Total No. of Questions : 6]

SEAT No. : ____

[Total No. of Pages : 1

P2299

[4156] - 109

M.Pharmacy (Sem. - I and II)

PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

(2008 Pattern)

Time :3 Hours] ***[Max. Marks :80***

Instructions to the candidates:-

1) ***Answer 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.***

SECTION - I

Q1) Explain in detail design, layout and operational facilities with services and utilities for sterile products powder ready for reconstitution. **[20]**

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

Q3) Explain revised schedule M and factory act. **[20]**

SECTION - II

Q4) Explain design and operation of Q.C. laboratory. **[20]**

Q5) Discuss design of plant support services in a pharmaceutical plant. **[20]**

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

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Total No. of Questions : 8]

SEAT No. : [ ]

[Total No. of Pages : 2

P2301

[4156] - 111

M.Pharmacy

STERILE PRODUCTS FORMULATION AND TECHNOLOGY

(2008 Pattern) (Sem. - I & II)

Time : 3 Hours] ***[Max. Marks : 80***

Instructions to the candidates:

1) ***Question Nos. 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 answer books.***
3) ***Neat diagrams must be drawn wherever necessary.***
4) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Discuss Liposomes as parenteral novel drug delivery system. **[12]**

Q2) Discuss formulation of injectable suspension on the basis of syringebility, ocular irritation potential, drug release properties and quality control tests of dried suspensions. **[14]**

Q3) Describe anatomy and physiology of eye relevant to ocular drug delivery and ocular pharmacokinetics. **[14]**

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

a) Packaging materials for closures for LVP.

b) Sterility testing for parenterals.

c) Parenteral drug delivery for Protein and peptide drugs.

P.T.O.

SECTION - II

Q5) Give the detailed account on validation of HVAC systems. **[12]**

Q6) Discuss the factors to be considered in selection of sterilization process for parenterals. Add a note on comparison of methods of sterilization. **[14]**

Q7) Explain in detail on design of aseptic facility for manufacturing of dry powders including layout and facility requirements. **[14]**

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

a) Validation of dry and moist heat sterilization process.

b) cGMP and regulatory guidelines for personnel for sterile manufacturing.

c) Hazards of injectables.

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Total No. of Questions :8]

SEAT No. :

P2302

[Total No. of Pages :2

[4156] - 112

M.Pharmacy (Sem. - I & II)

CHEMISTRY OF MEDICINAL NATURAL PRODUCTS

(2008 Pattern)

Time : 3 Hours] *[Max. Marks : 80*

Instructions to the candidates:

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

SECTION - I

Q1) Define Alkaloids, Protoalkaloids, Pseudoalkaloids. Write down details of chemistry and properties of Alkaloids. **[10]**

Q2) a) Mention the biosynthetic pathway for Hyoscyamine. **[7]**

b) Write general methods for extraction of Glycosides. Add method for isolation of Sennosides. **[8]**

Q3) a) Describe the structural elucidation of Atropine. **[7]**

b) Write down the general biogenetic pathway for formation of Steroids. **[8]**

Q4) Write note on (Any Two) **[15]**

a) Role of primary and secondary metabolites in plants.

b) Methods of extraction of essential oils.

c) Methods for extraction of Alkaloids.

P.T.O.

SECTION - II

Q5) Explain in detail chemistry and structure of Diosgenin. **[10]**

Q6) a) Write down the general properties of Steroids. **[7]**

b) Mention in detail about various properties of Flavonoids. **[8]**

Q7) a) Write the detail chemistry of plant pigments. **[7]**

b) Classify Terpinoids and give its chemistry. **[8]**

Q8) Write note on (Any Two). **[15]**

a) Physical and chemical properties of solasodine.

b) Properties of Carbohydrates.

c) Various methods of analysis of Diosgenin.

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Total No. of Questions :8]

SEAT No. :

P2303

[4156] - 113

[Total No. of Pages :1

M.Pharmacy (Sem. - I & II)

ACTIVE PHARMACEUTICAL INGRADIENTS (APIS) Manufacturing Technology

(2008 Pattern)

Time : 3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Q.no.1 and Q.5 are compulsory, Remaining any two Questions to be answered in Section I and Section II.***
2) ***Section I and II should be Answered in separate Answer sheet.***
3) ***Flow chart / figures carry full marks.***

SECTION - I

Q1) Give industrial manufacturing methods along with flow chart for Rifampicin and Adrenaline. **[12]**

Q2) Write in detail on technology involved in manufacturing of pharmaceuticals.**[14]**

Q3) Write a note on (Any two) : **[14]**

a) Nitration
b) Halogenation
c) Oxidation

Q4) Write a note on Biochemical processes in synthesis. **[14]**

SECTION - II

Q5) Write a note on Health Hazards in Manufacturing. **[12]**

Q6) Write a note on personal protection & Radiation detection and measurement.**[14]**

Q7) Write a note on Industrial manufacturing of sulphamethoxazole, and pentathol sodium with flow chart. **[14]**

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

a) Radiation hazards
b) Esterification
c) Animation

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Total No. of Questions :6]

SEAT No. :

