10]

Q2) Give brief account of green chemistry. Explain reactions using microwave and ultrasound energy. [15]

Q3) Explain Synthon approach for drug synthesis. Develop synthetic route for any two drugs using synthon approach. [15]

Q4) Write note on any Two : [15]

- a) Allylic bromination
- b) Free radical reaction
- c) Oppenauer oxidation

P.T.O.

SECTION - II

Q5) Explain mechanism, stereochemistry and applications of Grignard reaction. **[10]**

Q6) What is Pinacole - pinacolone rearrangement, explain along with reaction mechanism, stereochemistry and applications. **[15]**

Q7) Explain Stereospecificity and Stereoselectivity with suitable examples. **[15]**

Q8) Write note on any Two : **[15]**

- a) Suzuki coupling
- b) Wolf Kishner reduction
- c) Ionic liquid and Supercritical liquid



Total No. of Questions : 6]

SEAT No. :

P3575

[Total No. of Pages : 1

[4750] - 15

M. Pharmacy (Semester - I)
ADVANCED PHARMACOLOGY - I
(2008 Pattern)

Time :3 Hours]

[Max. Marks :80

Instructions to the candidates:

- 1) Answers to each section should be written in separate answer - books.*
- 2) Solve any two questions from each section.*

SECTION - I

Q1) Discuss the preclinical evaluation of antihypertensive agents. **[20]**

Q2) Discuss the preclinical evaluation of bronchodilators and antitussives. **[20]**

Q3) Write notes on (any two): **[20]**

- a) Patch clamp technique.
- b) Screening of anti - parkinsonian agents.
- c) Transgenic animals.

SECTION - II

Q4) Discuss the preclinical evaluation of anxiolytics and antidepressants. **[20]**

Q5) Discuss the preclinical evaluation of cardiac glycosides and antiarrhythmic agents. **[20]**

Q6) Write notes on (any two): **[20]**

- a) Screening of local anaesthetics.
- b) Breeding techniques for laboratory animals and CPCSEA guidelines for breeding of laboratory animals.
- c) RIA.



Total No. of Questions : 8]

SEAT No. :

P3576

[Total No. of Pages : 2

[4750] - 16

M. Pharmacy (Semester - I)
ADVANCED PHARMACOGNOSY
(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Question No.1 and Question No. 5 are compulsory out of remaining attempt two questions from Section - I and two questions from Section - II.*
- 2) *Answers to the two sections should be written in separate answer books.*
- 3) *Neat diagrams must be drawn wherever necessary.*
- 4) *Figures to the right side indicate full marks.*

SECTION - I

Q1) Explain various strategies used to enhance secondary metabolite production through tissue culture techniques. **[10]**

Q2) Answer the following :

- a) Explain application of tracer techniques in evaluation of biogenetic pathways of secondary metabolites. **[7]**
- b) Illustrate flavonoids as chemotaxonomic marker with suitable example. **[8]**

Q3) Explain the characteristics of natural products that make them appropriate material in discovering new drugs. Describe Vinca alkaloids as anticancer agent. **[15]**

Q4) Write note on the following (Any Three) : **[15]**

- a) Application of Chemotaxonomy in medicinal botany.
- b) Advantages of Chemotaxonomy.
- c) Strategies for selection of plant material for HTS.
- d) Flavouring agents derived from plants.

P.T.O.

SECTION - II

- Q5)** Elaborate a detail account of Flavanoids as Hypolipidaemic agents with suitable examples. **[10]**
- Q6)** Answer the following:
- a) Explain anticancer role of Taxol and its derivatives. **[7]**
 - b) Review the plants having Antidiabetic activity. **[8]**
- Q7)** Write various *in vivo* models used for evaluation of Immunomodulatory activity. Explain Ginseng as immunomodulatory agent. **[15]**
- Q8)** Write note on the following (Any Three): **[15]**
- a) Androgapholide as a Hepatoprotective agent.
 - b) Biopolymers as Pharmaceutical Excipients.
 - c) Photosensitizing agents derived from plants.
 - d) Biofuels.



