Total No. of Questions :6] **[Total No. of Pages :2**

P1831

[3957] - 101
M.Pharmacy (Sem. - I)
ADVANCED ANALYTICAL TECHNIQUES
(2008 Pattern)

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

Instructions to the candidates:

1) ***Question 1 and 4 are compulsory.***
2) ***Attempt any one question from the remaining in section I and any one question from the remaining questions of section II.***
3) ***Answers to the two sections should be written in separate books.***
4) ***Draw diagrams wherever necessary.***
5) ***Figures to the right indicate full marks.***

SECTION - I

Q1) a) Suggest suitable chemical structural formula for following spectroscopic data. **[8]**

MF $C_7H_{12}O_4$

IR : 1745 cm^{-1}

Proton NMR :

3.4	singlet	2H
1.3	triplet	6H
4.2	quartate	4H

b) Explain with example how inductive effect, mesomeric effect, resonance and ring strain affect absorption of IR radiation. **[8]**

c) What is Bragg's law? Write its significance. **[4]**

Q2) a) Discuss principle, instrumentation and applications of thermogravimetric analysis. **[8]**

b) Write about fundamental law of absorption and its applications in quantitative analysis. **[6]**

c) Write principle and applications of ESR spectroscopy **[6]**

Q3) a) Discuss modes of vibrations in linear and non linear molecule. **[6]**

b) Comment on hyphenated techniques **[8]**

c) Explain effect of polarity of solvent on absorption maxima in UV spectroscopy. **[6]**

P.T.O.

SECTION - II

Q4) a) Explain in detail the working of various pumps used in HPLC. **[10]**

b) Give different modes of fragmentation for amino acids and alcohols in EIMS. **[10]**

Q5) Following equation is a fundamental equation in HPLC technique. Explain clearly and in detail the meaning of various terms involved in the equation and how resolution [Rs] can be controlled through modification of these terms given in the equation. **[20]**

$Rs = ¼ (\alpha - 1) \sqrt{n} (K' / 1 + K')$

Q6) a) How will you differentiate / identify between the following pairs using mass spectrometry [MS] and / or Proton NMR spectrometry. **[10]**

i) para-n-Propyltoluene and 1'-Methylpropylbenzene.

ii) para-i-Propylethylbenzene and 1-methyl-3, 5-diethylbenzene.

b) Explain why and how derivatization is carried out in HPLC and GC. **[10]**

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Total No. of Questions :8] **[Total No. of Pages :2**

P1839

[3957] - 108

M.Pharmacy (Sem. - I & II)

QUALITY CONTROL & ASSURANCE OF PHARMACEUTICALS

(2008 Pattern)

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

Instructions to the candidates:

1) ***Question No. 1 and 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 books.***
4) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Discuss management of rejected & recovered materials in pharmaceutical processing. **[10]**

Q2) a) Explain the concept of quality culture & importance of staff training in maintaining it. **[8]**

b) Discuss hazards of mix-ups and cross contaminations. **[7]**

Q3) a) Define key personnel and explain the responsibilities of key personnel in pharmaceutical industry. **[8]**

b) Quality control of packaging materials. **[7]**

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

a) Good manufacturing practises.
b) Sanitation of manufacturing premises.
c) SOP on Personnel hygiene.

P.T.O.

SECTION - II

Q5) What is the significance of pharmaceutical manufacturing documentation? Explain in detail batch production & control record. **[10]**

Q6) a) Enlist component of HVAC system & detail the construction of HEPA filter unit. **[8]**

b) Explain the significance & procedure of cleaning validation. **[7]**

Q7) a) Explain the significance & procedure for pharmaceutical plant audit. **[8]**

b) Explain quality control of biological products. **[7]**

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

a) Validation master plan.
b) Drug master file.
c) Sanitation in aseptic area.

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Total No. of Questions :8] **[Total No. of Pages :2**

P1840

[3957] - 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. Attempt any two questions from remaining for section I and section II each.***
2) ***Figures to the right indicates full marks.***
3) ***Answers to the two sections should be written in separate answer books.***

SECTION - I

Q1) Describe the chemistry and structural elucidation of Caffeine. **[10]**

Q2) a) Discuss the methods of isolation of essential oil and separation of terpenoids from essential oil. **[8]**

b) Explain the biosynthesis of fatty acids. **[7]**

Q3) a) Explain the biosynthetic pathway of isoprenoid compounds. **[8]**

b) Describe the structural elucidation of morphine. **[7]**

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

a) Methods of extraction of alkaloids.

b) Isolation and purification of glycosides.

c) Shikimic acid Pathway.

P.T.O.