P2304

[Total No. of Pages :1

[4156] - 114
M.Pharmacy (Sem. - I & II)
CLINICAL TRIALS
(2008 Pattern)

Time : 3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Solve any two questions from each section.***
2) ***All questions carry equal marks.***
3) ***Answer to each section should be written in separate sheet.***

SECTION - I

Q1) Discuss importance of monitoring of clinical trials. **[20]**

Q2) Explain role of data collection, quality control of data and laboratory certification in the conduct of clinical trials. **[20]**

Q3) Describe principal, responsible conduct and supervision of ethics in the clinical trials. **[20]**

SECTION - II

Q4) Explain various routine terminologies of clinical trials. Add a note on types of clinical research. **[20]**

Q5) Write a role of FDA in various counteries in the new drug development. **[20]**

Q6) Justify importance of inclusion and exclusion criteria in the design of clinical trials. **[20]**

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Total No. of Questions :8]

SEAT No. :

P2305

[4156] - 115

[Total No. of Pages :1

M.Pharmacy (Sem. - I & II)

SAFETY PHARMACOLOGY

(2008 Pattern)

Time : 3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Question number 1 and 5 are compulsory. Out of remaining attempt any 2 questions from section -I and 2 questions from section - II.***
2) ***Separate answer book should be used for separate sections.***
3) ***Figures to the right indicate full marks.***

SECTION - I

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

Q2) Discuss in detail the study design and importance of mutagenicity studies. **[15]**

Q3) Explain various studies for carcinogenicity testing. **[15]**

Q4) Write notes on : **[15]**

a) Chronic toxicity testing.

b) Occular toxicity testing.

SECTION - II

Q5) Explain the new drug safety assessment as per ICH guidelines. **[10]**

Q6) Discuss the different methods for the pharmacovigilance data collection. **[15]**

Q7) Discuss Periodic Safety Update Reports (PSUR) for marketed drugs. **[15]**

Q8) Write notes on : **[15]**

a) Safety assessment of dermatological products.

b) Adverse Event (AE) reporting in clinical trial.

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Total No. of Questions :12]

SEAT No. :

P2306 [4156] - 116 [Total No. of Pages :2

M.Pharmacy (Sem. - I & II)
TRADITIONAL SYSTEMS OF MEDICINE AND AYURVEDIC FORMULATIONS
(2008 Pattern)

Time : 3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Answer any 4 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) ***Figures to the right indicate full marks.***

SECTION - I

Q1) What is Chinese system of medicine? Write theory and basic concept along with brief history of Chinese system of medicine. Write a brief note on Diagnosis and treatment of Chinese system of medicine. **[10]**

Q2) Write down the differences between. Ayurvedic medicines and Unani medicines with respect to History, philosophy and preparation of medicines. **[10]**

Q3) Enlist five drugs used in Ayurvedic medicines and Homeopathic medicines give their comparative account. **[10]**

Q4) What is Ethnopharmacognosy? Explain the role of Ethnopharmacognosy in modern drug discovery. **[10]**

Q5) Explain in detail method of preparation and characteristics of Avaleha. **[10]**

Q6) Write short note on any two : **[10]**

a) Homeopathic dilutions.

b) Role of Nidana sthana in Ayurvedic system of Medicine.

c) Rasayana.

P.T.O.

SECTION - II

Q7) Define Bhasma. Write its method of preparation, characteristics and storage conditions Enlist three examples of Bhasma along with their Therapeutic uses. **[10]**

Q8) Define Ghruta. Write its method of preparation, characteristics and storage conditions. Enlist three examples of Ghruta along with their Therapeutic uses **[10]**

Q9) What is Guggulu? Give characteristics and storage conditions for Sodhita Guggulu along with their Therapeutic importance. **[10]**

Q10) Describe in detail chemical methods of standardization of Ayurvedic dosage forms and their significance in standardization. **[10]**

Q11) Describe in brief Ayurvedic Hair care Cosmetic Formulations. **[10]**

Q12) Write a short note on any two : **[10]**

a) Traditionaly fermented Biomedicines

b) Kwatha

c) Characteristics of churna.

Total No. of Questions : 6]

SEAT No. : ____

P2288

[Total No. of Pages : 2

[4156] - 102

M.Pharm.

RESEARCH METHODOLOGY

(2008 Pattern) (Sem. - I)

Time :3 Hours] ***[Max. Marks :80***

Instructions to the candidates:-

1) ***Solve any two questions each from section I and section II.***
2) ***Figures to the right indicate full marks.***
3) ***Answers to the two sections should be written in separate answer 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 parts of research paper in detail. **[10]**

b) What is the objective of research? Describe patent oriented research. **[10]**

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

a) Techniques of documentation.

b) Descriptive data analysis.

c) Variables in experimental research.

SECTION - II

Q4) a) What is a patent? Describe importance of patent in research. **[10]**

b) Describe various grant schemes of AICTE and UGC. **[10]**

P.T.O.

Q5) Explain preparation of cost analysis report of research project. **[20]**

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

a) Industrial project as part of industry institute interaction.

b) Skills required for oral presentation.

c) Status of intellectual property rights in India.