Total No. of Questions : 8]

SEAT No. :

P3577

[Total No. of Pages : 1

[4750] - 17

M.Pharmacy (Semester - I)
ADVANCED QUALITY ASSURANCE TECHNIQUES
(c GMP & Documentation)
(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) Question numbers 1 and 5 are compulsory.*
- 2) Out of the remaining attempt any two questions from each section.*
- 3) Answer to the two sections should be written in separate answer books.*
- 4) Figures to the right indicate full marks.*

SECTION - I

- Q1)** Discuss SOP on handling market complaints. **[12]**
- Q2)** Explain the importance of time limit at various stages in manufacture. Add a note on sanitation in manufacturing area. **[14]**
- Q3)** Write a note on “Drug product salvaging” **[14]**
- Q4)** Discuss importance of Environmental Protection in pharmaceutical industry. **[14]**

SECTION - II

- Q5)** Write a note on design and structural features of manufacturing facility. Add a note on HVAC system. **[12]**
- Q6)** Discuss contents of “Site Master File” **[14]**
- Q7)** a) Explain maintenance of equipments in pharma manufacturing
b) What is outsourcing? **[14]**
- Q8)** What are the requirements for Expiration dating as per cGMP? Add a note on reference standards. **[14]**



Total No. of Questions : 8]

SEAT No. :

P3578

[Total No. of Pages : 2

[4750]-18

M. Pharmacy (Semester - I)

Traditional System of Medicine and Ayurvedic Formulations

(2008 Pattern)

[Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q. no. 1 and 5 are compulsory.*
- 2) *Out of the remaining attempt any two questions from Section I and any two questions from Section - II.*
- 3) *Answers to the Two sections should be written in separate books.*
- 4) *Figures to right indicate full marks.*

SECTION - I

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

Q2) a) Explain the principle of Ayurveda and add a note on Panchakarma [8]

b) What is Homeopathy system of medicine. Write a brief note on Homeopathic dilutions [7]

Q3) Give an account of Ethnopharmacognosy in modern drug discovery [15]

Q4) Write short notes (Any Three) [15]

- a) Charak Samhita
- b) Principle of Chinese system of medicine
- c) Rasayan in Ayurveda
- d) Acupuncture.

P.T.O.

SECTION - II

Q5) Write in detail about preparation of Bhasma in Ayurveda. Give the characteristics, evaluation parameters and storage conditions of Bhasmas. [10]

Q6) What is Asava and Arishta. Give their methods of preparation with examples [15]

Q7) Define Standardization and explain in detail Physical, Chemical and Microscopical methods of evaluation of herbal drugs. [15]

Q8) Write short notes (Any Three) [15]

- a) Churna
- b) Taila
- c) Lepa and Kvatha
- d) Ghruta.



Total No. of Questions : 6]

SEAT No. :

P3579

[Total No. of Pages : 2

[4750] - 19

M. Pharmacy (Semester - I & II)

BIOPHARMACEUTICS AND PHARMACOKINETICS

(2008 Pattern) (Elective)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) Answer any 02 questions from each section.*
- 2) Answers to the two sections should be written in separate books.*
- 3) Neat diagrams must be drawn wherever necessary.*
- 4) All questions carry equal marks.*

SECTION - I

Q1) What is in vitro in vivo correlation (IVIVC) ? Explain the need and objectives of IVIVC. Discuss various levels of IVIVC.

Q2) Discuss the methods of determination of rate of absorption.

Q3) Write notes on any two -

- a) Noyes - Whitney's dissolution rate law.
- b) Physiological transporter systems.
- c) In vitro models for determination of absorption.

P.T.O

SECTION - II

Q4) Write on assessment of various pharmacokinetic parameters when the drug is administered as IV infusion. Explain the need of loading dose in this case.

Q5) Discuss kinetics of protein binding.

Q6) Write notes on any two -

- a) Michaelis - Menten equation.
- b) Causes and detection of nonlinearity.
- c) Concept of clearance and its determination.



Total No. of Questions : 8]

SEAT No. :

P3580

[Total No. of Pages :2

[4750]-20

M. Pharm. (Semester - I & II)

STERILE PRODUCTS FORMULATION AND TECHNOLOGY

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) Question No. 1 and 5 are compulsory. Out of the remaining attempt two questions from section I and two questions from section II.*
- 2) Answers to the two sections should be written in separate books.*
- 3) Draw a neat and labeled diagrams wherever necessary.*
- 4) Figures to the right indicate full marks.*

SECTION - I

Q1) Explain in detail methods of preparation of liposomes and applications of liposomes for parenteral delivery. **[12]**

Q2) Explain in detail formulation and manufacturing of parenteral solution. **[14]**

Q3) Write a note on physicochemical properties of the drug studied during preformulation of the parenteral product. **[14]**

Q4) Write a short note on (Any Two) : **[14]**

- a) Ocular inserts
- b) Loaded erythrocyte
- c) Plastic as a packaging component for parenteral product.

P.T.O.