SECTION II

Q5) Describe the chemistry and structural elucidation of solasodine. **[10]**

Q6) a) Discuss in detail the chemistry of plant steroids. **[8]**

b) Classify flavonoids. Discuss the properties of flavonoids. **[7]**

Q7) a) Explain in detail the chemistry of disaccharides. **[8]**

b) Describe the structural elucidation of ephedrine. **[7]**

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

a) General reactions of monosaccharides.

b) Chemistry of diosgenin.

c) Chemistry of carotenoids.

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Total No. of Questions :8] **[Total No. of Pages :2**

P1841

[3957] - 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 about the appraisal of farm resources, capital resources, management factors, land resources and enterpreural aspects of farm analysis & farm planning. **[10]**

Q2) a) Discuss mechanization/modernization of Natural Products Market. **[8]**

b) Comment on - processing of an agricultural marketing. **[7]**

Q3) Write about

a) Farm planning & budgeting. **[8]**

b) Application of research in farm management. **[7]**

Q4) Write on - 'Co-operative processing / efforts among collectors & growers to store, transport & market the natural products'. **[15]**

P.T.O.

SECTION - II

Q5) Write about ex-situ and in-situ cultivation & conservation of medicinal plants. **[10]**

Q6) a) Write about cultivation economics and project proposals for few prioritized medicinal plants of India. **[8]**

b) Give an account on the legal requirements & processing techniques for marketing of raw materials and value added products in relation to herbal cosmetics. **[7]**

Q7) Discuss the general requirements to establish extraction unit based on herbs/herbal products. **[15]**

Q8) Write an essay on 'IPR in relation to medicinal herbs and herbal products'. **[15]**

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Total No. of Questions :8] **[Total No. of Pages :2**

P1842

[3957] - 118

M.Pharmacy (Sem. - I & II)

MEDICINAL PLANT BIOTECHNOLOGY

(2008 Pattern)

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

Instructions to the candidates:

1) ***Question No. 1 and 5 are compulsory. Out of remaining attempt any two questions from section I and section II.***
2) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Give detail account of pharmaceutical applications of enzyme immobilization. **[10]**

Q2) a) Write about purification of enzymes. **[8]**

b) Describe methods of protoplast fusion. **[7]**

Q3) a) Give an account of hairy root culture and multiple shoot culture. **[8]**

b) Enlist different physical methods of DNA mediated gene transfer. **[7]**

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

a) Somaclonal variation and synthetic seeds.

b) Ti plasmid.

c) Micropropagation.

P.T.O.

SECTION - II

Q5) Give an account of enzyme reactor. **[10]**

Q6) a) Describe method of gene transfer using vectors of Agarobacterium. **[8]**

b) Write about RAPD markers for genetic maping. **[7]**

Q7) a) Discuss RFLP genetic maps in plants. **[8]**

b) Give an account of physical maps using In situ hybridization. **[7]**

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

a) Mutation.

b) Hybridization.

c) Applications of PCR.

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Total No. of Questions :8] **[Total No. of Pages :2**

P1843

[3957] - 207
M.Pharmacy (Sem. - II)
(Spl. Pharmacology)
MOLECULAR PHARMACOLOGY
(2008 Pattern)

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

Instructions to the candidates:

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

SECTION - I

Q1) Enlist various endogenous bioactive molecules & discuss role of COX-2 regulators in inflammation. **[10]**

Q2) Classify Dopaminergic receptors. Add a note on various drugs acting on them. **[15]**

Q3) Define apoptosis. Describe it's pharmacological and clinical implications. **[15]**

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

a) Sodium channel modulators.

b) Cellular signaling mechanism of drug action.

c) Neuropeptides.

d) Angiotensin receptors.

P.T.O.

SECTION - II

Q5) What is chronopharmacology? Discuss implications of chronopharmacology to drug therapy. **[10]**

Q6) Enlist various laboratory animals. Write a note on application of transgenic mouse in experimental pharmacology. **[15]**

Q7) Define Immunopharmacology with respect to cellular cytotoxicity. **[15]**

Q8) Describe potential of human genome mapping in drug research. **[15]**

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Total No. of Questions :8] **[Total No. of Pages :2**

P1844

[3957] - 208
M.Pharmacy (Sem. - II)
(Spl. Pharmacognosy)
PHYTOCHEMISTRY & PHYTOPHARMACEUTICALS
(2008 Pattern)

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

Instructions to the candidates:

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

SECTION - I

Q1) Describe in detail methods of extraction, isolation, characterization and structure elucidation of Caffeine. **[10]**

Q2) Give the Instrumental identification of following phytoconstitutents. **[15]**

a) Gingerol

b) Curcumin

c) Vasicine

Q3) Explain in detail the chemistry of Saponins and give the Pharmaceutical profile of Glycyrrhizinic acid. **[15]**

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

a) IR spectral analysis of Rutin and Atropine.

b) Extraction and isolation of Sennosides.

c) Pharmaceutical significance of Taxol.

P.T.O.

