Total No. of Questions : 5]

SEAT No. :

P3682

[Total No. of Pages : 2

[6020]-1001

First Year M.Pharmacy

MPAT-101T : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Common for all specialization

(2019 Pattern) (Semester-I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) ***All questions are coppulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw suitable diagram wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Enlist ideal properties of detector Describe various pumps and detectors used in high performance Liquid chromatography. **[15]**

OR

Describe various columns and stationory phases used in Gas chromatography. Add a note on Affinity chromatography.

Q2) Attemp any TWO: **[15]**

a) Elucidate the structure of organic compound from the following data.

Molecular Formula : C_8H_8O

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

PMR : δ 9.9 (s,1H), δ7.3-7.8 (m, 4H), δ 2.4 (s, 3H)

b) Explain various types of ions formed in Mass spectrometry with suitable exapmles.

c) Elaborate the priniple and instrumentation of Differential Thermal Analysis.

d) Describe FT-IR. Enlist its advantages.

P.T.O.

Q3) Attempt any Three. **[15]**

a) Discuss about choice of solvent and solvent effect in UV-Visible spectroscopy.

b) Explain Phamaceutical Applications and Types of differential scanning calorimetry

c) Describe capillary electrophoresis.

d) Give difference between ^{13}C NMR and 'H NMR.

e) Write types of vibrations in IR spectrometry and Hooks law.

Q4) Give block diagram of Mass spectrometer with function of each port. Describe various types of Mass analyzers. **[15]**

OR

Define chemical shift. Write it's significance and formulas. Describe the factors affecting chemical shift in NMR.

Q5) Write a short note on (any three) **[15]**

a) Principle and Instrumentation of Thermogravimetric analysis.

b) Production of X-rays and different x-ray diffraction methods.

c) Principle and applications of Flome emission spectroscopy.

d) Instrumentation of X-ray diffraction techniques.

e) Moving boundry electrophoresis.

Total No. of Questions : 5]

SEAT No. :

P-3683

[Total No. of Pages : 2

[6020]-1002

M. Pharmacy

GOOD REGULATORY PRACTICES

(2019 Pattern) (Semester - I) (MRA101T)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Neat diagrams must be drawn wherever necessary.***

Q1) Answer any one (15 marks each) :

a) Explain in detail schedule M III.

b) Explain in detail CGMP.

Q2) Answer any two (7.5 marks each) :

a) Write a note on self - inspection.

b) Write in detail about HVAC.

c) Explain about stability testing of new dosage form.

d) What is concept of quality and explain total quality management?

Q3) Answer any three (5 marks each) :

a) Explain six sigma concept.

b) What are the types of validation, explain it?

c) Explain types of qualification.

d) Explain about stability testing principles of GDP.

e) Explain about water systems.

P.T.O.

Q4) Answer any one (15 marks each) :

a) Explain in detail ICH Q1A guideline.

b) Explain in detail controlling the GLP inspection process.

Q5) Answer any three (5 marks each) :

a) Write a note on ISO 13485

b) Explain the concepts of out of specification and change control with examples.

c) Write a note on GDP documentation.

d) Explain in detail types of qualification.

e) What are the principles of GDP and explain about the requirements of premises and equipments.

Total No. of Questions : 5]

SEAT No. :

P3684

[Total No. of Pages : 2

[6020]-1003

First Year M. Pharmacy

PHARMACEUTICAL BIOTECHNOLOGY

MPB-102T : Microbial and Cellular Biology

(2019 Credit Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Attempt any one out of two. **[1×15=15]**

a) What are in vitro screening technique. Explain assay of cytotoxicity, antitumour and antiviral assay.

b) Explain growth of animal cells in culture and application in Pharmaceutical Industry.

Q2) Attempt any two out of four. **[2×7.5=15]**

a) Explain RNA Splicing, editing and amplification.

b) What is mutagenesis. Explain types and application.

c) Explain lysogenic cycle.

d) Write therapies for common fungal infections.

Q3) Answer any three out of five. **[3×5=15]**

a) Differentiate between prokaryotes and eukaryotes.

b) Write a note on industrially important microorganism with examples.

c) Write a note on general procedure of cell culture & nutrient composition.

d) Write about bioenergetics. Explain various aerobic & anaerobic fuelling reactions.

e) What is cytotoxicity.

P.T.O.

Q4) Attempt any one out of two. **[1×15=15]**

a) Explain principle of microbial nutrition and explain factors affecting culture stability.

b) Write a note on DNA & RNA along with central dogma of molecular biology.

Q5) Attempt any three out of five. **[3×5=15]**

a) Explain in vitro screening technique.

b) Write a note on growth of viruses in cell culture propogation & enumeration.

c) Write the pathology of microbial diseases.

d) Explain Apoptosis.

e) Write in detail about cell division and its regulation.

Total No. of Questions : 5]

SEAT No. :

P3685

[Total No. of Pages : 2

[6020]-1004

First Year M. Pharmacy

MPC - 102T : ADVANCED ORGANIC CHEMISTRY - I

(2019 Credit Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Do not write anything on question paper except seat numbers.***
4) ***Draw neat diagrams and structures wherever necessary.***

Q1) Explain the protection for the amino groups and amino acids: carbomates and amides. **[15]**

OR

What is retrosynthesis and synthon approach? Add a note on C-X and C-C disconnections.

Q2) Answer any two of the following. **[15]**

a) Write in short about Debus-Radziszewski imidazole synthesis and Bernthsen Acridine synthesis.

b) Discuss the theory, mechanism and synthetic applications of Biginelli reaction.

c) Explain the guidelines for dissection of molecules and advantages of retrosynthesis.

d) What is nucleophilic substitution reaction. Explain about stereochemistry and factors affecting nucleophilic bimolecular substitution reactions.

P.T.O.

Q3) Answer any three of the following. **[15]**

a) Discuss Elimination reaction with respect to Hoffmann and Saytzeff's rule.

b) Discuss any two methods of determining reaction mechanism.

c) Write the synthesis of Ketoconazole and Sulfamerazine.

d) Elaborate on synthetic applications of Titanium chloride and diazomethane in organic reactions.

e) Write mechanism and synthetic applications of Mitsunobu reaction.

Q4) Describe the following reactions with mechanism and their relevant applications in synthesis of drugs. **[15]**

a) Knorr Pyrrole synthesis

b) Combes Quinoline synthesis

c) Smiles rearrangement

OR

Explain the method of formation, stability and synthetic applications of the following reaction intermediates:

a) Carbenes

b) Nitrenes

c) Free radicals

Q5) Write short notes on any three of the following. **[15]**

a) Protection of hydroxyl groups.

b) Shapiro and Suzuki reaction.

c) FGI and FGA.

d) Bimolecular Nucleophilic substitution reaction.

e) Synthetic applications of Dicyclohexylcarbidimide and diazopropane.

Total No. of Questions : 5]

SEAT No. :

P3686

[Total No. of Pages : 2

[6020]-1005

F.Y. M. Pharmacy

ADVANCED PHARMACOGNOSY - I

(2019 Credit Pattern) (Semester - I) (Credit System) (MPG - 102T)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Answer the question (Solve any one). **[15]**

a) Elaborate detail account of Current Good Agricultural Practices.

b) What is Marine natural product. Give general methods of isolation and purification of marine natural products.

Q2) Answer the following (Solve any two). **[15]**

a) Elaborate detail account of, importance of Pharmacognosy in herbal drug Industry.

b) Write a note on Poly unsaturated fatty acids

c) What are the different problems faced in research on marine drug with special attention on chemical Screening and their solution.

d) Write a note on FSSAI guideline.

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

a) Regulatory aspects of Nutraceuticals.

b) Bio drug-drug interaction with suitable examples.

c) Herbs as functional food

d) Write short note on Formulation and standiardisation of Nutraceuticals.

e) Health benefits of Turmeric

P.T.O.

Q4) Answer the question (Solve any one). **[15]**

a) Write in detail about the occurrence. Isolation and characteristic feature of Hesperidine and Rutin.

b) Elaborate WHO guidelines for safety monitoring of natural medicines.

Q5) Short notes (Solve any three) **[15]**

a) Occurrence and isolation of'Resvcratrol

b) Current trends and future scope on Nutraceuticals

c) Medicinal uses and health benefits Ginseng

d) Objectives and functions of Indian Council of Agricultural Research

e) Isolation of Ellagic acid.

Total No. of Questions : 5]

SEAT No. :

P3687

[Total No. of Pages : 2

[6020]-1006
F.Y. M. Pharmacy
BOS-PHARMACEUTICS
Drug Delivery Systems
(2019 Credit Pattern) (Semester - I) (MPH - 102T)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Answer any one out of two **[15]**

a) Classify Polymers with examples. Give elaborate account of evaluation of Polymers.

b) Classify various GRDDS approaches and explain in details floating drug delivery systems.

Q2) Answer any two out four **[2×7.5=15]**

a) What are the applications and limitations of transdermal DDS and approaches to overcome these limitations?

b) What is Pharmacogenetics and its importance in personalized medicines?

c) What is Robinson - Eriksen equation used in designing SRDFs?

d) What is B-D printing and its applications in DDS?