SECTION - II

Q5) Explain components of HEPA filter. Write a note on HEPA filter testing and Rating. **[12]**

Q6) What are different large scale sterilization process? Give the account of validation of Autoclave. **[14]**

Q7) Write a note on GMP and regulatory guidelines for the manufacturing of parenteral product. **[14]**

Q8) Write a short note on (Any Two) : **[14]**

- a) Parenteral devices-canula and catheter
- b) Layout of parenteral facility
- c) Mechanism, advantages and drawbacks of autoclave sterilization



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.



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



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.



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.



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 its modulators.
- b) Glutamate receptors.
- c) Phosphodiesterase 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.

⌚ ⌚ ⌚ ⌚

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.

⌚ ⌚ ⌚ ⌚

Total No. of Questions : 8]

SEAT No. :

P3581

[Total No. of Pages : 2

[4750] - 21

M.Pharmacy. (Semester - II)
DRUG REGULATORY AFFAIRS
(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q. No. 1 & 5 are compulsory, out of remaining attempt two questions from section-I and two questions from section-II.*
- 2) *Answer to the two sections should be written in separate books.*
- 3) *Figures to the right indicate full marks.*

SECTION - I

Q1) Write the constitution and composition of the State Pharmacy Councils. [10]

Q2) a) Write the salient features of Indian Patent Act 1970. [8]

b) Write the salient features of DPCO 1995. [7]

Q3) a) Explain the provisions related to Pollution and Environment Control Act. [8]

b) Write the qualification and duties of Drug Inspector. [7]

Q4) Write short notes on following (any three) [15]

a) Labeling of drugs.

b) Drug Master File

c) ISO

d) USFDA

SECTION - II

Q5) Explain the Schedule-M requirements related to premises, sanitation & hygiene. [10]

Q6) a) Write the functions of Central Drugs Laboratory. [8]

b) Write in detail about import of drugs. [7]

Q7) a) Elaborate the different sections of NDA. [8]

b) Write the conditions of loan license to manufacture for sale of drugs. [7]

P.T.O.

Q8) Write short notes on following (any three)

[15]

- a) Pharmacopeias.
- b) Good Clinical practices.
- c) WHO
- d) MSDS preparation



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 pharmacovigilance 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.



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.



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.



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) Disaccharides.
- d) Plant steroids.

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

OR

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



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]**



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.



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.



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.



Total No. of Questions : 6]

SEAT No. :

P3582

[Total No. of Pages : 2

[4750] - 22

M.Pharmacy (Semester - II)

ADVANCED MEDICINAL CHEMISTRY (M-II-3)

(Pharmaceutical Chemistry)

(2008 Pattern) (Theory)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q.No.1 and Q.No.4 are compulsory.*
- 2) *Attempt any one question from remaining questions from each section.*
- 3) *Write answers to section I and Section II in separate answer book.*

SECTION - I

Q1) a) Write applications of microorganisms in biotransformation of antibiotics. **[15]**

b) Write a note on enzyme immobilization techniques. **[5]**

Q2) a) What are the different types of receptors ? Explain the adrenergic receptors. **[15]**

b) Explain supporters and linkers in combinatorial chemistry. **[5]**

Q3) a) Explain applications of QSAR in drug design. **[10]**

b) Write a brief note on CADD. **[10]**

P.T.O.

SECTION - II

Q4) Write Synthetic routes giving detail mechanism of following drugs describing reaction conditions: (Any Two) **[20]**

- a) Gefitinib
- b) Risperidone
- c) Linezolid
- d) Diazepam

Q5) a) Write a note on Combinatorial chemistry. **[10]**

b) Draw synthesis scheme with detail mechanism of Diphenhydramine. **[10]**

Q6) Write notes on any two: **[20]**

- a) Enzyme inhibition
- b) Gene therapy
- c) Dopamine receptors



Total No. of Questions : 6]

SEAT No. :

P3583

[Total No. of Pages : 2

[4750] - 23

M.Pharm. (Semester - II)

CLINICAL PHARMACOLOGY

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q. 1 & Q.4 are compulsory.*
- 2) *Solve any one question from remaining two for each section.*

SECTION - I

Q1) Describe in detail the management of hypertension. **[20]**

Q2) a) Describe in detail pharmacotherapy of hyperlipidemia. **[10]**

b) Chronic obstructive pulmonary disease. **[10]**

Q3) a) Rational use of antibiotics. **[5]**

b) Management of angina pectoris. **[5]**

c) Role of immunomodulators in immunopharmacology. **[5]**

d) Antiemetics. **[5]**

SECTION - II

Q4) Define clinical pharmacology. Describe the different phases of clinical research. Add a note on controlled clinical trials. **[20]**

Q5) a) Discuss principles of therapeutic drug monitoring with suitable examples. **[10]**

b) Explain clinical practice guidelines and management of pulmonary embolism. **[10]**

P.T.O.