Total No. of Questions : 6] **SEAT No. :**

P2289 **[Total No. of Pages : 1**

[4156] - 103
M.Pharm.
(Spl. Pharmaceutics)
ADVANCED PHARMACEUTICS
(2008 Pattern) (Sem. - I)

Time :3 Hours] ***[Max. Marks :80***

Instructions to the candidates:-

1) ***Answer any two questions from each section.***
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 preformulation studies of conventional tablets. **[20]**

Q2) Classify polymers with suitable example and explain different techniques of thermal characterization of polymers. **[20]**

Q3) Discuss the following: **[20]**

a) Process of standardization of excipients.

b) Directly compressible excipients.

SECTION - II

Q4) Explain the concept of and role of documentation in **[20]**

a) Quality Assurance and

b) Total quality management.

Q5) Discuss the methods, formulation and evaluation of Microcapsules. **[20]**

Q6) What is need of optimization? Classify and explain the different optimization method with suitable examples. **[20]**

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Total No. of Questions : 8]

P2290

SEAT No. : [ ]

[Total No. of Pages : 2

[4156] - 104
M.Pharmacy.
(Spl. Pharmaceutical Chemistry)
ADVANCED PHARMACEUTICAL CHEMISTRY
(Sem. - I) (M-II-1) (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 any two questions from Section - I and Section - II.***
2) ***Answers to the two sections should be written in separate answer books.***
3) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Explain Stereospecificity and Stereoselectivity with suitable examples. **[10]**

Q2) What is resolution of racemic mixture? Discuss the methods for resolution of racemic mixtures. **[15]**

Q3) Design synthetic route/s for Trimethoprim and add a note on disconnection rules used in synthon approach. **[15]**

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

a) Conformation of monosubstituted cyclohexane.

b) Cahn-Ingold-Prelog System of R/S nomenclature.

c) Supercritical Liquids.

SECTION - II

Q5) Describe in brief the role of stereochemistry in pharmacokinetics and pharmacodynamics. **[10]**

P.T.O.

Q6) Design synthon approach route for synthesis of Ibuprofen and Rosiglitazone. **[15]**

Q7) Give a brief account of green chemistry, its advantage and add a note on reactions using microwave and ultrasound energy. **[15]**

Q8) Write a note on any two : **[15]**

a) Steric effect and Inductive effect.

b) Asymmetric Synthesis.

c) Heck Reaction.

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Total No. of Questions : 6]

SEAT No.:

P2291

[Total No. of Pages : 2

[4156]-101
M.Pharmacy
ADVANCED ANALYTICAL TECHNIQUES
(2008 Pattern) (Sem. - I)

Time : 3 Hours] *[Max. Marks : 80*

Instructions to the candidates:

1) ***Attempt any two questions from each section.***
2) ***Draw diagrams where necessary.***

SECTION - I

Q1) a) Elucidate the chemical structure from the following data : **[8]**

Molecular formula : C_8H_8O

IR : 1703cm^{-1}, 2733cm^{-1}, 2828cm^{-1}, 2922cm^{-1}, 3048cm^{-1}.

H^1 NMR :

2.4δ	singlet	3H
7.3 – 7.8δ	symmetric multiplet	4H
9.9δ	singlet	1H

b) With the help of a neat diagram explain the concept of powder X-ray diffraction and its application. **[8]**

c) What are isotope ion peaks in mass spectrometry? Give their significance. **[4]**

Q2) a) What is the meaning of Fourier Transformation in the context of IR spectroscopy? What advantages do FTIR spectrophotometers offer over dispersive instruments? Give a brief account of working of FTIR spectrophotometer. **[10]**

b) With the help of a phase diagram explain the concept of super critical fluids. Describe the instrumentation of super critical fluid chromatography. **[10]**

Q3) a) Compare and contrast between H^1 and C^{13} NMR spectroscopy. Explain the terms free induction decay and double resonance technique in NMR spectroscopy. **[8]**

P.T.O.

b) Give a detailed description of the instrumentation and applications of Differential Thermal Analysis. **[8]**

c) Write a note on Ion Pair chromatography. **[4]**

SECTION - II

Q4) a) Give an exhaustive account of Atmospheric Pressure Chemical Ionization (APCI) and electro spray interface (ESI) in LC-MS. **[8]**

b) Discuss sample handling methods for gases, liquids and solids in IR spectroscopy. **[8]**

c) Enlist the factors influencing chemical shift. **[4]**

Q5) a) Write a descriptive note on ESR spectroscopy. **[8]**

b) Comment on the fragmentation pathways in MS for the following classes of compounds - **[12]**

i) Alkanes.
ii) Alcohols.
iii) Aldehydes.
iv) Amides.

Q6) a) Describe the instrumentation for sample application, development, detection and quantification in HPTLC. **[10]**

b) Write short notes on : **[10]**

i) Detectors used in GC.
ii) Size exclusion chromatography.