SECTION - II

Q5) Explain the principle, procedure, and importance of following parameters in evaluation of Natural products as per WHO guidelines. **[10]**

a) Determination of Arsenic and Heavy metals.

b) Pesticide residue.

Q6) Describe in detail various pharmacological screening methods for evaluation of **[15]**

a) Hepatoprotective activity.

b) Anti epileptic activity.

Q7) Explain in detail the various methods and related equipment for extraction of herbal drugs. **[15]**

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

a) Pharmacological screening of Anti oxidants.

b) Evaluation of Herbal extracts.

c) Physical evaluation of crude drugs.

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Total No. of Questions : 6] **[Total No. of Pages : 1**

P1832

[3957]-102
M.Pharmacy
RESEARCH METHODOLOGY
(2008 Pattern) (Sem. - I)

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

Instructions to the candidates:

1) ***Attempt 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) ***All questions carry equal marks.***

SECTION - I

Q1) What is the purpose of research? Enlist the different types or research. Give the elaborated account of historical, descriptive and patent oriented research. **[20]**

Q2) a) Give the elaborated account on questionnaire contents and working. **[10]**

b) Enlist the different tools used in research for data collection. Add a note on Interview method along with merits and demerits. **[10]**

Q3) Write notes on any two of the following: **[20]**

a) Use of computer packages in documentation.
b) Student 't' test.
c) Importance of methodology and results and discussion in thesis writing.

SECTION - II

Q4) What is the meaning of hypothesis. Describe the various sources of hypothesis. Add a note on role of hypothesis in research. **[20]**

Q5) Give the salient features of techniques involved in oral presentation of research outcome. **[20]**

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

a) Use of bibliography in research.
b) Correlation data.
c) Use of visual aids in oral presentation.

Total No. of Questions : 6] **[Total No. of Pages : 1**

P1834

[3957]-103
M.Pharmacy
(Spl. Pharmaceutics)
ADVANCED PHARMACEUTICS - I
(2008 Pattern) (Sem. - I)

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

SECTION - I

Q1) Elaborate the preformulation studies of semisolids. **[20]**

Q2) Describe the biodegradable polymers and their significance. **[20]**

Q3) Write short notes (Any Two): **[20]**

a) Superdisintegrants.
b) Liquid crystals.
c) Overages and ICH guidelines.

SECTION - II

Q4) Explain the drug release modeling through polymer matrix and laminates. **[20]**

Q5) Discuss the significance of following optimization techniques: Simplex method, EVOP, Grid search method. **[20]**

Q6) Write short notes (Any Two): **[20]**

a) Validation of pharmaceutical processes.
b) Dissolution models.
c) Methods of microencapsulation.

Total No. of Questions : 8] **[Total No. of Pages : 2**

P1835

[3957]-104
M.Pharmacy
(Spl. Pharmaceutical Chemistry)
ADVANCED PHARMACEUTICAL CHEMISTRY
(2008 Pattern) (Sem. - I)

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

Instructions to the candidates:

1) ***Question No. 1 and 5 is compulsory. Out of the remaining attempt any two questions from each Section - I and Section - II.***
2) ***Write answer to Section - I and Section - II in separate answer book.***

SECTION - I

Q1) What are conformational isomers? Explain with examples how the pharmacological properties of drugs changes with conformational Isomerism. **[10]**

Q2) Discuss the mechanism, stereochemistry and applications of Grignard Reaction taking example of medicinal agent. **[15]**

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

a) Pinacol rearrangement.

b) Diazomethane and its synthetic applications.

c) Free radical reaction.

Q4) Explain synthone approach of designing drug synthesis. Develop the synthetic route for Terfenadine or Rosiglitazone using synthone approach. **[15]**

SECTION - II

Q5) What are chiral drugs? Explain how the chirality of medicinal agents affects the pharmacodynametic and pharmacokinetic properties. **[10]**

P.T.O.

Q6) Discuss the mechanism, stereochemistry and applications of Witting Reaction taking example of medicinal agent. **[15]**

Q7) What are reduction reactions? Explain Birch reduction. **[15]**

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

a) Ionic liquids and supercritical liquids.

b) Solvent free reactions by microwave and ultrasound energy.

c) Oppennauer oxidation.

Total No. of Questions : 8] **[Total No. of Pages : 2**

P1836

[3957]-105
M.Pharmacy
(Spl. Pharmacology)
ADVANCED PHARMACOLOGY
(Pre-clinical Evaluation of Drugs)
(2008 Pattern) (Sem. - I)

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

Instructions to the candidates:

1) ***Question No. 1 and 5 are compulsory. Answer any two questions from the remaining.***
2) ***Answers to the two sections should be written in separate books.***
3) ***Neat diagrams must be drawn wherever necessary.***

SECTION - I

Q1) Explain in detail 3 Rs in Animal Experimentation. Discuss how these 3 Rs can be achieved while preparation of research protocol as per form - B. **[10]**

Q2) Discuss in detail organization of preclinical screening programme. Explain in detail all the safety assessment tests. **[15]**

Q3) Explain the latest structure and function of Institutional Animal Ethical Committee as per CPCSEA. Write in detail structure, layout of an animal house. Add a note on handling and breeding techniques of laboratory animals. **[15]**

Q4) Write a Note on Any Two: **[15]**

a) Patch Clamp Technique.

b) Limitations of *In vitro* testing of drugs.

c) Alternatives to Animal Studies.