- Q6)** a) Management of peptic ulcer [5]
b) Anticoagulants [5]
c) Digitalis glycosides [5]
d) Therapeutic utility of beta blockers in myocardial infarction [5]



Total No. of Questions : 8]

SEAT No. :

P3584

[Total No. of Pages : 2

[4750] - 24

M. Pharmacy (Semester - II)

PHYTOCHEMISTRY AND PHYTOPHARMACEUTICALS

(2008 Pattern)

Time :3 Hours]

[Max. Marks :80

Instructions to the candidates:

- 1) *Question Nos. 1 and 5 are compulsory. Out of the remaining attempt 2 questions from Section I and 2 questions from Section II.*
- 2) *Answers to the two sections should be written in separate answer books.*
- 3) *Neat diagrams must be drawn wherever necessary.*

SECTION - I

Q1) Describe in brief chemistry of flavonoids. How are flavonoids isolated? Explain with example of Quercetin. **[10]**

Q2) a) Write method of extraction, characterization & structural elucidation of Morphine. **[7.5]**

b) Write an elaborate account on chemical & pharmacological profile of **any one** of the following: **[7.5]**

i) Sennosides

ii) Taxol

Q3) What do you understand by Standardization of phytopharmaceuticals? Mention the role of spectroscopy & chromatographic techniques in Standardization of Bacosides and Curcumin. **[15]**

Q4) Write a note on following (**any two**) **[15]**

a) Chemical Profile of Digoxin.

b) Extraction of alkaloids.

c) Standardization of phylanthin

P.T.O.

SECTION - II

Q5) Describe WHO guidelines for quality control of herbs. Write principle & procedure of Bitterness value. **[10]**

Q6) a) Describe the infrastructure required for production of herbal extracts. **[7.5]**

b) Write a note on evaluation of herbal extracts. **[7.5]**

Q7) Describe Invivo & Invitro screening methods for evaluation of **[15]**

a) Hepatoprotectives.

b) Antioxidants.

Q8) Write note on following (**any two**) **[15]**

a) Sterility, stability & Preservation of extracts.

b) Screening of Antiinflammatory Drugs.

c) Determination of pesticide residue.



Total No. of Questions : 6]

SEAT No. :

P3585

[Total No. of Pages : 1

[4750] - 25

M. Pharmacy (Semester - II)
PHARMACEUTICAL VALIDATION
(Spl. Quality Assurance Techniques)
(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q.1 and Q.5 are compulsory. Out of remaining solve any 1 from Section I and any 1 from Section II.*
- 2) *Figures to the right indicate full marks.*

SECTION - I

- Q1)** a) Define validation, write its importance and its types. [10]
b) What is validation master plan? Elaborate its contents. [10]
- Q2)** a) Define calibration and write a note on calibration master plan. [10]
b) Explain equipment validation of steam autoclave. [10]
- Q3)** Write short note on: [20]
a) Operation qualification and performance qualification.
b) Vendor certification.

SECTION - II

- Q4)** a) Explain process validation of tablet by dry granulation. [10]
b) Write short note on cleaning method validation. [10]
- Q5)** Explain validation of the following utility service: HVAC. [20]
- Q6)** Write short note: [20]
a) Computer system validation.
b) Performance of UV visible spectrophotometer.



Total No. of Questions : 8]

SEAT No. :

P3586

[Total No. of Pages : 2

[4750] - 26

M. Pharmacy (Semester - II)
FORMULATIONS AND DEVELOPMENT
(2008 Pattern)

Time : 3 Hours]

[Max Marks :80

Instructions to the candidates:

- 1) *Question No. 1 and 5 are compulsory. Out of the remaining attempt two questions from section - I and two questions from Section - II.*
- 2) *Answers to two sections should be written in separate answer books.*
- 3) *Neat diagrams must be drawn wherever necessary.*
- 4) *Figures to the right indicate full marks.*

SECTION - I

Q1) Explain in detail various approaches for taste masking. **[12]**

Q2) Explain the concept of Gastro retentive drug delivery systems. **[14]**

Q3) What are the characteristics of ideal package? Discuss the regulatory Perspective of selection of Pharmaceutical packaging material for various formulations. **[14]**

Q4) Write notes on ANY TWO: **[14]**

- a) Self emulsified drug delivery systems.
- b) Excipients used for pulsatile drug delivery systems.
- c) Buccal formulations.

SECTION - II

Q5) Discuss role of propellants in inhalation aerosols. Add a note on quality assurance of Aerosol formulation. **[12]**

Q6) Discuss need problems in veterinary dosage forms. Explain formulation strategy to administer veterinary dosage forms via drinking water. **[14]**

P.T.O.