Q3) Answer any three out of five **[3×5=15]**

a) What are applications of enteric coated tablet/capsule? Describe disintegration test for enteric coated tablet.

b) What are hydrogels and their applications?

c) What is an ideal biodegradable polymer support answer with examples and applications?

d) What is HPMC, its types and applications?

e) Explain with the help of dose response graph SR and IR formulations.

P.T.O.

Q4) Answer any one out of two **[1×15=15]**

a) Explain in details challenges for designing protein and peptide DDS and ways to overcome it.

b) What is iontophoresis and sonophoresis and its applications in DDS.

Q5) Answer any three out of five short notes **[3×5=15]**

a) Evaluation of oral SR tablet.

b) Nasal and transdermal vaccines.

c) Principle of feedback regulated DDS.

d) Buccal tablet.

e) Telepharmacy.

Total No. of Questions : 5]

SEAT No. :

P-3688

[Total No. of Pages : 2

[6020]-1007

M. Pharmacy (Theory)

ADVANCED PHARMACOLOGY - I

(2019 Pattern) (Semester - I) (MPL-102T)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Answer the following (1 out of 2) : **[15]**

a) Define and classify Receptors. Explain structural and functional families of receptors with their respective transduction systems.

b) Classify non narcotic analgesics. Explain the pharmacology of salicylates in detail.

Q2) Solve any 2 out of 4 : **[15]**

a) Define diuretics. Classify diuretics and write the mechanism of action and therapeutic uses of Acetazolamide.

b) Write note on 5HT3 antagonists.

c) Briefly classify sympathomimetics and parasympathomimetic with examples.

d) Explain role of cholinesterase inhibitors as Anti -Alzheimer's medication.

Q3) Write Short note on (any 3 out of 5) : **[15]**

a) Non adrenergic non cholinergic transmission.

b) Benzodiazepines as anti anxiety medication.

c) H1 receptor antagonist.

d) Significance of Protein binding in drugs actions.

e) Pharmacological actions of organic nitrates.

P.T.O.

Q4) Answer the following (1 out of 2) : **[15]**

a) Define heart failure. Write the pharmacology of digitalis.

b) Discuss in brief about synthesis, storage, metabolism and receptors available for adrenaline.

Q5) Write Short note on (any 3 out of 5) : **[15]**

a) Phosphodiesterase inhibitors.

b) NMDA Agonists

c) Antiplatelet drugs.

d) Linear and non-linear compartment models.

e) Dopaminergic agonists.

Total No. of Questions : 5]

SEAT No. :

P-3689

[Total No. of Pages : 2

[6020]-1008

M.Pharmacy (Pharmaceutical Quality Assurance)

MQA 102T : QUALITY MANAGEMENT SYSTEMS

(2019 Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Describe strategic planning and its implementation in pharmaceuticals.

OR

Explain total quality management in detail. **[15]**

Q2) **Attempt any two** **[15]**

a) Explain importance about concept of IPQC in pharmaceutical industry.

b) Give significance of line clearance.

c) Elaborate on NABL certification and accreditation.

d) Describe elements of a PQS as per ICHQ10.

Q3) **Attempt any three :** **[15]**

a) Explain statistical control charts.

b) Give reasons for benchmarking.

c) Explain principles of six sigma.

d) Brief on ISO guidelines.

e) Explain quality metrics of pharmaceutical industry.

P.T.O.

Q4) Explain in detail models of cost of quality. **[15]**

OR

Explain ICH Q8 in detail.

Q5) **Write short note on (Any three)** **[15]**

a) Out of specifications.

b) Corrective and preventive Actions.

c) Statistical process control.

d) HACCP.

e) Photostability testing of drug and drug products.

x x x

Total No. of Questions : 5]

SEAT No. :

P-3690

[Total No. of Pages : 2

[6020]-1009

F.Y. M.Pharmacy

MRA - 102 T : DOCUMENTATION AND REGULATORY WRITING

(2019 Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) **Answer any one :** **[15]**

a) Write a note on post approval changes (SUPAC) :

b) Explain in detail CTD Module 3.

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

a) Explain inspection of manufacturing facilities by regulatory agencies.

b) Explain in detail DMF.

c) Write a note on preparation and conduct of Audit.

d) Write a note on post marketing reporting requirements.

Q3) **Answer any three :** **[15]**

a) Explain product development report.

b) Explain CTD Model 1.

c) Write down difference between CTD and ACTD.

d) What is mean by Internal and External audit, timeline for audit and audit follow up.

e) Explain in brief product life cycle management.

P.T.O.

Q4) **Answer any one :** **[15]**

a) Explain in detail site master tile.

b) Explain in detail ACTD.

Q5) **Answer any three :** **[15]**

a) Write a note on exploratory product development brief for drug substance and product.

b) What are the types of audit, explain it.

c) Write a note on inspection of drug distribution channel.

d) Explain corrective and preventive actions.

e) Explain root cause analysis.

x x x

Total No. of Questions : 5]

SEAT No. :

P-3694

[Total No. of Pages : 2

[6020]-1013

M. Pharmacy

MPH-103T : MODERN PHARMACEUTICS

(2019 Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figures to right indicate full marks.***
3) ***Draw well labeled diagram wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Define optimization. Give advantages of optimization & explain in detail about factorial design. **[15]**

OR

What are large volume parenterals? Elaborate its formulation components.

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

a) Discuss effect of friction & distribution forces in tablet compression.

b) Explain validation of mixer granulator.

c) Discuss various dissolution models.

d) Elaborate self emulsifying drug delivery.

Q3) Attempt any three : **[15]**

a) Explain wetting in suspension.

b) Discuss qualification of facilities.

c) Elaborate on stability testing.

d) Give significance of similarity (f_2) & dissimilarity (f_1) factor.

e) Explain pharmacokinetic parameters.

P.T.O.

Q4) Explain in detail physics of tablet compression. **[15]**

OR

Explain in detail current good manufacturing practices.

Q5) Write short notes on (any three) : **[15]**

a) Types of process validation

b) Heckel plot & its significance.

c) Sales fore casting

d) Process of material management

e) Concept of total quality management

⌘⌘⌘

Total No. of Questions : 5]

SEAT No. :

P-3695

[Total No. of Pages : 2

[6020]-1014

M. Pharmacy

MPL - 103T : PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(2019 Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

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 various methods employed in the screening of anti-hyperlipidemic agents. **[15]**

OR

Discuss the various methods employed in the screening of anti-fertility agents.

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

a) Describe in detail the different in vivo models employed in the screening Alzheimer disease.

b) Discuss the various methods employed in the screening of COPD drugs.

c) Discuss the various methods employed in the screening of analgesic agents.

d) Describe the screening methods for anxiolytic agents.

Q3) **Attempt any three :** **[15]**

a) Write the screening methods of anti-emetic drugs.

b) Describe the screening methods for anti-diarrheal agents.

c) Describe the screening methods for diuretics agents.

d) Write the screening methods for anti-inflammatory agents.

e) Explain various methods used in screening of immunomodulators.

P.T.O.

Q4) Discuss the various methods employed in the screening of anti-anginals agents. **[15]**

OR

Describe the screening methods for anti-atherosclerotic agents.

Q5) **Write short note on any three :** **[15]**

a) Screening methods for Immunosuppressant agents

b) Euthanasia of experimental animals

c) Maintenance and applications of Transgenic animals

d) Good laboratory Practice of experimental animals

e) General principles of bioassay

▽▽▽▽

Total No. of Questions : 5]

SEAT No. : ____

P-3696

[Total No. of Pages : 2

[6020]-1015

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA103T : QUALITY CONTROL AND QUALITY ASSURANCE

(2019 Pattern) (Semester - I)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates :

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

Q1) Discuss in detail In process quality control and finished products quality control in Pharma industry according to Indian pharmacopoeias. **[15]**

OR

Define and elaborate the concept of "Quality Assurance" and summarize the job responsibilities of head of "Quality Control" department and head of "Quality Assurance" department.

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

a) Explain about purchase specifications and maintenance of stores for raw materials.

b) Discuss about hygiene and personal records as per cGMP guidelines.

c) Write principle of Quality Audit. How checklists are important during audits.

d) Briefly describe the importance of Training in Pharmaceutical manufacturing.

Q3) Attempt any three. **[15]**

a) BMR

b) GLP

c) IPQC of Sterile products

d) Significance of personnel training

e) SOP

P.T.O.

Q4) Give overview of ICH guidelines - QSEM, with special emphasis on Q series guidelines. **[15]**

OR

Discuss GMP contents as per Schedule M.

Q5) Write short notes on any three. **[15]**

a) CTD and eCTD
b) Three tier documentation
c) Intellectual property rights
d) Production record review and change control
e) Mix-ups and cross contamination

Total No. of Questions : 5]

SEAT No. :

P-3697

[Total No. of Pages : 2

[6020]-1016

M. Pharmacy

MRA 103T : CLINICAL RESEARCH REGULATIONS

(2019 Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) **Attempt any one** **[15]**

a) Explain in details the drug development process in clinical research including various phases of clinical research.

b) What are the Clinical Research Regulations in India regarding Schedule'Y' and Medical Device guidance.