P.T.O.

SECTION - II

Q5) Discuss the design and procedures for screening of diuretic agents. **[10]**

Q6) Discuss the animal models for evaluation of antiparkinsonian agents. **[15]**

Q7) Write in detail principle of design and animal models for screening of drugs used in treatment of cardiac arrhythmia. **[15]**

Q8) Write a Note on Any Two: **[15]**

a) Screening of Histamin antagonists.

b) Evaluation of androgens.

c) Methods to test drugs acting as laxatives.

Total No. of Questions : 8] **[Total No. of Pages : 2**

P1837

[3957]-106
M.Pharmacy
(Spl. Pharmacognosy)
ADVANCED PHARMACOGNOSY
(2008 Pattern) (Sem. - I)

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

Instructions to the candidates:

1) ***Question No. 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 books.***
3) ***Neat diagrams must be drawn wherever necessary.***
4) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Describe biotic and abiotic elicitors-induced production of secondary metabolites using plant cell culture. **[10]**

Q2) a) What is chemotaxonomy? What are its advantages & limitations over other methods of classifications? Explain the term divergence & convergence. **[7]**

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

Q3) Enlist various strategies used to enhance secondary metabolite production through tissue culture techniques. Describe genetic manipulation using plant cell culture. **[15]**

Q4) Write a Note on Any Two: **[15]**

a) Coloring pigments derived from plants.

b) Photosensitizing agent.

c) Applications of biopolymers as pharmaceutical excipients.

d) Biofuel.

P.T.O.

SECTION - II

Q5) Write various in vitro & in vivo models used in the evaluation of anticancer activity with suitable examples. **[10]**

Q6) 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. **[15]**

Q7) a) Explain the antidiabetic role of flavonoids. **[7]**

b) Review the plants having hepatoprotective activity. **[8]**

Q8) Write a Note on Any Three: **[15]**

a) Flavonoids as anti-inflammatory agents.

b) Role of high throughput screening (HTS) in drug discovery.

c) Bioreactor for the production of secondary metabolites.

d) Camptothecin.

Total No. of Questions : 6] **[Total No. of Pages : 1**

P1838

[3957]-107
M.Pharmacy
(Spl. Quality Assurance Techniques)
ADVANCED QUALITY ASSURANCE TECHNIQUES
(2008 Pattern) (Sem. - I) (Theory)

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

Instructions to the candidates:

1) ***Solve any two questions from Section - I and two questions from Section - II.***
2) ***All questions carry equal marks.***

SECTION - I

Q1) What is materials management in pharmaceutical industry? Write in details about every aspect of materials management. **[20]**

Q2) Explain how validation is important in pharmaceutical manufacturing and discuss various steps involved in validation of equipments with reference to tablet dosage form. **[20]**

Q3) a) Quality control of sterile product.

b) Steps in Environmental Protection.

[20]

SECTION - II

Q4) Explain different components of quality assurance and discuss their importance in pharmaceutical manufacturing. **[20]**

Q5) Enlist various important facilities and discuss their relevance in building construction to provide suitable atmosphere for Pharmaceutical Industry. **[20]**

Q6) a) IPQC tests for Tablets and Capsules.

b) Plant level document.

[20]

Total No. of Questions : 8] **[Total No. of Pages :2**

P1850

[3957]-110
M.Pharmacy
BIOPHARMACEUTICS AND PHARMACOKINETICS
(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 2 questions from section I and 2questions from section II.***
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.***
5) ***Use of logarithmic tables slide rule, Mollier charts, electronic pocket calculator and steam tables is allowed.***

SECTION - I

Q1) Describe Wagner Nelson method for determination of absorption rate constant. What is the limitation of this method? **[10]**

Q2) What is the significance of P gP(permeability glycoprotein) as an efflux transporter system in Development of targeted drug delivery system for brain? Explain with suitable example the drug design accordingly. **[15]**

Q3) Explain in detail the method of determination of hybrid first order constants for any drug that follows two compartment model and administered as i. v. bolus dose. **[15]**

Q4) Write short notes on any three. **[15]**

a) Design and evaluation of bioequivalence studies.

b) In vivo/biological models for permeability studies.

c) Blood placental barrier.

d) Model independent approach in bioequivalence studies.