Total No. of Questions : 6]

SEAT No. :

P2292

[Total No. of Pages : 1

[4156] - 206
M. Pharm. (Sem. - II)
(Spl. Pharmacology)
CLINICAL PHARMACOLOGY
(M - III-3) (2008 Pattern)

Time : 3 Hours] *[Max. Marks : 80*

Instructions to candidates:

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

SECTION - I

Q1) Define clinical pharmacology. Describe types of clinical research. Add a note on protocol for clinical trials with suitable examples. **[20]**

Q2) a) Discuss general management guidelines for hypertension. **[10]**

b) What do you mean by clinical practice guidelines? Explain it with asthama management. **[10]**

Q3) a) Steps of drug discovery process. **[5]**

b) Renal dialysis in renal disease management. **[5]**

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

d) Management of pulmonary embolism. **[5]**

SECTION - II

Q4) a) Discuss role of rational use of antibiotics towards control of resistance development to antibiotics. **[10]**

b) Write a detailed note on principles of Cancer Chemotherapy. **[10]**

Q5) a) Justify role of invivo and invitro tests in immunological investigation. **[10]**

b) Explain need of ethics for clinical trials with suitable examples. **[10]**

Q6) a) Drug dose adjustment in renal impairment. **[5]**

b) Management Chronic Obstructive Pulmonary edema. **[5]**

c) Current research of drugs for AIDS. **[5]**

d) Management of full blown hepatitis - B. **[5]**

Total No. of Questions : 8]

SEAT No. :

P2293

[Total No. of Pages : 2

[4156]-201
M.Pharmacy
DRUG REGULATORY AFFAIRS
(2008 Pattern) (Sem. - II) (m-3)

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) ***Answers 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 Pharmacy Council of India, also state the registration procedure of pharmacist. **[10]**

Q2) a) Write the functions of Central Drugs Laboratory. **[8]**

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

Q3) a) Elaborate the different sections of NDA. **[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) US-FDA.

d) Spurious & Adulterated drugs.

SECTION - II

Q5) Explain the WHO guidelines related to premises undergoing manufacturing of sterile products. **[10]**

Q6) a) Write the salient features of Indian Patent Act 1970. **[8]**

b) Write the salient features of Drug Price Control Order 1995. **[7]**

P.T.O.

Q7) a) Explain the provisions related to Pollution and Environment Control Act. **[8]**

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

Q8) Write short notes on following (any three) : **[15]**

a) Indian Pharmacopeias.

b) Good laboratory practices.

c) Industrial Safety and Health.

d) MSDS preparation.

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Total No. of Questions : 6]

SEAT No. :

P2294

[Total No. of Pages : 2

[4156]-204
M.Pharmacy
(Pharmaceutical Chemistry)
ADVANCED MEDICINAL CHEMISTRY
(2008 Pattern) (Sem. - II) (M-II-3)

Time :3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Q.No.1 & Q.No.4 are compulsory.***
2) ***Solve any one question from remaining questions from each section.***

SECTION - I

Q1) a) Write microbiological conversion of prostaglandins giving suitable examples. **[15]**

b) Write a note on CADD. **[5]**

Q2) a) Explain in detail nicotinic acetyl cholinergic receptors. **[10]**

b) Explain various aspects of combinatorial chemistry. **[10]**

Q3) Write synthesis routes giving detail mechanism for following (any two): **[20]**

a) Dapsone.

b) Vitamin B.

c) Citrazine.

d) Linezolide.

SECTION - II

Q4) a) Write a detail note on Opoide Receptors. **[10]**

b) Write a note on Enzyme Immobilization techniques. **[10]**

Q5) a) Sketch out the synthetic strategies for any one of the following : **[10]**

i) Fexofenadine.

ii) Diazepam.

b) Explain applications of Gene Therapy. **[10]**

P.T.O.

Q6) Write a note on any two : **[20]**

a) GABA Receptors.

b) Enzyme Inhibition.

c) Coupling agents in combinatorial chemistry.

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Total No. of Questions : 6]

SEAT No. :

P2295

[Total No. of Pages : 2

[4156] - 105
M. Pharmacy (Sem. - I)
(Spl. Pharmacology)
ADVANCE PHARMACOLOGY (Preclinical Evaluation of Drugs)
(2008 Pattern) (M-III-1)

Time : 3 Hours] *[Max. Marks : 80*

Instructions to the candidates:

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

SECTION - I

Q1) What are various breeding techniques of laboratory animals?

a) How the type of breeding govern preclinical Pharma-Cological Screenings? Justify with examples. **[10]**

b) Discuss preclinical evaluation of antihypertensive drugs. **[10]**

Q2) a) Justify use of invitro testing of drugs over invivo tests. Give any one example of invitro tests. **[10]**

b) Enlist various modern methods of pharmacological evaluation. Add a note on Patch Clamp technique. **[10]**

Q3) a) Alternatives to animal studies. **[10]**

b) Preclinical evaluation of CNS stimulants. **[5]**

c) ELISA. **[5]**

SECTION - II

Q4) a) Discuss importance of preclinical evaluation over invitro tests. Explain various animals models for convulsions. **[10]**

b) Enlist various proformas for animal studies. Describe Proforma - B in details. **[10]**

P.T.O.