Q7) Discuss in detail generation and significance of Nanopharmaceuticals. **[14]**

Q8) Write notes on ANY TWO: **[14]**

- a) Penetration enhancer in semisolid formulation
- b) Semisolid based on Niosomes.
- c) Metered dose inhalers.



Total No. of Questions : 6]

SEAT No. :

P3587

[Total No. of Pages : 2

[4750] - 27

M.Pharmacy (Spl. Pharmaceutical Chemistry) (Semester - II)

DRUG DESIGN

(2008 Pattern) (M-II-4)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Question Nos. 1 & 4 is compulsory.*
- 2) *Answer any one question from Section - I and any one question from Section - II from the remaining.*
- 3) *Answer to the two sections should be written on separate books.*
- 4) *Figures to the right indicate full marks.*

SECTION -I

Q1) a) Enlist various physicochemical properties of drug molecule that affects the biological activity. Explain in brief about effect of ionization and hydrogen bonding on biological activity with suitable examples. [15]

b) Write significance of A.D.M.E in drug design. [5]

Q2) a) What are prodrugs? Write about designing of drug based on metabolism studies with examples. [15]

b) Bioprecursor prodrugs. [5]

Q3) Explain in brief about QSAR with its advantage and application. Discuss Hansch's Model. [20]

SECTION -II

Q4) Explain the concept of antagonism and enzyme inhibition were proved to be excellent tools in the process of drug design with suitable examples. [20]

Q5) a) Write a note on indirect drug design. [10]

b) Explain in brief about conformational search technique in CADD. [10]

Q6) Write a short note on (Any Two) :

[20]

- a) Three dimensional QSAR.
- b) Steric features of drug and their effects on the biological activity.
- c) Craig plot & cluster analysis.

☺ ☺ ☺ ☺

Total No. of Questions : 6]

SEAT No. :

P3588

[Total No. of Pages : 2

[4750] - 28

M. Pharmacy (Semester - II)
MOLECULAR PHARMACOLOGY
(Spl. Pharmacology)
(2008 Pattern) (M-II-4)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Answer any two questions from each section.*
- 2) *Answer to the two sections should be written in separate answer books.*
- 3) *Neat diagrams must be drawn wherever necessary.*

SECTION - I

- Q1)** a) Discuss the recent advances in drugs acting on dopamine receptors. [10]
b) Enlist the various endogenous bioactive molecules. Add note on modulators of NO and endothelin. [10]
- Q2)** a) Discuss the recent advances in drugs acting on GABA and benzodiazepine receptors. [10]
b) What are reactive oxygen intermediates? Explain therapeutic implications of antioxidants. [10]
- Q3)** a) Purinergic receptors and modulators. [5]
b) Neurosteroids. [5]
c) Glutamate receptors. [5]
d) Transgenic animals in experimental pharmacology. [5]

P.T.O

SECTION - II

- Q4)** a) Define immunopharmacology. Explain antibody mediated immunity. [10]
b) Discuss the implications of Human Genome Mapping in Drug research. [10]
- Q5)** a) Explain the process of Apoptosis with its clinical implications. [10]
b) Explain role of chronopharmacology on drug therapy. [10]
- Q6)** a) Cholinergic receptors. [5]
b) Arachidonic acid derived metabolites. [5]
c) Drugs acting on hormone receptors. [5]
d) Sodium channel modulators. [5]



Total No. of Questions : 8]

SEAT No. :

P3589

[Total No. of Pages : 2

[4750] - 29

M. Pharmacy (Semester - II)

NOVEL DRUG DELIVERY SYSTEM

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Attempt any two questions each from the Section - I and Section - II.*
- 2) *Figures to the right indicate full marks.*
- 3) *Answer to two sections must be written in separate answer books.*

SECTION - I

Q1) What is chrono therapeutics? Describe formulation of and evaluation of pulsatile drug delivery system. **[20]**

Q2) Describe mechanisms of transports of drugs through mucosal routes? Write a note on penetration enhancers. **[20]**

Q3) Give detailed account of formulation mechanisms in gastric retentive drug delivery system. **[20]**

Q4) Write short notes (any two) : **[20]**

- a) Influence of drug properties on design of sustained release drug delivery systems.
- b) Biodegradable microspheres.
- c) Osmotic drug delivery.

P.T.O

SECTION - II

Q5) Describe evaluation of colon targeted drug delivery. **[20]**

Q6) Drug targeting using monoclonal antibodies. **[20]**

Q7) Describe formulation considerations for protein and peptide drugs. **[20]**

Q8) Write notes on (any two) : **[20]**

- a) Microbial approach for colon specific drug delivery formulation.
- b) Enhanced permeation and retention effect.
- c) Formulation of transdermal drug delivery system.