Q2) **Attempt any Two** **[15]**

a) Describe briefly biostatistics applied in clinical research.

b) Regulatory guidelines on Dose Response Information to support drug register.

c) CFR 21 part 50: Protection of human subjects (USA).

d) Good Pharmacovigilance Practices (USA).

Q3) **Attempt any Three** **[15]**

a) Write in brief about GHTF study group 5 guidance documents.

b) ANDA regulations, governing clinical trials.

c) Provide the details about ISO 14155.

d) FDA Safety Reporting Requirements for BA/BE studies.

e) What information is provided in EU Annual Safety Report (ASR)?

P.T.O.

Q4) **Attempt any one** **[15]**

a) Discuss the salient features and a brief historical perspective on the origin of the Good Clinical Practice guidelines.

b) Discuss Bioavailability and Bioequivalence requirements according to CFR 21 part 320. Add a note on FDA Med Watch.

Q5) **Write short note on (Any three)** **[15]**

a) Post Marketing Surveillance.

b) Clinical research regulations in European Union.

c) Role of placebo in clinical trials.

d) Format used for application for approval of a new drug.

e) ICMR ethical guidelines for biomedical research.

x x x

Total No. of Questions : 5]

SEAT No. : ____

P3698

[Total No. of Pages : 2

[6020]-1017

F.Y. M. Pharmacy (Pharmaceutical Biotechnology)

MPB - 104T : ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

(2019 Credit Pattern) (Semester - I)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

1) ***All Questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagram wherever necessary.***
4) ***Do not write any thing on question paper except Seat No.***

Q1) Attempt any One out of Two: **[1×15=15]**

a) Explain in detail about various methods for gene manipulation.

b) Discuss various drug delivery approaches for therapeutic proteins.

Q2) Attempt Any Two out of Four: **[2×7.5=15]**

a) Explain microbial biodegradation of chemical and industrial wastes.

b) Discuss various purification techniques for enzymes production.

c) Explain selection and screening process in r-DNA.

d) Disucss DNA sequence analysis methods.

Q3) Attempt Any Three out of Five: **[3×5=15]**

a) Write applications of PCR in r-DNA.

b) Write role of cloning vectors in r-DNA techniques.

c) Describe flow chart for the production of amylase enzyme.

d) Briefly explain various oncogenes.

e) Write the applications of microbes in environment monitoring.

P.T.O.

Q4) Attempt any One out of Two: **[1×15=15]**

a) Define Biosensors? Discuss various concept in construction of different types of Biosensors and their applications.

b) Discuss various cell signaling defects and diseases.

Q5) Attempt Any Three out of Five: **[3×5=15]**

a) r-DNA production of Erythropoietin.

b) Gene therapy.

c) Xenobiotics.

d) Human Genome Project.

e) Transgenic animals.

Total No. of Questions : 5]

SEAT No. : [ ]

P3699

[Total No. of Pages : 2

[6020]-1018

F.Y. M.Pharm.

MPC - 104T : CHEMISTRY OF NATURAL PRODUCTS

(2019 Credit Pattern) (Semester - I) (Theory)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

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

Q1) Solve any 1 question out of 2: **[15]**

Explain how anticancer drug therapy has developed from certain plants.

OR

Define and classify Terpenoids. Discuss isolation of Terpenoids and Comment on isoprene rule. Explain structural elucidation of monoterpenoids with examples.

Q2) Solve any 2 questions out of 4: (7.5 marks each question) **[15]**

a) What are characterization details for Vit-D.

b) Explain development of Artemisinin as antimalarial agent.

c) Write a note on rDNA technology and drug discovery.

d) Discuss in detail structural elucidation of ephedrine.

Q3) Solve any 3 questions out of 4: (5 marks each question) **[15]**

a) Write structure elucidation methods for steroids.

b) Explain chemistry of beta lactam antibiotics.

c) How do you elucidate structures of tri-terpenoids.

d) Discuss structural elucidation of Quercetin.

P.T.O.

Q4) Answer any 1 question out of 2: **[15]**

Explain the significance of alkaloid use in therapy with examples and highlight on their isolation process.

OR

Discuss structural characterization using IR, ^{1}H-NMR, ^{13}C-NMR and Mass spectroscopy for following compounds : Morphine, Penicillin.

Q5) Write short notes on any 3 out of 5: (5 marks each question) **[15]**

a) Physiological significance of Folic acid supplements.

b) Development of Teprotide in Cardiovascular drug therapy.

c) Explain hybridoma technology in brief and add a note on its clinical significance.

d) Write the active constituents present in following crude drugs: Swertia Chirata and Gymnema Sylvestre in diabetic therapy.

e) Discuss clinical applications of gene therapy.

Total No. of Questions : 5]

SEAT No. :

P3700

[Total No. of Pages : 2

[6020]-1019

F.Y.M.Pharm. (Pharmacognosy)
INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY
(2019 Credit Pattern) (Semester - I) (MPG104T)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) *All questions are compulsory.*
2) *Figures to the right indicate full marks.*
3) *Draw well labelled diagram wherever necessary.*
4) *Do not write anything on question paper except seat number.*

Q1) Describe WHO guidelines for quality assessment of herbal drugs. **[15]**

OR

Describe Indian and international patent laws applicable to Herbal medicines and their process. **[15]**

Q2) Attempt any two **[15]**

a) Explain national and international regulatory status of herbal drugs.

b) Write note on foreign Trade policy of India.

c) How stability testing of natural products is performed.

d) What are set of international standards on quality management?

Q3) Attempt any three. **[15]**

a) Describe procedure for Indian patent filing.

b) What are pilot plant and scale up techniques?

c) What are rights of patents?

d) How natural local resources are protected legally?

e) What are the methods of selecting projects?

P.T.O.

Q4) Describe in detail about the Good manufacturing practices for production of herbal dosage forms. **[15]**

OR

Explain requirements of herbal industry involved in production of phytomedicines. **[15]**

Q5) Write short note on (any three). **[15]**

a) Monograph of herbal drugs.

b) Siddha and Unani pharmacopoeia

c) Total quality management

d) Plant design steps

e) Trade - Related aspects of intellectual property rights

Total No. of Questions : 5]

SEAT No. : ____

P-3701

[Total No. of Pages : 2

[6020]-1020

M. Pharmacy

REGULATORY AFFAIRS

(2019 Pattern) (Semester - I) (MPH-104T)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

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

Q1) Attempt any one : **[15]**

a) Describe Drug Master File in detail.

b) Write in detail about master formula record.

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

a) Give detailed account of Hatch Waxman Act.

b) Write a note on 21 CFR.

c) Describe CMC.

d) What is informed consent? Write its procedures.

Q3) Attempt any three : **[15]**

a) Explain NDA regulatory approval process.

b) Write a short note on outsourcing BA & BE to CRO.

c) Explain Industry & FDA liaison.

d) Describe post marketing surveillance.

e) Write a short note on regulation of medical devices.

P.T.O.

Q4) Attempt any one. **[15]**

a) Describe objectives & organization of ICH. Elaborate on ICH-Q guidelines.

b) Write a note on development of clinical trial protocols & describe institutional review board.

Q5) Attempt any three : **[15]**

a) Describe ANDA regulatory approval process.

b) Write in short about CTD & ECTD formats.

c) Write short note on safety monitoring in clinical trials.

d) Write in short on Investigational Medical Products Dossier (IMPD).

e) Explain regulatory requirements of EU countries.

Total No. of Questions : 5]

SEAT No. :

P-3702

[Total No. of Pages : 2

[6020]-1021

M. Pharmacy

CELLULAR AND MOLECULAR PHARMACOLOGY

(2019 Pattern) (Semester - I) (MPL 104T)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Describe structure and function of cells in detail. **[15]**

OR

Discuss pharmacogenomics. Explain role of gene variation in health.

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

a) Explain in detail principles and applications of flow cytometry.

b) Explain in brief effect of polymorphism in drug metabolism.

c) Discuss the role of caspases in apoptosis.

d) Describe how cell signaling and communication takes place between cells.

Q3) Attempt any three : **[15]**

a) Explain structure and function of plasma membrane of cell.

b) Describe the types of Immunotherapeutics.

c) Explain principles and applications of flow cytometry.

d) What is DNA electrophoresis? Give its applications.

e) Comment on basic equipments used in cell culture lab.

P.T.O.

Q4) Discuss the principles and applications of DNA recombinant technology. **[15]**

OR

Explain the types of ELISA. Give its advantages, disadvantages and applications.

Q5) Write short notes on any three : **[15]**

a) General procedure for cell culture

b) Cryopreservation

c) JAK/STAT signaling pathway

d) Gene sequencing

e) SDS PAGE

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Total No. of Questions : 5]

SEAT No. :

P-3703

[Total No. of Pages : 2

[6020]-1022

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA-104T : PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

(2019 Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates :

1) ***All questions are compulsory.***
2) ***Figures to the right side indicate full marks.***
3) ***Draw well labelled diagram wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) a) What is importance of technology transfer in pharmaceutical industry? Discuss the steps involved in technology transfer. **[15]**

OR

b) Discuss in detail various quality control tests for glass & plastic containers. **[15]**

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

a) What is Investigational New Drug Application (IND)? Describe the contexts of IND.

b) Discuss the significance of solubility. Explain the role of surfactants in solubility enhancement along with suitable examples.

c) Explain the concept of pilot plant scale up. Give the objective & significance of pilot plant scale up.

d) What is stability testing of pharmaceuticals products? Discuss about the accelerated stability testing.