SECTION - II

Q5) How non linear kinetics of a drug is detected? Explain the causes of non linearity and significance. Give 'New Drug Application' requirements for a drug that follows Non linearity. **[10]**

Q6) What are drug displacement interactions due to protein binding? Why all displacement interactions are not clinically significant? Explain with examples. **[15]**

P.T.O.

Q7) The elimination half life of the Tobramycin was reported to be 2.15 hours and the volume of distribution was reported to be 33.5% of body weight. What is the dose for an 80 Kg individual if a steady state level of 2.5 μg/mL is desired?
Assume that the drug is given by iv bolus injection every 8 hours. **[15]**

Q8) Write short notes on any three. **[15]**

a) Determination and significance of 'Area under the curve'.

b) Kinetics of protein binding.

c) Significance of Vmax and km.

d) Apparent volume of distribution.

♦♦♦♦

Total No. of Questions : 8] **[Total No. of Pages :2**

P1851

[3957]-111
M.Pharmacy
STERILE PRODUCTS FORMULATION & TECHNOLOGY
(2008 Pattern) (Sem. - I & II)

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

Instructions to the candidates:

1) ***Question No. 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.***
4) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Discuss physicochemical properties of drugs affecting design of parenteral dosage form. **[10]**

Q2) Explain the physiological considerations of LVP's. Discuss formulation and manufacturing process of LVP's. **[15]**

Q3) a) Discuss physiological factors affecting formulation of ophthalmic products. **[8]**

b) Explain Nanoparticles in parenteral drug delivery. **[7]**

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

a) Liposomes in parenteral drug delivery.

b) Glass as a Parenteral packaging material.

c) Pyrogen Testing of sterile dosage forms.

SECTION - II

Q5) Describe construction, working and validation of HEPA filter. **[10]**

Q6) Describe in detail process selection and process specification in sterilization of parenterals. **[15]**

Q7) Explain overview of GMP and regulatory guidelines in parenteral manufacturing. **[15]**

P.T.O.

Total No. of Questions : 8] **[Total No. of Pages :1**

P1852

[3957]-116
M.Pharmacy
TRADITIONAL SYSTEMS OF MEDICINE AND AYURVEDIC FORMULATIONS
(2008 Pattern) (Sem. - I & II)

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

Instructions to the candidates:

1) ***Question Nos. 1 & 5 are compulsory. Answer any two questions from the remaining.***
2) ***Answers to the two sections should be written in separate books.***
3) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Write note on Ayurvedic cosmetic formulations. **[10]**

Q2) What is homeopathic system of medicine? Write about history, principles, homeopathic dilutions and herbs used in homeopathy. **[15]**

Q3) What is 'Guggulu'? Explain the process of sodhana. What are the characteristic of 'Sodhita guggulu' and how it is preserved? **[15]**

Q4) What is ethnopharmacognosy? How knowledge is affected by habitat change, species loss and the cultivation and hybridization of the plant? **[15]**

SECTION - II

Q5) What is Unani system of medicine? Write about its history and Unani medicines in Asia. **[10]**

Q6) Write brief note on standardization of Ayurvedic dosage forms using physical & chemical methods. **[15]**

Q7) Write note on acupuncture and moxibustion as Chinese system of medicine and its safety. **[15]**

Q8) Write down the differences between Ayurvedic medicine and homeopathic medicine with respect to history, philosophy and preparation of medicine. **[15]**

♦♦♦♦

Total No. of Questions : 8] **[Total No. of Pages :1**

P1853

[3957]-201
M.Pharmacy
DRUG REGULATORY AFFAIRS
(2008 Pattern) (Sem. - II)

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

Instructions to the candidates:

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

SECTION - I

Q1) Explain in detail organisation structure and working of WHO and US - FDA. **[10]**

Q2) a) Explain the functions of Drug Inspector. **[8]**

b) Comment on salient features of pollution control Act. **[7]**

Q3) Comment on the provisions related to cosmetics under Drug & Cosmetics Act. **[15]**

Q4) Write in detail on Narcotic & Psychotropic Substances Act 1985. **[15]**

SECTION - II

Q5) Give the salient features of NDA. **[10]**

Q6) Explain the concept of 'Novelty' as applicable to patents. Give suitable examples. **[15]**

Q7) Compare and contrast the GMP of U.S.FDA and Indian regulatory body. **[15]**

Q8) Write short notes on (any three) **[3 × 5 =15]**

a) DMF

b) Copyright

c) Industrial safety

d) Latest edition of I.P.