Q5) a) Explain role of radioligand binding assay in pharmacological evaluation. **[10]**

b) Define preclinical screening, discuss it's organisation and safety assessment tests. **[10]**

Q6) a) Evaluation of hypoglycemic agent. **[5]**

b) Ethical requirements of CPCSEA. **[5]**

c) Use of animal cell lines. **[5]**

d) Preclinical Screening of antidepressants. **[5]**

Total No. of Questions : 8]

SEAT No. :

P2296

[Total No. of Pages : 2

[4156] - 106
M. Pharm. (Sem. - I)
(Spl. Pharmacognosy)
ADVANCED PHARMACOGNOSY - I
(2008 Pattern)

Time : 3 Hours] *[Max. Marks : 80*

Instructions to the candidates:

1) ***Question Nos. 1 and 5 are compulsory. Answer any TWO questions from the remaining.***
2) ***Answer to the two sections should be written in separate books.***
3) ***Neat diagrams must be drawn wherever necessary.***
4) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Enlist various strategies used to enhance secondary metabolite production through tissue culture techniques. Describe genetic manipulation using plant cell culture. **[10]**

Q2) a) What are the advantages and limitations of chemotaxonomy over morphological methods of classification? Write its applications. **[7]**

b) Describes the terpenes as chemotaxonomic marker with suitable examples. **[8]**

Q3) What are the characteristics of natural products that make them an appropriate material in discovering new drugs? Describe camptothecin and its derivatives as anti-cancer agents. **[15]**

Q4) Write note on the following (any THREE): **[15]**

a) Biodiesel.
b) Coloring and dying agents of plant origin.
c) Photosensitizing agents of plant origin.
d) Bioreactors for production of secondary metabolites.

SECTION - II

Q5) Enlist techniques used in the study of plant biosynthesis. Describe sequential analysis technique along with various methods used for detection and measurement of radio labeled precursors. **[10]**

P.T.O.

Q6) a) Review the plants having hepatoprotective activity. **[7]**

b) Explain paclitaxel as anticancer agent. **[8]**

Q7) Write various in vitro and in vivo models used in the evaluation of antidiabetic activity. Explain various mechanisms through which phytochemicals mediate antidiabetic effect. **[15]**

Q8) Write note on the following (any THREE): **[15]**

a) Biopolymers.

b) Role of High Throughput Screening (HTS) in drug discovery.

c) Flavonoids as anti-inflammatory agents.

d) Precursor feeding technique for production of secondary metabolites.

Total No. of Questions : 6]

SEAT No. :

P2297

[Total No. of Pages : 1

[4156] - 107
M. Pharm. (Sem. - I)
(Spl. Quality Assurance Techniques)
ADVANCED QUALITY ASSURANCE TECHNIQUES - I
(2008 Pattern)

Time : 3 Hours] *[Max. Marks : 80*

Instructions to the candidates:

1) ***Question No. 1 and Question No. 4 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 QA, write its functions. **[10]**

b) Write importance of Documentation. Elaborates Master Production and control Records. **[10]**

Q2) a) What are GMP issues for personnel? **[10]**

b) What is change control? Explain and design documents for change control. **[10]**

Q3) Write Short Note: **[20]**

a) Material Management.

b) Quality management system.

SECTION - II

Q4) Elaborate site master file. **[20]**

Q5) a) Explain outsourcing with respect to Pharma industry. **[10]**

b) Elaborate site and plant security and safety. **[10]**

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

a) Handling of recall, returned products, complaints and adverse effect.

b) Internal audit.

Total No. of Questions : 8]

SEAT No. :

P2298

[Total No. of Pages : 2

[4156] - 108

M. Pharm. (Sem. - I & II)

QUALITY CONTROL & ASSURANCE OF PHARMACEUTICALS

(2008 Pattern)

Time : 3 Hours] *[Max. Marks : 80*

Instructions to the candidates:

1) ***Question No. 1 & 5 are compulsory.***
2) ***Solve any TWO from the remaining questions for each section.***
3) ***Answers to the two sections should be written in separate answer books.***
4) ***Figures to the right indicates full marks.***

SECTION - I

Q1) Describe in brief about revised schedule M. **[10]**

Q2) a) Discuss in details about points to be considered for IPQC in manufacturing and packaging operations. **[8]**

b) Write in brief about material management. **[7]**

Q3) a) Define key personnel and explain job responsibilities of Quality control and Production Heads. **[8]**

b) Discuss importance of Equipment logs with suitable examples. **[7]**

Q4) Write short note on: **[15]**

a) Sanitation of manufacturing premises.

b) Components of Quality Assurance.

c) SOP on dispensing of materials.

SECTION - II

Q5) Explain in detail about Validation Master Plan. **[10]**

Q6) a) Write in detail about contents of M.P.C.R. **[8]**

b) Define Sterilization, explain various methods of sterilization. **[7]**

P.T.O.

Q7) a) Write a note on Process Validation. **[8]**

b) Explain various steps and procedures for self inspection and internal audit of quality control department. **[7]**

Q8) Write short note on: **[15]**

a) Media Fill Test.

b) B.P.C.R.

c) HVAC.