Q3) Attempt any three : **[15]**

a) Explain the Bar-Zakay model of technology transfer. Explain the lessons learned from this model.

b) Discuss the challenges in scale up of new drug products.

P.T.O.

c) Give the functions of Pharmaceutical Packaging.

d) Give the importance of particle size, shape & surface area in preformulation studies.

e) Write about format & contents of Abbreviated New Drug Application (ANDA).

Q4) What is SUPAC? Discuss in detail SUPAC guidelines for change in site, batch size, manufacturing equipment & process along with suitable example. **[15]**

OR

Discuss in detail about the large scale manufacturing techniques for parenteral dosage forms.

Q5) Write short notes on Any three : **[15]**

a) Post marketing surveillance.

b) Types of glass used for Pharmaceutical Packaging.

c) Significance & need of preformulation studies.

d) Surfactants & its importance.

e) Documentation in technology transfer.

Total No. of Questions : 5]

SEAT No. :

P-3704

[Total No. of Pages : 2

[6020]-1023

M.Pharmacy

MRA - 104T : REGULATION AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

(2019 Pattern) (Semester - I)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Answer any one : **[15]**

a) Enlist types of patent and explain in brief various types of patent.

b) Write in detail Rules, Regulations, Guidelines & Standards regulatory filing of drugs & cosmetics, medical devices, Biologicals & Herbals & Food and Neutraceuticals.

Q2) Answer any two : **[7½ marks each]**

a) Write about the things required to be written in an application form for obtaining a license for carrying out manufacturing of alcoholic preparations.

b) Define Illicit Traffic. Discuss in detail the power of central government to permit, control & regulate certain operations under NDPS Act 1985.

c) Give rules, regulations, guidelines & standards for regulatory filing of food and nutraceuticals.

d) What is geographical indication (GT) & what is its function? Name the legislation for its protection in India & briefly outline the procedure of registration.

P.T.O.

Q3) Answer any three : **[5 marks each]**

a) Explain in brief patent filing procedure.

b) Distinguish between product patent & process patent.

c) Give any three conditions of license granted to a person for import of drugs for Examination, Test and Analysis.

d) Prohibition of advertisement of certain drugs for treatment of diseases & disorders under drugs and magic remedies act 1955.

e) What international conventions protect copyright & related rights?

Q4) Answer any one : **[15]**

a) What are bioavailability & bioequivalence? Discuss in brief about BCS classification of drugs.

b) Comment on patent act 1970 & its amendments. Explain in brief the patent filing procedure. What are differences between product patent & process patent?

Q5) Answer any three : **[5 marks each]**

a) State the power, duties & responsibilities of Excise officer.

b) What is ICH? Discuss ICH guidelines for stability study.

c) Define Industrial Design & discuss the need to protect it as an intellectual property.

d) Briefly discuss Regulatory requirements of Clinical Trials.

e) What is Stem Cell Research? Discuss ICMR-DBT guidelines for Stem Cell Research.

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Total No. of Questions : 5]

SEAT No. :

P-3705

[Total No. of Pages : 2

[6020]-2001

M.Pharmacy

MPB - 201T : PROTEIN & PROTEIN FORMULATION

(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Attempt any one from the following : **[15]**

a) Explain the concept, applications & limitation of tryptic peptide mapping.

b) Explain 2D-Gel electrophoresis. Write principle & applications of 2D-Gel electrophoresis.

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

a) Write a note on Edman sequencing.

b) Discuss forced degradation studies relevance to development of protein therapeutics.

c) Explain different types of proteomics.

d) Discuss ICAT labeling technique for protein quantification.

Q3) Attempt any three from the following : **[15]**

a) What is PEGylation? Write properties & benefits of PEGylation in protein formulations.

b) Write three distinct steps for protein characterisation. Explain protein sequence strategies.

c) Explain different types of mass spectrometry for protein structure.

d) Discuss the role of X-ray crystallography in protein structure determination.

e) Define protein engineering. Write a short note on approaches used in protein engineering.

P.T.O.

Q4) Attempt any one from the following : **[15]**

a) Enlists various methods for protein sequencing. Explain Edman degradation technique in detail.

b) Write a note on Biophysical characterization of proteins.

Q5) Write short note on (Any three) : **[15]**

a) A note on ACEI inhibitors

b) A note on thrombin inhibitors

c) A note of HIV protease inhibitors.

d) A note on Rai-Farnesyl transferase inhibitors.

e) Discuss Isolation of intracellular protein.

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Total No. of Questions : 5]

SEAT No. : ____

P-3706

[Total No. of Pages : 3

[6020]-2002

M. Pharmacy

MPC201T : ADVANCED SPECTRAL ANALYSIS

(2019 Pattern) (Semester - II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates :

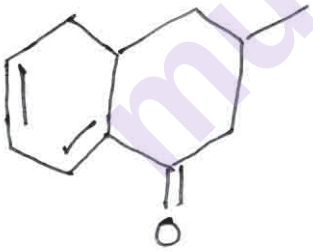
1) ***All questions are compulsory.***
2) ***Neat labeled diagrams must be drawn wherever necessary.***

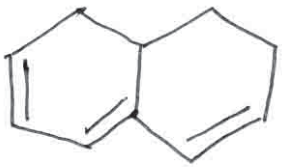
Q1) Elaborate principle, instrumentation and applications of LC-MS. **[15]**

OR

Explain woodward-fieser rule for assessment of λ_{max} for 1,3-butadienes and α, β-carbonyl compounds.

Predict the λ_{max} of following compound (Any one)

i) 

ii) 

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

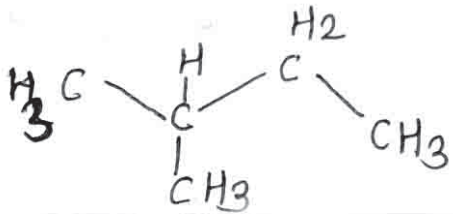
a) Compile principle and instrumentation of supercritical fluid chromatography.

b) Explain COSY and HETCOR techniques.

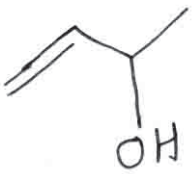
c) Elaborate Mc-Lafferty rearrangement with suitable example.

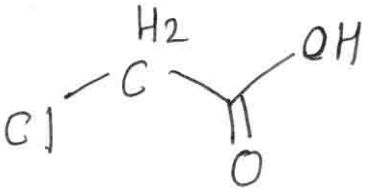
P.T.O.

d) Explain the number of signals and their splitting in following compounds.

i) 

ii) 

iii) 

iv) 

Q3) Attempt any three : **[15]**

a) Discuss use of thermal methods in analysis of pharmaceutical drugs with suitable eamples.

b) Determine IR interpretation of following compounds (Any two).

i) Amines

ii) Alcohols

iii) Carbonyl compounds.

c) What is ortho effect in mass spectrometry. Explain with example.

d) Discuss the radioimmunoassay of Digitalis.

e) How will you differentiate ethyl acetate and methyl acetate from their NMR spectra?

Q4) a) Determine the probable structure of compound. **[15]**

MF : $C_4H_{10}O$

IR (cm^{-1}) : 3375, 2983, 2890, 1035

^{1}HNMR (δppm) : i) δ1.03, doublet, 6H

ii) δ1.92, multiplet, 1H

iii) δ2.11, doublet, 2H

iv) δ5.11, singlet, 1H

b) Compile LC - FTIR.

OR

Explain different rules used in fragmentation of organic compounds.

Q5) Write short note on (any three) **[15]**

a) ATR in IR spectroscopy

b) Flash chromatography

c) ELISA

d) Ring Rules in MS

e) Bioassay

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Total No. of Questions : 5]

SEAT No. :

P-3707

[Total No. of Pages : 2

[6020]-2003

M. Pharmacy

MPG 201 T : MEDICINAL PLANT BIOTECHNOLOGY

(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Write historical perspective and recent development of plant biotechnology as a source of plant biotechnology. **[15]**

OR

What is plant cell cloning? Explain different methods of cloning and its applications.

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

a) Write applications of PCR in plant genome analysis.
b) Explain DNA recombinant technology with its applications.
c) Write a note on 'Single cell protein'.
d) Explain immobilization techniques of plant cell and its applications

Q3) **Attempt Any Three:** **[15]**

a) Explain hairy root culture and its applications.
b) Explain DNA replication with the help of suitable diagram.
c) Explain organogenesis and embryogenesis in brief.
d) Explain the process of protoplast fusion with example.
e) What is biotransformation? Explain bioreactors for pilot and large scale cultures of plant cells.

P.T.O.