Total No. of Questions : 8]

SEAT No. :

P3590

[Total No. of Pages : 1

[4750] - 30

M. Pharm. (Semester - II)

INDUSTRIAL PHARMACOGNOSY

(2008 Pattern)

Time :3 Hours]

[Max. Marks :80

Instructions to the candidates:

- 1) *Q. No. 1 and Q. No. 5 are compulsory, Out of remaining solve any two from Section I and Section II.*
- 2) *Answer to the two Sections should be written in separate books.*

SECTION-I

- Q1)** Explain the demand for Medicinal Plants and Herbal medicine. [10]
- Q2)** Describe the export potential for Spices, Phytopharmaceutical products and Medicinal Plants used in cosmetics and aromatherapy. [15]
- Q3)** Discuss the technology involved in production of. [15]
- a) Emetine
 - b) Diosgenin
 - c) Cocaine
- Q4)** Express in brief the Global regulatory requirements for Herbal Medicines.[15]

SECTION-II

- Q5)** Elaborate in detail salient features of Indian Patent Act. [10]
- Q6)** Give in brief the classification of Medicinal Plants based industries for medicinal and aromatic plants in India. [15]
- Q7)** Comment on "Technical steps involved in extraction of Medicinal Plants" [15]
- Q8)** Clarify the contribution of Medicinal Plants in economic growth potential of India. [15]



Total No. of Questions : 8]

SEAT No. :

P3591

[Total No. of Pages : 2

[4750] - 31

M.Pharmacy (Semester - II)

QUALITY PLANNING AND ANALYSIS

(2008 Pattern)

Time :3 Hours]

[Max. Marks :80

Instructions to the candidates:-

- 1) *Question numbers 1 and 5 are compulsory.*
- 2) *Out of the remaining attempt any two questions from each section.*
- 3) *Answers to the two sections should be written in separate answer books.*
- 4) *Figures to the right indicate full marks.*

SECTION - I

Q1) Define 'Control' and list universal sequence of steps to achieve control.
Add a note on self control. [12]

Q2) Discuss steps in structuring an audit program. Write a note on audit report.
[14]

Q3) How is quality measured in manufacturing operations? Comment on
'Quality culture'. [14]

Q4) Write the criteria for 'self inspection' and comment on inspection accuracy.
[14]

P.T.O.

SECTION - II

- Q5)* How is Quality related to Productivity, cost, cycle time and value? [12]
- Q6)* State two quality dimensions. What are the ways to motivate for quality as per Maslow's theory? [14]
- Q7)* What criteria must be met while setting operational goal? Highlight advantages of statistical process control. [14]
- Q8)* While developing quality culture, why is it necessary to provide evidence of management leadership? Explain the concept of Error-Proofing the process. [14]



Total No. of Questions : 8]

SEAT No. :

P3592

[Total No. of Pages : 2

[4750]-32

M. Pharmacy (Semester - I & II)

ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)

Manufacturing Technology

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q. no. 1 and 5 are compulsory. Out of remaining questions solve any two questions from Section - I and any two questions from Section - II.*
- 2) *Section - I and Section - II should be answered in separate Answer books.*
- 3) *Draw well labeled diagrams wherever necessary.*

SECTION - I

Q1) Give an account of manufacturing technology by Alkylation and Hydrolysis process. [12]

Q2) Write detail account of manufacturing methods, flow charts for Benzocaine and Aspirin. [14]

Q3) Give an account of Unit process in synthesis. Discuss about fine chemicals in industry. [14]

Q4) Write short note on. (Any Two) [14]

- a) Heavy chemicals
- b) Nitration
- c) Biochemical process in synthesis

P.T.O.

SECTION - II

Q5) Write an account of Industrial noise, noise measuring equipments. [12]

Q6) Give an account of forms of Atmospheric contaminants in manufacturing industry. [14]

Q7) Write detail account of Radiation hazards in manufacturing unit. [14]

Q8) Write short notes on (Any two): [14]

- a) Flow chart for Rifampicin
- b) Industrial centrifuges.
- c) Chemical mixtures.