Total No. of Questions : 8]

SEAT No. :

P2300

[Total No. of Pages : 2

[4156] - 110
M. Pharm. (Sem. - I & II)
BIOPHARMACEUTICS AND PHARMACOKINETICS
(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) ***Answer to the two sections should be written in separate books.***
3) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Discuss regulatory aspects of bioavailability/bioequivalence studies for controlled drug delivery systems. **[10]**

Q2) What is the need to establish IVIVC while applying NDA/ANDA? From various levels of IVIVC which is acceptable to regulatory authorities and why? **[15]**

Q3) Describe significance of p-Gp transporter system. Suggest conceptual approaches of drug design to escape this efflux system. **[15]**

Q4) Write notes on any three: **[15]**

a) Wagner-Nelson method.
b) Criteria for biowaivers to in vivo bioequivalence study.
c) Bioequivalence study protocol.
d) Dissolution improvement.

SECTION - II

Q5) Why detection of nonlinearity is important? If drug is following non linear kinetics; what are regulatory requirements of its in vivo pharmacokinetic (clinical) studies? **[10]**

Q6) a) 'Drug displacement interactions are many times clinically non significant'. Justify this statement. **[5]**

b) What is clearance and its relevance as fundamental pharmacokinetic parameter? **[10]**

P.T.O.

Q7) A patient on an antibiotic (fu=0.8)100 mg every 12 hrs. intramuscularly was found to have creatinine clearance of 5mL/min. Should the dose be adjusted? If So, **[15]**

a) Adjust the dose by keeping dosing interval constant.

b) Adjust the dosing interval keeping the dose same.

Q8) Describe compartment modeling with its assumptions. Add a note on two compartment model. **[15]**

Total No. of Questions : 8]

P2307

SEAT No. : ____

[Total No. of Pages : 1

[4156] - 117
M.Pharmacy (Sem. - I & II)
NATURAL PRODUCTS MANAGEMENT
(2008 Pattern)

Time : 3 Hours] ***[Max. Marks : 80***

Instructions to the candidates:

1) ***Question No. 1 and 5 are compulsory. Out of the remaining solve any two questions from Section - I and any two questions from Section - II.***
2) ***Answers to the two sections should be written in separate answer books.***

SECTION - I

Q1) Write in detail about management of various resources in farm planning. **[10]**

Q2) Enumerate various factors affecting the demand and supply of natural products. Explain them. **[15]**

Q3) What are the requirements for cultivation and quality control of prioritized medicinal plants in India. Explain. **[15]**

Q4) Write a detail note on various Government schemes and programs to develop medicinal plants in India. **[15]**

SECTION - II

Q5) What are essential requirements of herbal extraction unit? Describe them in detail. **[10]**

Q6) Write a detail note on IPR related to herbs and herbal products. **[15]**

Q7) Discuss in detail regulatory aspects and processing methods for herbal cosmetics. **[15]**

Q8) Explain National and International trading of phytoconstituent. **[15]**

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Total No. of Questions : 12]

P2308

SEAT No. : ____

[Total No. of Pages : 2

[4156] - 118
M.Pharmacy (Sem. - I & II)
MEDICINAL PLANT BIOTECHNOLOGY
(2008 Pattern)

Time : 3 Hours] ***[Max. Marks : 80***

Instructions to the candidates:

1) ***This question paper consists Section - I and Section - II.***
2) ***Use two separate answer books for the Section - I & Section - II.***
3) ***Section - I carries 6 questions of 10 marks each. Answer any four questions in Section - I.***
4) ***Section - II carries 6 questions of 10 marks each. Answer any four questions in Section - II.***
5) ***Enter the question number clearly in the margin of the answer book beside each of your answer.***
6) ***Figures to the right indicate full marks.***

SECTION - I

Q1) What is the Genetic code? What are its salient features? Explain in detail transfer of information via the genetic code. **[10]**

Q2) Give the list of stages where gene expression is regulated? What is Transcriptional regulation? Explain following statement "*Transcription of a gene by RNA polymerase can be regulated by at least five mechanisms*".**[10]**

Q3) What is Recombinant DNA Technology? Write a note on Creating recombinant DNA. What are the properties of organisms containing recombinant DNA. **[10]**

Q4) What is Hairy Root Culture & Multiple Shoot Culture? Write a note on their Applications. **[10]**

Q5) Write a detail note on In Vitro Methods for the Conservation of Endemic Species. **[10]**

P.T.O.

Q6) Write short note on any two : **[10]**

a) Somaclonal Variation : Benefits & disadvantages.

b) Growth regulators in the production of secondary metabolities.

c) Chemodemes.

d) Protoplast culture.

SECTION - II

Q7) What are Enzyme reactors? Classify enzyme reactors. Draw a neat labeled diagram of batch membrane reactor (MR). Explain its working. **[10]**

Q8) Write a detail note on Uses of PCR in gene mapping. **[10]**

Q9) What are molecular maps? What is restriction fragment length polymorphisms (RFLPs) technique? What are its applications? What are alternatives available to the restriction fragment length polymorphisms (RFLPs) technique? **[10]**

Q10) What are transgenic plants? What are currently researched plant vaccines? What are edible vaccines? What are ethical issues involved in edible vaccines? What are benefits of edible vaccines. **[10]**

Q11) What are different Gene transfer strategies? Write a detail note on Agrobacterium-mediated gene transfer. **[10]**

Q12) Write short note on any two : **[10]**

a) Immobilization of enzymes & its applications.

b) Papain.

c) An autoradiograph.

d) RAPD (random amplification of polymorphic DNA) markers & Limitations of it.