Q4) What is transgenic plant? Explain various methods used in gene identification, localization and sequencing of genes. **[15]**

OR

Define genetic code? What are its silent features? Explain regulation of gene expression with suitable example.

Q5) **Write Short Notes on (Any Three) :** **[15]**

a) Synthetic seed and monoclonal variations.

b) Precursors and elicitors on production of secondary metabolites.

c) Gene transfer in plants and their applications.

d) Applications of fermentation technology.

e) Production of enzymes of pharmaceutical interest by fermentation technology.

Total No. of Questions : 5]

SEAT No. :

P3708

[Total No. of Pages : 2

[6020]-2004

First Year M. Pharmacy

MPH - 201T : MOLECULAR PHARMACEUTICS (Nano Tech and Targeted DDS)

(2019 Credit Pattern) (Semester - II) (Theory)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Long answer questions (Solve 1 out of 2). **[15]**

a) What is need of drug targeting? Discuss events and biological processes involved in drug targeting.

b) What are nanoparticles? Discuss preparation and evaluation nanoparticles.

Q2) Solve any two out of four. **[15]**

a) What is the challenge before formulation scientist in brain specific delivery?

b) Preparation and evaluation of dry powder inhalers

c) Write in details on applications of monoclonal antibodies.

d) Comment on antisense molecules.

Q3) Answer the following (any three out of five). **[15]**

a) Discuss the advantages and disadvantages of Pressurized meter dose inhalers.

b) Formulation and evaluation of microspheres S.V. Shirolkar 31-5-22

c) Which is the most convenient method for preparation of liposomes? Explain with reasons.

d) What are the strategies for tumor targeting.

e) Nonviral gene transfer.

P.T.O.

Q4) Solve any one of two. **[15]**

a) Explain application of aptamers therapeutics and diagnosis

b) Write in detail on ex-vivo and in-vivo gene therapy.

Q5) Write short notes on (any three out of five) **[15]**

a) Aquasomes.

b) Containers for Pressurized meter dose inhalers.

c) Viral gene transfer.

d) Electrosomes.

e) Phytosomes.

Total No. of Questions : 5]

SEAT No. :

P3709

[Total No. of Pages : 2

[6020]-2005

F.Y. M. Pharmacy

ADVANCED PHARMACOLOGY - II

(2019 Credit Pattern) (Semester - II) (Theory) (MPL - 201T)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Answer the following. (1 out of 2) **[15]**

a) Write Pharmacological actions, mode of action, adverse effects and therapeutic applications of Corticosteroids.

b) Classify antibiotics. Briefly explain the mechanism of action, antimicrobial spectrum, antimicrobial resistance and therapeutic uses of Cephalosporins.

Q2) Solve any 2 out of 4. **[15]**

a) Classify antiemetic drugs. Write Pharmacology of prokinetic agents.

b) Write mechanism of action, therapeutic uses and toxicity of Zidovudine.

c) Describe role of immunosuppressive agents in Immunopharmacology.

d) Define Asthma. Write the role of Beta 2-Agonists in the treatment of asthma.

Q3) Answer the following (any 3 out of 5). **[15]**

a) Discuss mechanism of action, therapeutic uses and adverse reactions of proton pump inhibitors.

b) What is antimicrobial resistance? Explain biochemical mechanisms of antimicrobial resistance.

c) Define free radicals and antioxidants. Write the role of free radicals in the etiopathology of diabetes.

d) Explain correlation circadian rhythm and diseases with appropriate examples.

e) Write the mechanism of action, antimicrobial spectrum and resistance of Ciprofloxacin.

P.T.O.

Q4) Answer the following (1 out of 2). **[15]**

a) Classify antimalarials. Discuss in brief the Pharmacology of Chloroquine.

b) Classify anticancer agents with examples. Discuss in detail Pharmacology of hormones as anticancer agents.

Q5) Write short note on (any 3 out of 5) **[15]**

a) Anthelmintic Drugs

b) Lipoic acid as an antioxidant.

c) Management of constipation.

d) Nitroimidazoles.

e) Monoclonal antibodies.

Total No. of Questions : 5]

SEAT No. : [ ]

P3710

[Total No. of Pages : 2

[6020]-2006

F.Y. M.Pharm.

PHARMACEUTICAL QUALITY ASSURANCE

MQA-201 T : Hazard and Safety management

(2019 Credit Pattern) (Semester-II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

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

Q1) What are the sources of chemical hazards? Explain with suitable examples control measures for management of chemical hazards. **[15]**

OR

Discuss the ICH guideline on Risk assessment. Explain in detail any three risk management tools.

Q2) Attemp any two. **[15]**

a) Discuss in detail about renewable and non-renewable resources.

b) Enlist and explain the various fire extinguishment system.

c) Explain the seg-protective measures against work place hazards.

d) Explain in brief air circulation and maintainence in non-sterile area.

Q3) Attempt any Three. **[15]**

a) Explain the elements of a safety programme and safety management.

b) Explain the concept of ecosystem with its structure and functions.

c) Describe the TLV concept and its limits.

d) Explain the sources of fire hazards.

e) Explain the concept of fire triangle and its requirements to pose afire hazard.

P.T.O.

Q4) Discuss the sources of air based hazards and management of air based hazards. **[15]**

OR

Elaborate on the contents of a MSDS and its significance.

Q5) Write short notes on (any three) **[15]**

a) Briefly explain BOD and COD measurement and its significance.

b) Give in detail strategies for handling flammable solvent hazard.

c) Discuss the storage and disposal of radio active waste.

d) Discuss mineral and forests as natural resource.

e) Write a note on factories act.

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Total No. of Questions : 5]

SEAT No. :

P3711

[Total No. of Pages : 2

[6020]-2007

First Year M. Pharmacy

MRA-201T : REGULATORY ASPECTS OF DRUGS AND COSMETICS

(2019 Credit Pattern) (Semester - II) (Theory)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Answer any one. (15 marks each)

a) Explain in detail about legislation and regulations for import, manufacture, distribution and sale of cosmetics in Canada.

b) Explain the organization, structure and functions of FDA.

Q2) Answer any two. (7.5 marks each)

a) Describe the changes induced by Hatch Waxman Act in US.

b) Describe organization and structure EMA.

c) Describe Eudralex directives for human medicines.

d) Explain in detail regulatory approval process for AMDA.

Q3) Answer any three. (5 marks each)

a) Write a note on APEC.

b) Write a note on DMF systems in US.

c) Write a short note on certificate of suitability in EDQM.

d) Write a note on investigation new drug application.

e) Write a note on GCC.

P.T.O.

Q4) Answer any one. (15 marks each)

a) Explain in detail marketing Authorization procedures in EU.

b) Explain in detail regulatory considerations for manufacturing, packaging. And labelling of Pharmaceuticals in Japan.

Q5) Answer any three. (5 marks each)

a) Write a note on regulatory requirements for orphan drugs in US.

b) Describe active substance master file (ASMF) system in EU.

c) Describe post marketing surveillance in Japan.

d) Write a note on DMF system in Japan.

e) Write a note on Purple Book.

Total No. of Questions : 5]

SEAT No. : ____

P-3712

[Total No. of Pages : 2

[6020]-2008

M. Pharmacy (Pharm Biotechnology)

MPB202T : IMMUNOTECHNOLOGY

(2019 Pattern) (Semester - II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates :

1) ***Answer all questions.***
2) ***Figures to the right indicate full marks.***
3) ***Draw neat and well labeled diagram wherever necessary.***

Q1) Attempt any one out of two : **[1×15=15]**

a) What are cytokines? Explain their biological functions.

b) Discuss in detail about Antigen presenting cells, their types and functions.

Q2) Attempt any two out of Four : **[2×7.5=15]**

a) Discuss classical pathway of complement system.

b) Give examples of organoleptic Autoimmune diseases.

c) Write advantages and drawbacks of live attenuated vaccines.

d) Explain various types of Hypersensitivity reactions.

Q3) Attempt any three out of five: **[3×5=15]**

a) Discuss about primary lymphoid organs.

b) Enlists Cytokines that regulate adaptive immune response.

c) List out activators for alternative pathway.

d) Explain conjugate vaccines.

e) Discuss various types of systemic Autoimmune diseases.

P.T.O.

Q4) Attempt any one out of two: **[1×15 = 15]**

a) What are monoclonal Antibodies? Write their details methods for production.

b) Discuss on attenuated and inactivated virul vaccines.

Q5) Attempt any three out of five: **[3×5=15]**

a) Interferon-γ

b) Antigen - Antibody interaction reaction.

c) Myasthenia gravis.

d) Mechanism of phagocytosis.

e) Applications of hybridoma technology.

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

P-3713 **[Total No. of Pages : 2**

[6020]-2009

M.Pharmacy (Pharmaceutical Chemistry)

MPC 202T : ADVANCED ORGANIC CHEMISTRY - II

(2019 Pattern) (Semester - II) (Theory)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labelled diagrams wherever necessary.***
4) ***Do not write anything on the question paper except seat number.***

Q1) What are different types of ultrasound assisted reactions? Explain with suitable examples Homogeneous and Heterogenous Liquid - Liquid and Liquid - Solid Ultrasound assisted reactions. **[15]**

OR

What are recemates? Explain various methods for resolution of recemates.