♦♦♦♦

Total No. of Questions : 8] **[Total No. of Pages :2**

P1854

[3957]-202
M.Pharmacy
(Spl. Pharmaceutics)
FORMULATIONS AND DEVELOPMENT
(2008 Pattern) (Sem. - II)

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

Instructions to the candidates:

1) ***Question Nos. 1 & 5 are compulsory.***
2) ***Solve any two questions from the remaining in Section - I and Section - II.***
3) ***Figures to the right indicate full marks.***
4) ***Answers to the two sections should be written in separate answer books.***

SECTION - I

Q1) How do multiple emulsions differ from micro emulsions? Explain with the help of ternary phase diagrams the selection of various phases in the formulation of microemulsions and SMEDDS. **[10]**

Q2) Discuss in detail various types of gastroretentive drug delivery systems. **[15]**

Q3) How can pulsatile delivery system be formulated? **[15]**

Q4) Write short notes on any three (5 marks each): **[15]**

a) Emulgels based on liposomes.

b) Mouth dissolving tablets.

c) Sublingual formulations.

d) Penetration enhancers in semisolid preparations.

SECTION - II

Q5) What are the different types of containers used for aerosol Preparations? Discuss in detail the two phase and three phase system mode of operation of aerosols. **[10]**

Q6) Explain in detail the packaging material development for regulated markets for conventional and novel drug delivery systems. **[15]**

Q7) Discuss in detail veterinary specialized dose dispensers. Add a note on the need and problems of designing veterinary dosage forms. **[15]**

P.T.O.

Total No. of Questions : 8] **[Total No. of Pages :1**

P1855

[3957]-203
M.Pharmacy
(Spl. Pharmaceutics)
NOVEL DRUG DELIVERY SYSTEMS
(2008 Pattern) (Sem. - II)

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

Instructions to the candidates:

1) ***Question Nos. 1 & 5 are compulsory.***
2) ***Solve any two questions from the remaining in Section - I and Section - II.***
3) ***Figures to the right indicate full marks.***
4) ***Answers to the two sections should be written in separate answer books.***

SECTION - I

Q1) Explain mechanisms of floating drug delivery? Describe its evaluation. **[10]**

Q2) What are the basic components of transdermal drug delivery system? Describe development of TDDS based on adhesive - dispersion type system. **[15]**

Q3) What is chronotherapeutics? Describe formulation and evaluation of pulsatile delivery system. **[15]**

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

a) Biodegradable microspheres.

b) Long acting contraceptive formulations.

c) Mechanism of transmucosal transport of drugs.

SECTION - II

Q5) Describe evaluation procedures for colon targeted drug delivery. **[10]**

Q6) Describe different approaches to targeting drug delivery to brain. **[15]**

Q7) Describe the protein and peptide drug delivery. Give its limitations. **[15]**

Q8) Write notes (any three) **[15]**

a) Drug targeting using monoclonal antibodies.

b) Stabilization of protein and peptide drugs.

c) Microbial approach for colon specific drug delivery.

d) Lacriserts.

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Total No. of Questions : 6] **[Total No. of Pages : 2**

P1856

[3957]-204
M.Pharmacy
ADVANCED MEDICINAL CHEMISTRY
(Spl. Pharmaceutical Chemistry)
(2008 Pattern) (Sem. - II)

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

Instructions to the candidates:

1) ***Write any two questions from Section - I and two questions from Section - II.***
2) ***Write answer to Section - I and Section - II in separate answer book.***

SECTION - I

Q1) a) Write the microbial conversions of prostaglandins giving suitable examples. **[15]**

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

Q2) a) Discuss in detail different types of receptors. Highlight the features of models of cholinergic receptors. **[15]**

b) Explain the enzyme immobilization techniques. **[5]**

Q3) Write the synthetic steps with reaction conditions and mechanism involved in following synthesis (Any Two): **[20]**

a) Dapsone.

b) Ziprasidone.

c) Cetrizine.

SECTION - II

Q4) a) Discuss the various theories proposed for drug-receptor interactions. **[15]**

b) Give brief note on Gene Therapy. **[5]**

P.T.O.

Q5) a) Explain the various aspects of combinatorial chemistry. **[10]**

b) Explain the role of QSAR in drug design. **[10]**

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

a) GABA receptors.

b) Enzyme inhibition.

c) HTS.

Total No. of Questions : 6] **[Total No. of Pages : 2**

P1857 **[3957]-205**

M.Pharmacy
(Spl. Pharmaceutical Chemistry)
DRUG DESIGN
(2008 Pattern) (Sem. - II) (Theory)

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

Instructions to the candidates:

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

SECTION - I

Q1) Explain in detail QSAR with its advantage and its application. Discuss Hansch's LFER model in detail. **[20]**

Q2) a) Explain the significance of ADME in drug design. **[10]**
b) Explain in detail analog approach for drug design with suitable example. **[10]**

Q3) Explain various approaches of drug design in detail with suitable examples. **[20]**

SECTION - II

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

Q5) a) Explain the conformational search techniques in CADD. **[10]**
b) Explain the concept of prodrugs in drug design. **[10]**

P.T.O.

Q6) Write short notes on *any four*: **[20]**

a) Rigid docking.

b) Excluded volume & shape analysis.

c) Artificial neural network in drug design.

d) Quantum mechanics.

e) Force fields.