Total No. of Questions : 8]

SEAT No. :

P3593

[Total No. of Pages : 2

[4750]-33

M. Pharmacy (Semester - I & II)

SAFETY PHARMACOLOGY

(2008 Pattern)

[Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q. no. 1 and 5 are compulsory. Out of remaining attempt any 2 questions from section - I & 2 questions from section - II*
- 2) *Separate answer book should be used for separate sections.*
- 3) *Figures to right indicate full marks.*

SECTION - I

Q1) Explain the new drug safety assessment as per ICH guidelines. [10]

Q2) Discuss in details various in vitro? In vivo studies for genotoxicity. [15]

Q3) Write the importance and study design for repeat dose toxicity. [15]

Q4) Write notes on [15]

- a) Risk benefit assessment in clinical trials.
- b) Periodic safety update reports (PSUR)

P.T.O.

SECTION - II

Q5) Discuss the Importance, scope and principles of safety pharmacology. [10]

Q6) Define pharmacovigilance. Write the process of collection and reperting of pharmacovigilance data. [15]

Q7) Discuss in detail the study design and importance of carcinogenicity. [15]

Q8) Write notes on [15]

- a) Ocular toxicity testing.
- b) Analysis of safety pharmacological data.



Total No. of Questions : 8]

SEAT No. :

P3594

[Total No. of Pages : 2

[4750]-34

M. Pharmacy (Semester - I & II)
CHEMISTRY OF MEDICINAL NATURAL PRODUCTS
(2008 Pattern)

[Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q. no. 1 and 5 are compulsory. Out of remaining solve any two from section I and any two from section II.*
- 2) *Answers to the two sections should be written on separate answer books.*
- 3) *Figures to the right indicate full marks.*

SECTION - I

Q1) Write the biogenetic pathway for Tryptophan and Tyrosine derived alkaloids. [10]

Q2) Describe chemistry of Saponin glycosides and isolation of Glycerhizin. [15]

Q3) Focus on spectral data to explain structure of Caffeine. [15]

Q4) Write short note on. (Any Two) [15]

- a) Secondary metabolites
- b) Analytical methods for Atropine.
- c) Cardiac glycosides.

P.T.O.

SECTION - II

Q5) Explain the structure of Diosgenine by spectral study. [10]

Q6) Define and classify flavonoids. Add note on Anthocyanins. [15]

Q7) Classify terpenoids. Explain methods of extraction of essential oils. [15]

Q8) Write short note on (Any two) [15]

- a) Plant pigments
- b) Monosacharides
- c) Oleogum resins.



Total No. of Questions : 8]

SEAT No. :

P3595

[Total No. of Pages : 1

[4750]-35

M. Pharmacy (Semester - I)
NATURAL PRODUCT MANAGEMENT
(2008 Pattern)

[Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Q. No. 1 and 5 are compulsory. Out of remaining solve any two from section I and any two from section II.*
- 2) *Answers to the two sections should be written on separate answer books.*
- 3) *Figures to the right indicate full marks.*

SECTION I

- Q1)* Describe the relationship between demand and supply of material in market. [10]
- Q2)* Explain management of crop using Land, Labour and Machine. [15]
- Q3)* Write a detail note on various plans by Indian Government for development of medicinal plants. [15]
- Q4)* Explain in detail the essential factors for cultivation of preoritize medicinal plants in India. [15]

SECTION II

- Q5)* Explain the legal method for trading of herbal cosmetics in and across the country. [10]
- Q6)* Describe in detail the procedure for patenting herbal products. [15]
- Q7)* Brief on design and development of herbal extraction unit. [15]
- Q8)* Write a detail note on trading of Nutraceuticals in international market. [15]



Total No. of Questions : 8]

SEAT No. :

P3596

[Total No. of Pages : 2

[4750] - 36

M. Pharmacy (Semester - I)

CLINICAL TRIALS

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) Question No.1 and 5 are compulsory. Solve any two questions from the remaining in section I and section II.*
- 2) Write answers for section - I and section - II in separate answer sheets.*
- 3) Figures to the right indicate full marks.*
- 4) Draw well labeled diagrams wherever necessary.*

SECTION - I

Q1) Discuss various steps involved in clinical trial design. **[10]**

Q2) Justify role of informed consent and institutional review board in ethical conduct of clinical trials. **[15]**

Q3) What is new drug development process? Explain in detail different phases of clinical trials. **[15]**

Q4) Write short notes on (any two) **[15]**

- a) Role of FDA in clinical trial.
- b) Types of clinical research.
- c) Advantages and disadvantages of clinical trial designs.

P.T.O

SECTION - II

Q5) Discuss Clinical trial protocol. **[10]**

Q6) Explain role and responsibility of various stakeholders of clinical trials. **[15]**

Q7) Explain concept and importance of Therapeutic drug monitoring. **[15]**

Q8) Write short notes on (any two) **[15]**

- a) Case report forms.
- b) ICH-GCP guidelines.
- c) Laboratory certification.