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

a) Explain about E & Z nomenclature with suitable examples.

b) Discuss solid phase synthesis and add a note on various solid supports and linkers used.

c) Describe organo - catalysis with suitable examples.

d) Elaborate on Principles of Green Chemistry.

Q3) **Attempt any three :** **[15]**

a) Write about Ziegler - Natta catalysis.

b) Discuss uses of Transition metal catalysis with examples.

c) Processes of Photochemical reactions.

d) Write about Mechanism and different types of pericyclic reactions.

e) Various protection and deprotection strategies in solid phase peptide synthesis.

P.T.O.

Q4) Define asymmetric synthesis, explain different method of asymmetric synthesis with suitable examples. **[15]**

OR

Elaborate on different types of catalysis and their advantages and disadvantages.

Q5) **Write short notes on (Any three) :** **[15]**

a) Describe the applications of Microwave assisted reactions.

b) Merits and demerits of Microwave assisted synthesis.

c) Continuous flow reactors.

d) Solution phase peptide synthesis

e) Applications of Ionic Liquids and Solvent free reactions.

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Total No. of Questions : 5]

SEAT No. :

P-4339

[Total No. of Pages : 2

[6020]-2010

M.Pharmacy

MPG - 202T : ADVANCED PHARMACOGNOSY -II

(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

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) **Attempt any one question from the following :** **[15]**

a) Elaborate detail account Ethnopharmacology in drug evaluation and drug discovery process with suitable examples.

b) Elaborate detail account determination of Microbial Contamination and Heavy Metals in herbs and their formulations along with its significance.

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

a) Comment on different Causes and Measures of Adulteration with suitable examples.

b) Describe in details Validation of Herbal Therapies

c) Explain Toxicity studies as per OECD Guidelines

d) Elaborate detail analytical profile of *Andrographis paniculata* along with its Pharmacological significance.

Q3) **Attempt any three questions from the following :** **[15]**

a) Explain the different Regulations of Herbal Remedies.

b) Comment on analytical profile of *Embelica officinalis*.

c) Comment on the Role of Ethnobotany in herbal drug evaluation.

d) Comment on analytical profile of *Curcuma longa*.

e) Explain in detail Determination of Foreign Matter along with its significance on quality of crude drugs.

P.T.O.

Q4) **Attempt any one question from the following :** **[15]**

a) Elaborate with suitable examples various Pharmacokinetic and Pharmacodynamic issues produced in herbal remedies.

b) Discuss in detail in *Vivo* screening techniques for Hepatoprotective and Cardioprotective drugs.

Q5) **Write short note on (Any three) :** **[15]**

a) Impact of Ethnobotany on traditional medicine.

b) Analytical profiles of *Coleus forskholii*.

c) Phytotoxin.

d) Analytical profiles of *Psoralea corylifolia*.

e) In *Vivo* screening techniques for Wound healing drugs.

▽▽▽▽

Total No. of Questions : 5]

SEAT No. :

P-3714

[Total No. of Pages : 2

[6020]-2011

M. Pharmacy

MPH202T : ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS

(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) ***All questions are Compulsory.***
2) ***Neat labelled diagrams must be drawn wherever necessary.***
3) ***Use of non-scientific calculator is allowed.***

Q1) Enlist and discuss in detail various factors that affect the drug absorption from gastrointestinal tract. **[15]**

OR

Discuss the concept of BCS and add a note on in vitro methods for permeability studies.

Q2) Answer the following (any 2) : **[15]**

a) Describe in detail active transport of drug.

b) Name the methods used to calculate K_E from urinary excretion data. What are the advantages of urinary data over plasma data?

c) Compare bioavailability and bioequivalence. Elaborate on various study designs used for bioequivalence studies.

d) Describe two compartment open model and estimate hybrid order (first) constants (alpha and beta).

Q3) Answer the following (Any 3) : **[15]**

a) A 70 kg patient is to be given a drug by i.v. infusion the drug has half life of 22 hours, apparent volume of distribution Vd 15.7 litres and the desired Css is 0.0002 mcg/ml. Assuming one compartmental kinetics, calculate infusion rate Ro to achieve desired Css and loading dose (i.v. bolus) to achieve Css.

P.T.O.

b) Describe how dissolution profiles of two dosage forms are compared?

c) Enlist various important pharmacokinetic parameters. Elaborate on the determination of various parameters related to elimination and their importance.

d) What are the various mechanisms for drug-drug interaction in GIT?

e) What in nonlinear pharmacokinetics? What are the causes and how will you determine the nonlinearity?

Q4) Define IVIVC. Discuss different levels of IVIVC along with its applications in pharmaceutical Industry. **[15]**

OR

Discuss the assumptions, limitations and significance of pH-partition hypothesis.

Q5) Write Short note on (Any 3) : **[15]**

a) Wagner - Nelson method.

b) Biosimilar drug products.

c) Pharmacokinetic applications to modified drug release products.

d) Compartment modelling.

e) Study parameters in BA studies.

Total No. of Questions : 5]

SEAT No. :

P3715

[Total No. of Pages : 2

[6020]-2012
F.Y. M. Pharmacy
MPL - 202T : PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - II
(2019 Credit Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Attempt any one **[15]**

a) Explain the importance and methods for test item characterization in regulatory toxicity study.

b) What is reproductive toxicity study. Discuss in brief segment I and III studies in relation to female reproductive toxicity testing.

Q2) Attempt any Two **[15]**

a) Describe in details the Tier 1 and Tier 2 safety pharmacological studies.

b) Discuss the principles of toxicokinetic.

c) Write the alternative methods for animal toxicity studies.

d) Define teratogenicity. Explain the method for teratogenicity studies (Segment II)

Q3) Attempt any Three **[15]**

a) Explain the importance of EPA guidelines for toxicity studies.

b) Explain the types of toxicity studies with examples.

c) Discuss the acute eye irritation studies.

d) Write the inhalation study as per OECD guideline.

e) Define IND. Write the list of studies needed for IND submission.

P.T.O.

Q4) Attempt any one **[15]**

a) Discuss in brief about origon, concepts and importance of safety pharmacological studies.

b) Explain the OECD principles of Good laboratory practice. Write in short about importance in drug development.

Q5) Write short notes on (Any Three) **[15]**

a) Skin sensitization studies.

b) Schedule Y

c) Importance of Toxicokinetics

d) Types of OECD studies

e) HERG assay

Total No. of Questions : 5]

SEAT No. :

P3716

[Total No. of Pages : 2

[6020]-2013
F.Y. M. Pharmacy
MQA - 202T : PHARMACEUTICAL VALIDATION
(2019 Credit Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Attempt Any One question of the following. **[1×15=15]**

a) What is the need to validate analytical method? Explain parameters for method validation as per ICH guidelines.

b) What are the types of steam used in pharmaceutical industry? How is steam system validated?

Q2) Attempt Any Two questions of the following. **[2×7.5=15]**

a) Explain significance of Transfer of Technology.

b) What is patent application? Explain its types.

c) Differentiate between OQ and PQ using suitable example.

d) Explain the importance of "Factory Acceptance Test" and "Site Acceptance Test"

Q3) Attempt Any Three questions of the following. **[3×5=15]**

a) Explain method precision & system precision.

b) Describe "Media fill validation"

c) What is concurrent validation?

d) What are different stages of process validation as per USFDA guidelines?

e) Comment on qualification of Tunnel sterilizer.

P.T.O.

Q4) Attempt Any One of the following questions **[1×15=15]**

a) Elaborate concept of Intellectual property, IP protection in pharmaceutical industry.

b) Explain the importance of qualification of analytical instruments. Discuss qualification of FTIR.

Q5) Write short notes on Any Three: **[3×5=15]**

a) Prospective validation.

b) Calibration of weights.

c) Filter integrity test.

d) Qualification of capsule filling machine.

e) Operational Qualification tests for Gas Chromatograph.

Total No. of Questions : 5]

SEAT No. :

P3717

[Total No. of Pages : 2

[6020]-2014
F.Y. M. Pharmacy
MRA - 202T : REGULATORY ASPECTS OF HERBALS & BIOLOGICALS
(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Answer any one. (15 Marks each).

a) Explain marketing authorization procedure for vaccine regulations in USA.

b) Explain marketing authorization procedure for vaccine regualtions in European Union.

Q2) Answer any two (7½ marks each).

a) Write a note on pharmaconvigilance.

b) What are the preclinical & clinical development considerations for biologics as per USFDA.

c) Explain what are the CTD module 3 data requirements for market authorization application as per India.

d) Explain what are the CTD .1 data requirements. For market authorization application as per India.

Q3) Answer any three (5 marks each)

a) What are the regulatory requirements for blood products as per USA regulations?

b) What are the data requiremtns for preclinical studies as per India regulations?

P.T.O.

c) Write a note on the reference product as Per EU.

d) What are the applications of biosimilars approach as per EU?

e) What are the principles for establishing biosimilarity?

Q4) Answer any one. (15 marks each)

a) Explain in detail comparability or biosimilarity assessment as per European Union.

b) Write in detail about GMP requirements for biologicals as per Indian regulations.