Total No. of Questions : 8] **[Total No. of Pages : 2**

P1858 **[3957]-209**

M.Pharmacy
(Spl. Pharmacognosy)
INDUSTRIAL PHARMACOGNOSY
(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 books.***
3) ***Neat diagrams must be drawn wherever necessary.***

SECTION - I

Q1) Describe international/world wide trade of medicinal plants & derived products. **[10]**

Q2) Elaborate production and utilization of medicinal plants in India, with suitable examples. **[15]**

Q3) Explain role of medicinal and aromatic plants in future economic growth & development of herbal medicine industry. **[15]**

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

a) Herbal Drug Regulation.

b) Indian spices & their export potential.

c) Phytopharmaceutical production in India.

P.T.O.

SECTION - II

Q5) Classify plant based industry. Elaborate scope of herbal drugs referring to various plant based industries. **[10]**

Q6) Elaborate the requirements of an ideal herbal extraction unit. Comment with reference to infrastructure & staff requirements. **[15]**

Q7) Elaborate utilization of Aromatic plant & derived products with reference to Indian trade. **[15]**

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

a) Global regulatory status of herbal medicine.

b) Production technique of Cinchona alkaloid.

c) IPR & Herbal patents.

Total No. of Questions : 6] **[Total No. of Pages : 2**

P1859

[3957]-210
M.Pharmacy
(Spl. Quality Assurance Tech.)
PHARMACEUTICAL VALIDATION
(2008 Pattern) (Sem. - II)

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

Instructions to the candidates:

1) ***Question Nos. 1 and 4 are compulsory. Out of the remaining attempt one question from Section - I and one question from Section - II.***
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) a) Define validation; elaborate its benefits, Types and component. **[10]**

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

Q2) What is importance of Equipment validation? Elaborate URS, DQ, IQ OQ and PQ of Fluid bed dryer and Autoclave. **[20]**

Q3) a) Define analytical method validation. Discuss validation parameters with respect to HPLC method. **[10]**

b) Give qualification of UV/Visible spectrophotometer. **[10]**

SECTION - II

Q4) a) Write importance of process validation. Elaborate validation of ampoules and vials. **[10]**

b) Write short note on vendor certification. **[10]**

P.T.O.

Q5) a) What is significance of cleaning validation? Discuss cleaning validation of Double cone mixer. **[10]**

b) Explain Validation of HAVAC system. **[10]**

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

a) Computer System Validation.

b) Validation of integrated line by media fill test.

Total No. of Questions : 8] **[Total No. of Pages : 2**

P1860

[3957]-211
M.Pharmacy
(Spl. Quality Assurance Tech.)
QUALITY PLANNING AND ANALYSIS
(Theory) (2008 Pattern) (Sem. - II) (Revised Course)

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

Instructions to the candidates:

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

SECTION - I

Q1) What is Sampling? Enumerate different sampling plans. Justify situation and conditional criteria. Where it is applied? Discuss the characteristics of good sampling plan. **[12]**

Q2) 'Poor Quality and High Cost' *Vs* 'Quality improvement and cost reduction' if studied meticulously can help in industrial progress. Comment. **[14]**

Q3) Describe and justify the relevant importance of planning to maintain & achieve quality in manufacturing operations. **[14]**

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

a) Contribution of Prof. Juran, Prof. Deming and Prof. Crosby in Quality field.

b) Motivation.

c) Quality Surveys.

SECTION - II

Q5) Define Audit and explain its scope in improving the quality of different systems and operations. What are the characteristics of a good auditor? Where surprise audit is carried out? **[12]**

P.T.O.

Q6) Explain the term: Inspection, testing & measurement. How will you decide to what extent inspection is necessary and its accuracy? **[14]**

Q7) Define Statistics. Discuss the advantages of Statistics on Process Control. Explain different statistical control charts used in the industry. **[14]**

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

a) Sporadic & Chronic Quality problems.

b) SKIP - LOT Sampling Plan & its Utility.

c) Quality Improvement Programme (QIP).

Total No. of Questions : 8] **[Total No. of Pages : 2**

P1861

[3957]-114
M.Pharmacy
CLINICAL TRIALS
(2008 Pattern) (Sem. - I & II)

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) ***Figures to the right indicate full marks.***
3) ***Write answers for Section - I and Section - II in separate answer sheets.***

SECTION - I

Q1) Discuss collection, monitoring and interpretation of data in clinical trials. **[10]**

Q2) Describe ethical issues in clinical trials with special mention of Helsinki declaration. **[15]**

Q3) Explain importance of ICH-GCP guidelines in clinical trial. **[15]**

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

a) Case report forms.

b) Role of CRO in clinical trials.

c) Computer application in data analysis.