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Total No. of Questions : 8]

P2309

SEAT No. : ____

[Total No. of Pages : 2

[4156] - 202

M.Pharmacy

(Spl. Pharmaceutics)

FORMULATIONS AND DEVELOPMENT

(Sem. - II) (M - I - 3) (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 answer books.***
3) ***Neat diagrams must be drawn wherever necessary.***
4) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Give a general account of the different methods used for masking the bitterness of an orally administered drug. **[12]**

Q2) What are the characteristics of an ideal package? What factors should be considered while developing the package for a particular formulation? **[14]**

Q3) Discuss the concept of colon-specific drug delivery with suitable examples. **[14]**

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

a) Evaluation of glass ampoules and vials.

b) Microemulsions.

P.T.O.

SECTION - II

Q5) Discuss the concept, advantages, limitations and formulation aspects of dry powder inhalers (DPIs). **[12]**

Q6) Give an account of the various types of oral veterinary products citing their advantages and limitations. **[14]**

Q7) Discuss the following : **[14]**

a) Transdermal drug penetration enhancement.

b) Polymers for controlled drug delivery.

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

a) Foils, films, laminates for packaging.

b) Propellants for inhalation aerosols.

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Total No. of Questions : 6]

SEAT No. :

P2310

[Total No. of Pages : 1

[4156] - 203

M.Pharmacy

(Spl. Pharmaceutics)

NOVEL DRUG DELIVERY SYSTEMS

(2008 Pattern) (Sem. - II)

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) ***Answers to the two sections must be written in separate answer books.***

SECTION - I

Q1) Give detailed account of various formulation mechanisms in gastric retentive drug delivery system. **[20]**

Q2) Explain the transport of drugs across mucosal membrane and give various types and mechanism of action of penetration enhancers. **[20]**

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

a) Pulsatile drug delivery.
b) Long acting contraceptive formulations.
c) Osmotic drug delivery system.

SECTION - II

Q4) Describe barrier to transport of protein and peptide drugs and formulation Considerations for their delivery. **[20]**

Q5) Describe the methods of active and passive targeting using particulate carriers. Describe use of liposomes for drug targeting. **[20]**

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

a) Analysis of protein drugs.
b) Resealed erythrocytes.
c) Regulatory considerations in controlled release drug delivery system.

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Total No. of Questions : 6] **SEAT No. :**

P2311 **[Total No. of Pages : 1**

[4156] - 205
M.Pharmacy
(Spl. Pharmaceutical Chemistry)
DRUG DESIGN
(2008 Pattern) (Sem. - II) (M - II - 4)

Time :3 Hours] ***[Max. Marks :80***

Instructions to the candidates:-

1) ***Answer any two questions from section I and any two questions from section II.***
2) ***All questions carry equal marks.***

SECTION - I

Q1) a) Enumerate the different physicochemical properties of a drug molecule that influence the biological activity and describe in detail about hydrogen bonding and ionization influences on biological activity. **[15]**

b) Write in brief about Bioprecursor prodrugs. **[5]**

Q2) a) What are Prodrugs? Discuss designing of drug molecule based on metabolism studies with suitable examples. **[15]**

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

Q3) Write a note on (ANY TWO) **[20]**

a) Steric features of drugs and its effects on the biological activity.
b) Indirect Drug design.
c) Craig plot and Cluster analysis.

SECTION - II

Q4) a) What is Bioisoterism? Give classification of bioisosters. Write applications of Bioisoterism in designing of new drug molecule. **[15]**

b) Discuss in short drug design through Conjunction. **[5]**

Q5) What is QSAR? Give advantages and disadvantages of QSAR. Explain Hantzsch analysis and Free Wilson analysis. **[20]**

Q6) Write a note on (ANY TWO) **[20]**

a) Computer Aided Drug Design.
b) 3D QSAR.
c) Drug design based on Enzyme inhibition.

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Total No. of Questions : 6]

SEAT No. :

P2312

[Total No. of Pages : 1

[4156] - 207
M.Pharm. (Sem. - II)
(Spl. Pharmacology)
MOLECULAR PHARMACOLOGY
(2008 Pattern) (M - III - 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) Enlist various endogenous bioactive molecules. Add a note on modulators of NO and endothelins. **[20]**

Q2) a) Discuss recent advances of drugs acting on cholinergic receptors. **[10]**

b) Explain pharmacological and clinical implications of apoptosis. **[10]**

Q3) a) Potential of human genome mapping in drug research. **[5]**

b) Sodium channel modulators. **[5]**

c) Neurosteroids. **[5]**

d) Cyclic nucleotides. **[5]**

SECTION - II

Q4) a) Write a note on cellular cytotoxicity in immunopharmacology. **[10]**

b) Describe application of transgenic mouse in pre-clinical pharmacology. **[10]**

Q5) a) Explain concept of Cardiac and Vascular remodeling with suitable examples. **[10]**

b) Justify role of high throughput screening in molecular pharmacology. **[10]**

Q6) a) Neuropeptide modulators. **[5]**

b) Drugs acting on hormone receptors. **[5]**

c) Implications of chronopharmacology to drug therapy. **[5]**

d) Cellular Signaling systems. **[5]**

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Total No. of Questions : 8]