Q5) Answer any three. (5 marks each)

a) Write a note on biological & biosimilars enlist differences biological products.

b) Write a note on advertising regulations as per EU.

c) What are the labeling requirements for blood products as per USA Indian regulations?

d) What are the labeling requirements for blood products as per USA regulations?

e) What are the stability requirements for vaccines as per European union.

Total No. of Questions : 5]

SEAT No. :

P-3718

[Total No. of Pages : 2

[6020]-2015

F.Y. M. Pharmacy

MPB 203T : PHARMACEUTICAL BIOTECHNOLOGY
Bioinformatics & Computer Technology
(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

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

Q1) Attempt any one out of two : **[1 × 15 = 15]**

a) Define bioinformatics. What are its databases?

b) Explain in detail multiple sequence alignment.

Q2) Attempt any two out of four : **[2 × 7½ = 15]**

a) Discuss protein informatics.

b) What is FASTA and BLAST?

c) What is drug designing? Explain its principle.

d) Write a note on protein binding.

Q3) Attempt Any three out of Five : **[3 × 5 = 15]**

a) What is homology modeling?

b) Write about Five types of data used in bioinformatics.

c) What are the components of bioinformatics?

d) Write application of bioinformatics.

e) Write a note on structural databases.

P.T.O.

Q4) Attempt any one out of two : **[1 × 15 = 15]**

a) Discuss various types of docking & methods of protein ligand docking.

b) Write in detail about evolutionary change in nucleotide sequence & add a note on nucleotide substitution.

Q5) Attempt any three out of Five : **[3 × 5 = 15]**

a) Discuss methods of threading technique.

b) Explain in detail Genetic mapping.

c) Explain the principle of drug design.

d) Write a note on Nematode biology.

e) Classify methods of protein ligand docking.

Total No. of Questions : 5]

SEAT No. :

P-3719

[Total No. of Pages : 2

[6020]-2016

M. Pharmacy

MPC 203 T : COMPUTER AIDED DRUG DESIGN

(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Answers to the two sections should be written in separate answer books.***
3) ***Neat labeled diagrams must be drawn wherever necessary.***
4) ***Figures to the right indicate full marks.***

Q1) Citing suitable examples explain the role of CADD in drug discovery. **[15]**

OR

Give a detailed account on the use of CADD for predicting ADMET properties of new chemical entities for drug likeliness.

Q2) Attempt Any Two : **[15]**

a) What is a pharmacophore? Explain the process of identifying several features of a pharmacophore, citing a suitable example.

b) Explain the process of generation of a protein structure to be used in molecular modeling.

c) Explain the process Energy Minimization Methods employed in Molecular Modeling and Docking.

d) Detail the experimental and theoretical approaches for the determination of physico-chemical parameters of drug-like molecules.

Q3) Attempt Any Three : **[15]**

a) Free Wilson analysis.

b) What is AchE? Explain the process of studying molecular docking and drug receptor interactions with AchE.

P.T.O.

c) Describe the process of predicting the functional components in receptor/ enzyme and studying the cavity size.

d) Describe various strategies to design and develop drug molecules.

e) What are the in silico screening protocols for drug design.

Q4) Describe the importance of molecular and quantum mechanics in drug design. **[15]**

OR

Describe the advancement of drug design in the field of HMG-CoA reductases focusing on the role of CADD.

Q5) Write short notes on (Any Three) : **[15]**

a) Analysis of a receptor (or enzyme)-interaction.

b) Conformational analysis.

c) Contour map analysis.

d) Development of agents acting on HMG-CoA reductase using CADD.

e) *Hansch* analysis.

Total No. of Questions : 5]

SEAT No. :

P-3720

[Total No. Of Pages : 2

[6020]-2017
F.Y.M.Pharmacy (Pharmacognosy)
MPG 203 T: INDIAN SYSTEM OF MEDICINE
(2019 Pattern) (Semester-II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates :

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

Q1) **Answer the following :**

a) Explain shelf life and stability studies of ISM formulation. **[15]**

OR

b) Explain Good manufacturing practice of Indian system of medicine.**[15]**

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

a) Explain Aromatherapy in detail.

b) Explain Geographical indication bill

c) Explain various meditation and meditation techniques.

d) What is Gunapadam.Explain in detail?

Q3) **Solve (Any -Three) :** **[15]**

a) Explain CCRAS in detail.

b) Elaborate Ayurveda system of medicine.

c) Explain challenges in monitoring the safety of herbal medicines.

d) Elaborate raw drugs in Siddha system of medicine.

P. T. O

Q4) **Attempt any one question of following :** **[15]**

a) Explain principles of treatment in Homeopathy system of medicines

b) What is Naturopathy? Write a note on treatment modalities in naturopathy

Q5) **Write a short note on any three :** **[15]**

a) ISM

b) GAP

c) Explain Yoga system in detail.

d) CCRS

e) Explain Preparation technique as per Unani Pharmacopeias

Total No. of Questions : 5]

SEAT No. : ____

P-3721

[Total No. Of Pages : 2

[6020]-2018
F.Y.M.Pharmacy
(MPH 203T) Computer Aided Drug Development
(2019 Pattern) (Semester-II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates :

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

Q1) **Answer in detail (solve 1 out of 2) :** **[1 × 15 = 15]**

a) Explain quality by design approach in pharmaceutical development in light of ICH & 8 (R2)

b) Explain the concept of optimization using design of experiments (DOE).

Q2) **Answer the following (solve 2 out of 4) :** **[2 × 7.5 = 15]**

a) Explain drug absorption with their parameters

b) Give historical perspective of application of computers in pharmaceutical industry.

c) Explain in detail development of pharmaceutical emulsion and microemulsion as drug carrier.

d) Write a short note on p-gp and BBB choline transporter

Q3) **Answer the following (solve 3 out of 5) :** **[3 × 5 = 15]**

a) Explain in detail computer simulation in isolated tissue and organ.

b) Write the benefits of pharmaceutical automation in packaging.

c) Explain in detail artificial intelligence (AI)

d) Compare between population and non-population PK/PD.

e) Explain BCRP and hPEPT1

P. T. O

Q4) **Answer the following (solve 1 out of 2) :** **[1 × 15 = 15]**

a) Write in detail about in silico modelling techniques used to study intestinal permeation of drugs

b) Explain in detail fed Vs fasted state and biowaiver consideration.

Q5) **Answer the following (solve 3 out of 5) :** **[3 × 5 = 15]**

a) Write an account on robotics and its applications.

b) Write a short note ethics of computing in pharmaceutical research.

c) Compare descriptive and mechanistic models

d) Write note on legal protection of innovative uses of computers in R&D

e) Mention various fields of pharmaceutical automation along with advantages and disadvantages.

Total No. of Questions : 5]

SEAT No. : [ ]

P3722

[Total No. of Pages : 2

[6020]-2019

F.Y. M.Pharm.

MPL 203T : PRINCIPLES OF DRUG DISCOVERY

(2019 Pattern) (Semester - II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

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

Q1) Long Answer question.

Explain target identification and validation in drug discovery process. Add note on role of Transgenic animals in target validation. **[15]**

OR

a) Explain rational approach for drug design. **[8]**

b) Explain in brief the role of bioinformatics in Target Identification. **[7]**

Q2) Medium Length answer Solve any two. **[2×7½=15]**

a) What is QSAR? Give advantages and disadvantages of QSAR.

b) Explain Hantzsch analysis and Free Wilson analysis.

c) Write about characteristics and impact of biomarkers

d) Describe types of protein structure.

Q3) Short answer questions solve any three. **[3×5=15]**

a) Write a note on ELISA.

b) Write electrophysiological patch clamp process.

c) Write in details Importance of Radio Ligand assay system.

d) Applications of Biomarkers in Drug Discovery

e) Explain in details importance of Molecular Docking

P.T.O.

Q4) Long answer questions.

a) Write a note on prediction of protein structure. **[8]**

b) Describe various lead seeking methods in drug design. **[7]**

OR

Explain G-protein coupled receptor (GPCRs). Note on Pharmacophore based screening. **[15]**

Q5) Short notes any Three. **[3×5=15]**

a) Write a Principle involved in design of pro-drug.

b) Application of NMR in Protein structure prediction

c) Definition of Biomarkers and their Classification

d) Note on Proteonomics

e) Role of Enzyme inhibition in Drug Discovery Process.

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Total No. of Questions : 5]

SEAT No. : [ ]

P3723

[Total No. of Pages : 2

[6020]- 2020
F.Y.M. Pharmacy
MQA203T : AUDITS AND REGULATORY COMPLIANCE
(2019 Credit Pattern) (Semester - II) (Theory)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Discuss quality systems approach to pharmaceutical cGmp regulations in detail. **[15]**

OR

Describe importance of audit in pharmaceutical industry. Explain audit planning in detail.

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

a) Explain the auditing parameters in general areas of interest in the water and raw materials in microbiological laboratory.

b) Explain audit checklist in drug industry.

c) Discuss the auditing of tableting and capsule department.

d) Discuss external audit and internal audit with its advantages.