SECTION - II

Q5) Enlist various parts of clinical trial design. Add a note on risk and benefit calculations. **[10]**

Q6) Name various stakeholders of clinical trials. Discuss responsibilities of physicians. **[15]**

P.T.O.

Q7) Justify role of therapeutic drug monitoring towards quality control in clinical trials. **[15]**

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

a) Hypothesis in clinical trial design.

b) Institutional review board.

c) NDA.

Total No. of Questions : 6] **[Total No. of Pages : 2**

P1862

[3957]-113
M.Pharmacy
ACTIVE PHARMACEUTICAL INGREDIENTS MANUFACTURING TECHNOLOGY
(2008 Pattern) (Sem. - I & II)

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.***
3) ***Neat diagrams must be drawn wherever is necessary.***

SECTION - I

Q1) Describe the technology of animation by reduction using iron and acid for the manufacturing of aromatic amines, illustrate with examples. **[20]**

Q2) Describe in detail manufacture of following drugs with process and instrumentation diagram (any two): **[20]**

a) Rifampicin.

b) Adrenaline.

c) Benzocaine.

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

a) Fluidized bed dryers.

b) Industrial centrifuges.

c) Counter current extractions.

SECTION - II

Q4) Discuss in detail the acylation and esterification process in the manufacture of pharmaceuticals. **[20]**

P.T.O.

Q5) a) Give detailed account of Health hazard in manufacturing facility with respect to Bioethics and Bio-safety. **[10]**

b) Write notes on any two: **[10]**

i) Atmospheric contaminants.

ii) Detection and sampling.

iii) Environment protection laws related to Pharma Industry.

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

a) Oxidation in drug synthesis.

b) Crystallizers used in pharmaceuticals.

c) Stoichiometry in drug synthesis.

Total No. of Questions : 6] **[Total No. of Pages : 1**

P1863

[3957]-109

M.Pharmacy

PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

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

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 books.***
3) ***Neat diagrams must be drawn wherever necessary.***

SECTION - I

Q1) Discuss the design, layout and operational facilities for tablets. **[20]**

Q2) Explain in detail regulatory requirements of pharma facilities with reference to revised schedule M & factory act. **[20]**

Q3) Explain in detail design, layout and operational facilities with services and utilities for sterile products powders ready for reconstitution. **[20]**

SECTION - II

Q4) Discuss in detail designing of plant support services. **[20]**

Q5) Discuss in detail design of effluent treatment plant. **[20]**

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

Total No. of Questions : 8] **[Total No. of Pages :1**

P1864

[3957]-115
M.Pharmacy
SAFETY PHARMACOLOGY
(2008 Pattern) (Sem. - I & II)

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

Instructions to the candidates:

1) ***Q 1 & Q 5 are compulsory.***
2) ***Attempt any 2 questions from the remaining in each section.***
3) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Define safety Pharmacology. What is its scope? **[10]**

Q2) Enlist the regulatory requirements for the new drug safety assessment as per ICH, OECD and USFDA guidelines. **[15]**

Q3) Write notes on: **[15]**

a) Analysis of safety pharmacological data.

b) EMEA guidelines on safety assessment of new drug.

Q4) Give the principles and study design of acute, sub - acute and chronic toxicities in pre - clinical studies. **[15]**

SECTION - II

Q5) Define Pharmacovigilance. What are its objectives and functions? **[10]**

Q6) Write notes on: **[15]**

a) Safety testing for dermatological products.

b) Risk - benefit assessment.

Q7) Describe the pre - clinical safety studies on genotoxicity, reproductive and ocular toxicity. **[15]**

Q8) What is adverse event monitoring during clinical trials? Discuss the data collection, reporting methods, assessment and analysis of the same. **[15]**

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Total No. of Questions : 8] **[Total No. of Pages : 1**

P1865

[3957]-206
M.Pharmacy.
(Spl. Pharmacology)
CLINICAL PHARMACOLOGY
(2008 Pattern) (Sem. - II)

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

Instructions to the candidates:

1) ***Question number 1 and 5 are compulsory. Out of the remaining attempt any two questions from Section-I and two questions from Section-II.***
2) ***Answers to the two Sections should be written in separate book.***
3) ***Figures to the right indicate full marks.***

SECTION - I

Q1) Discuss the management of peptic ulcers. **[10]**

Q2) Explain the mechanism of resistance to antibiotics. Add a note on measures to minimize the antibiotic resistance. **[15]**

Q3) Explain the pharmacotherapy of congestive heart failure. **[15]**

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

a) Responsibilities of Investigator.
b) Management of coagulation disorder.

SECTION - II

Q5) Discuss the process of new drug development process. Add a note on ethics in clinical trial. **[10]**

Q6) Describe the management of asthma. **[15]**

Q7) Discuss the current concepts in the management of cancer. **[15]**

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

a) Renal dialysis.
b) Immunosuppresants.

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