Total No. of Questions : 6]

SEAT No. :

P3597

[Total No. of Pages : 1

[4750] - 37

M. Pharmacy (Semester - I)

PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) Answer 2 questions from Section - I and 2 questions from Section - II.*
- 2) Answers to the two sections should be written in separate answer books.*
- 3) Neat diagrams must be drawn wherever necessary.*
- 4) Figures to the right indicate full marks.*

SECTION - I

Q1) Discuss the design, layout and operational facilities for Liquid orals. [20]

Q2) Discuss the design, layout and operational facilities for Capsule. [20]

Q3) Discuss in detail regulatory requirements of Pharma facilities with reference to cGMP. [20]

SECTION - II

Q4) What is effluent ? Write importance of effluent treatment plant. Explain in detail its design. [20]

Q5) Explain design of pharmaceutical plant support services. [20]

Q6) Explain design of water stream and compressed air as utility services. [20]



Total No. of Questions : 10]

SEAT No. :

P3598

[Total No. of Pages : 2

[4750] - 38

M. Pharm.

MEDICINAL PLANT BIOTECHNOLOGY

(2008 Pattern)

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *This question paper consist of two sections; Section - I and Section - II.*
- 2) *Use two separate answer books for the Section - I & Section -II.*
- 3) *Solve any four questions from section I & Solve any four questions from section II*
- 4) *Enter the question number clearly in the margin of the answer book beside each of your answer.*
- 5) *Figures to the right indicate full marks.*

SECTION - I

- Q1)** a) What is *Agrobacterium tumefaciens* ?
b) Write down principle involved in the *agrobacterium tumefaciens* gene transfer to plant cell. [10]
- Q2)** 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]
- Q3)** What is an 'Endemic Species' ? What is paleoendemism and neoendemism ? What is the meaning of *Ex-situ* conservation?
What is the meaning of *In-situ* conservation ? What are benefits of *in-situ* conservation ? [10]

P.T.O.

Q4) Chloroplasts have their own DNA, often abbreviated as ctDNA, or cpDNA. Briefly explain Molecular structure of ctDNA, or cpDNA.

What is the translocon on the outer chloroplast membrane (TOC) & The translocon on the inner chloroplast membrane (TIC) ? **[10]**

Q5) Write short notes on (any two): **[10]**

- a) Polyploidy
- b) Classification of Elicitors for Production of Secondary metabolites
- c) Micro RNA
- d) A Mutation & Induced Mutation

SECTION - II

Q6) What are Genetically modified crops (GMCs, GM crops, or biotech crops)? Write down Applications of Transgenic Plants. **[10]**

Q7) What is an Immobilized Enzyme ? What are its commercial uses ? What are different ways by which one can immobilize an enzyme. **[10]**

Q8) What are restriction enzymes ? What are its types ? **[10]**

Q9) What are Plasmids ? Write a breif note on Plasmid as vectors. What is Horizontal & Vertical gene transfer mechanism ? **[10]**

Q10) Write short note on (any two): **[10]**

- a) Edible vaccines: current status and future.
- b) Advances in Plant Chromosome Analysis.
- c) Papain.
- d) Bromelain.



Total No. of Questions : 6]

SEAT No. :

P3599

[Total No. of Pages :2

[4750]-39

M.Pharmacy (Semester - I)

**QUALITY CONTROL AND ASSURANCE OF
PHARMACEUTICALS
(2008 Pattern)**

Time : 3 Hours]

[Max. Marks : 80

Instructions to the candidates:

- 1) *Question number 1 and 4 are compulsory. Out of remaining solve any one question from section - I and section - II.*
- 2) *Answer to the two sections should be written in separate answer book.*
- 3) *Draw well labeled diagrams wherever necessary.*

SECTION - I

Q1) Highlight various aspects of user requirement specification, design, size, construction and maintenance of dry powder mixer. **[20]**

Q2) a) Discuss the sources of contamination in sterile formulations and methods followed to control the contamination. **[10]**

b) Describe various aspects of self inspection. **[10]**

Q3) Write short note on : **[20]**

a) Master validation plan and calibration

b) Provide contents of typical Batch packaging record

P.T.O.

SECTION - II

Q4) Provide typical MPCR for enteric coated tablet formulation. **[20]**

Q5) a) Provide SOP on "Product Recall" and formats required to comply the procedure as per GMP. **[10]**

b) Describe in detail quality manual by typical pharmaceutical organisation. **[10]**

Q6) Write note on : **[20]**

a) IPQC in manufacturing of sterile dosage forms and QA relevance

b) Returned goods and waste materials management-Documentation and Role of QA