SEAT No. :

P2313

[Total No. of Pages : 2

[4156] - 208

M.Pharmacy

(Spl. Pharmacognosy)

PHYTOCHEMISTRY & PHYTOPHARMACEUTICALS

(2008 Pattern) (Sem. - II)

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) Explain role of flavanoids in herbal Drug Research. Mention role of spectroscopy & chromatographic techniques in evaluation of crude drugs. Support your answer with two examples. **[10]**

Q2) a) Write method of extraction, characterization & structure elucidation of Digoxin or Diosgenin. **[7.5]**

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

i) Morphine ii) Grgometrine

Q3) State term standardization. Write its significance in herbal Drug Industry. Explain with reference to following phytopharmaceuticals: **[15]**

a) Solasodine b) Gingerol.

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

a) Chemical Profile of sennosoids.

b) Taxol.

c) Importance of curcumin in pharma industry.

P.T.O.

SECTION - II

Q5) Enlist various parameters recommended by WHO for evaluation of herbal drugs. Write principle & procedure of following: **[10]**

a) Pesticide residue.

b) Bitterness value.

Q6) a) Describe process, equipment of production of herbal extracts. **[7.5]**

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

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

a) Anti - oxidant activity.

b) Anti - diabetic activity.

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

a) Sterlity, stability & Preservation of extracts.

b) Determination of Arsenic & heavy metals.

c) Herbal extraction unit.

Total No. of Questions : 8]

SEAT No. :

P2314

[Total No. of Pages : 1

[4156]-209
M.Pharmacy
(Spl. Pharmacognosy)
INDUSTRIAL PHARMACOGNOSY
(2008 Pattern) (Sem. - II) (M-IV-4)

Time :3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Question Number 1 and Question Number 5 are compulsory, out of remaining attempt any two from Section - I and Section - II.***
2) ***Answers to the two sections should be written in separate answer books.***

SECTION - I

Q1) Discuss in brief the scope for future economic growth of medicinal plants in National economy. **[10]**

Q2) Comment on "Demand and worldwide trend for medicinal plants". **[15]**

Q3) Write in detail the production and utilization of medicinal plants in India. **[15]**

Q4) What are major importing - exporting regions and countries associated with Medicinal plants and derived products? Elaborate the scope for international trade in medicinal plants and derived products. **[15]**

SECTION - II

Q5) Elaborate in brief the production of spices in Indian trade of medicinal and aromatic plants. **[10]**

Q6) What are different types of extracts used in Herbal formulations? Give in detail methods involved in standardization of extracts. **[15]**

Q7) Describe the classification of medicinal plants based industry for medicinal and aromatic plants in India. **[15]**

Q8) Discuss in brief Global regulatory requirements of Herbal medicines. **[15]**

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Total No. of Questions : 6]

SEAT No. :

P2315

[Total No. of Pages : 1

[4156]-210
M.Pharmacy
(Spl. Quality Assurance Techniques)
PHARMACEUTICAL VALIDATION
(2008 Pattern) (Sem. - II)

Time :3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Q.No.1 and Q.No.4 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) Define validation, elaborates its importance and types. **[20]**

Q2) a) What is validation master plan, elaborates its contents. **[10]**

b) Define calibration and write a short note on calibration master plan. **[10]**

Q3) Write Short Note : **[20]**

a) Vendor Certification.

b) Validation of integrated line by media fill test.

SECTION - II

Q4) a) Discuss any five parameters of analytical method validation. **[10]**

b) Explain validation of HPLC instrument. **[10]**

Q5) a) Write importance of cleaning method validation and explain any one equipment cleaning validation. **[10]**

b) Write validation of HVAC system. **[10]**

Q6) a) What are steps involved in process validation. Explain validation of coated tablet. **[10]**

b) Explain validation of dry powder mixer. **[10]**

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Total No. of Questions : 8]

SEAT No. :

P2316

[Total No. of Pages : 1

[4156]-211
M.Pharmacy (Sem. - II)
(Spl. Quality Assurance Techniques)
QUALITY PLANNING & ANALYSIS
(2008 Pattern)

Time :3 Hours] *[Max. Marks :80*

Instructions to the candidates:

1) ***Q.No.1 & 5 are compulsory.***
2) ***Answer any two questions from Section - I and any two questions from Section - II.***
3) ***Answers to the two sections should be written on separate answer books.***
4) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Explain the Juran's triology for maintaining quality. **[12]**

Q2) Explain the role of Statistics in quality control. **[14]**

Q3) Explain the role of Inspections in maintaining quality. **[14]**

Q4) Write short notes on : any two **[14]**

a) Prof. Deming & Prof. Crosbey's contribution.
b) Quality Surveys.
c) Inspection Planning.

SECTION - II

Q5) Explain the role of Planning in maintaining quality in manufacturing. **[12]**

Q6) Explain in detail 'quality improvement & cost reduction. **[14]**

Q7) How quality culture may be developed in industry? **[14]**

Q8) Write short notes (any two) : **[14]**

a) SKIP-LOT Sampling Plan.
b) Quality Improvement Programme.
c) Quality Audits.

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