Q3) Attempt any three. **[15]**

a) Explain types of water to be used in pharmaceutical industry. Explain in detail water for injection system.

b) Outline classification of deficiencies.

c) Discuss duties of quality control unit under cGMP regulations.

d) Elaborate ware house audit.

e) Discuss responsibilities of auditor and auditee.

P.T.O.

Q4) Discuss the importance of HVAC auditing in a sterile manufacturing plant.Give a detailed account of auditing these systems. **[15]**

OR

Discuss the importance of microbiology laboratory audit. Give a detail account on the process of auditing a microbiology laboratory.

Q5) Write short notes on (any three) **[15]**

a) Auditing ETP.

b) Process audit and product audit.

c) Audit of packaging material vendor.

d) Corrective and preventive action.

e) Audit report.

Total No. of Questions : 5]

SEAT No. :

P3724

[Total No. of Pages : 2

[6020]-2021

F.Y M.Pharmacy

MRA - 203T : REGULATORY ASPECTS OF MEDICAL DEVICES

(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instruction to the candidates:

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

Q1) Answer any one. **[15]**

a) Write a note on regulatory approval process for medical devices (510k) premancet notitication.

b) Explain in detail validation and verification of medical devices.

Q2) Answer any two. **[15]**

a) Write a note on labeling requirements 21CFR part 801.

b) Write a note on post marketing surveillance of medical devices as per USA.

c) Write a note on product lifecycle of medical devices.

d) Write a note on adverse event reporting of medical devices.

Q3) Answer any three. **[15]**

a) Explain in detail ISO 13485.

b) Write a note on GHTF organization structure, purpose and functions.

c) What are the quality system requirements as per china.

d) Write down differences between medical devices and pharmaceutical.

e) Write note on clinical investigation of medical devices.

P.T.O.

Q4) Answer any one. **[15]**

a) Explain in detail quality system requirements 21CFR part 820.

b) Explain in detail regulatory registation process of JAPAN.

Q5) Answer any three. **[15]**

a) Write a note on clinical investigation plan for medical devices.

b) Write a note on pre-mancet approval

c) Explain global medical devices nomenclature

d) Explain medical devices working groups

e) What are the quality system requirements for medical devics as per JAPAN.

Total No. of Questions : 5]

SEAT No. :

P-3725

[Total No. Of Pages : 2

[6020]-2022
M.Pharmacy
Biological Evaluation of Drug Therapy
(Semester-II) (2019 Pattern) (MPB 204T)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates :

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

Q1) **Answer any One: (15 marks each)** **[15]**

a) Define biologic medicines. Explain in detail the role of biological medicines in skin diseases and blood disorders.

b) Define bioassay. Explain in detail its principles, scope, and limitations.

Q2) **Answer any Two :(7.5 marks each)** **[15]**

a) Explain types of bioassay.

b) Describe the bioassay of oxytocin.

c) Describe sub-acute and chronic toxicity studies

d) Write a note on mutagenicity toxicity studies.

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

a) Explain pharmacodynamic methods of assessing bioavailability

b) Define bioavailability. Write a note on the absolute and relative bioavailability.

c) Describe pyrogen testing of parenteral.

d) Explain in detail the role of biologic medicines in organ transplantation.

e) Explain in detail the role of biologic medicines concerning autoimmune disorders.

P.T.O.

Q4) **Answer any One: (15 marks each)** **[15]**

a) Define bioequivalence. Explain bioequivalent studies.

b) Explain various methods to calculate ED50

Q5) **Answer any Three: (5 marks each)** **[15]**

a) Explain measurement of bioavailability from urinary excretion data.

b) Explain the terms pyrogens, endotoxins, and exotoxins in detail.

c) Write a note on preclinical drug evaluation.

d) Define bioequivalence and the concept of equivalent.

e) Write a short note on the assay of vitamin B-12.

Total No. of Questions : 5]

SEAT No. :

P-3726

[Total No. Of Pages : 2

[6020]-2023
F.Y.M.Pharmacy
(MPC 204T) Pharmaceutical Process Chemistry
(2019 Pattern) (Semester-II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates :

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

Q1) **Answer any One:** **(15 marks)**

a) Write briefly about principle, construction, working operation of plate and frame filter press.

b) Enlist and briefly explain various unit operations. Give detail account on crystallization.

Q2) **Answer any Two :** **(15 marks)**

a) Write the kinetics and mechanism of aromatic nitration.

b) Discuss types of evaporators used in evaporation.

c) Write about fire hazards and types of fire and fire extinguishers.

d) Discuss the different oxidizing agents used in oxidation.

Q3) **Answer any Three:** **(15 marks)**

a) Explain hydrogen transfer reactions in reduction

b) Write the kinetics, mechanism and types of halogenation reactions.

c) Explain aerobic and anaerobic fermentation with examples.

d) Define extraction. Write about types of extraction.

e) What is Mier's theory of crystallization and its limitations.

P.T.O

Q4) **Answer any One:** **(15 marks)**

a) Define distillation. State types of distillation. Explain in detail azeotropic distillation.

b) Write the principle and general methods of preparation of polymorphs, hydrates, solvates and amorphous APIs.

Q5) **Write a short note on (any Three):** **(15 marks)**

a) Scale - up process of APIs.

b) Factor affecting evaporation.

c) Genotoxic impurities.

d) Production of statins

e) Ozonolysis.

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

P-3727 **[Total No. of Pages : 2**

[6020]-2024

First Year M. Pharmacy (Pharmacognosy)

MPG 204T : HERBAL COSMETICS

(2019 Pattern) (Semester - II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

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

Q1) Explain the formulation and evaluation of herbal shampoo. **[15]**

OR

Discuss method of preparation and standardization of mouth washes and dentifrices.

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

a) Explain formulation and evaluation of Face powder.

b) Discuss method of preparation of moisturizing cream.

c) Explain in details manufacturing and evaluation of cleansing cream.

d) Explain regulatory aspects related herbal cosmetics.

Q3) Solve Any three : **[15]**

a) Discuss export and import of herbal cosmetics.

b) Explain method of preparation of hair oil of herbal origin.

c) Explain toxicity of cosmetics.

d) Discuss formulation and standardization of baby product.

e) Describe lipsticks as herbal cosmetic.

P.T.O.

Q4) Attempt any one question of following : **[15]**

a) Explain physiology and chemistry of skin and pigmentation.

b) Explain raw material, preservatives and surfactants used in herbal cosmetics.

Q5) Write a short note on any three : **[15]**

a) Economic aspects of natural cosmetics.

b) Quality Control Method of herbal Shampoo.

c) Compatibility studies of herbal cosmetics.

d) Evaluation of herbal lotion.

e) Sunscreen product.

Total No. of Questions : 5]

SEAT No. :

P3728

[Total No. of Pages : 2

[6020]-2025
First Year M.Pharmacy
PHARMACEUTICS
MPH - 204T : Cosmetic and Cosmeceuticals
(2019 Pattern) (Semester - II)

Time : 3 Hours] *[Max. Marks : 75*

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Define cosmetic as per D & C Act 1940. Explain in brief the provisions relating to manufacture of cosmetics. **[15]**

OR

Explain the structure and function of skin. Explain the formulation development of cold cream.

Q2) Attempt Any Two: **[15]**

a) Protocol for skin sensitivity tests.

b) Discuss about the Face wash and scrubs.

c) Elaborate the evaluation of lipstick finished product.

d) Soaps and syndetbars.

Q3) Attempt Any Three: **[15]**

a) Building blocks for formulation of Shampoo.

b) Perfumes and its classification.

c) Antimicrobials used as preservatives.

d) Deodrants and Antiperspirants.

e) Emollients used in skin care cosmetics.

P.T.O.

Q4) Explain in detail about the formulation ingredients of various dental Products. Add a note on evaluation of dentifrices. **[15]**

OR

What do you mean by Herbal cosmetics and explain the challenges involved in developing these products. Write in detail about the formulation of herbal oral care products.

Q5) Write short notes on (Any three): **[15]**

a) Nail care products.

b) Surfactants used in cosmetic preparation.

c) Nail lacquer.

d) COSMOS body members and their rules.

e) Oral care products.

Total No. of Questions : 5]

SEAT No. : [ ]

P3729

[Total No. of Pages : 2

[6020]-2026

F.Y. M.Pharmacy

MPL - 204T : CLINICAL RESEARCH AND PHARMACOVIGILANCE

(2019 Credit Pattern) (Semester - II) (Theory)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***All questions carry equal marks.***

Q1) Long Answer questions: **[15]**

a) Define Good Clinical Practice (GCP). Explain clinical trial phases and note on principles of ICH-GCP guidelines.

OR

b) Write in detail ethics involved in GCP study. Note on Institutional Review Board (IRB) and concept of informed consent for clinical study.

Q2) Medium Length Answers Solve Any Two: **[2×7½=15]**

a) Principles of Biomedical Research in Clinical trials.

b) Importance of Activities of Indian Council of Medical Research (ICMR) for clinical trials.

c) Explain case control and Cohort study in clinical trial.

d) Methods of Detection of Adverse Drug Reactions (ADRs).

Q3) Short Answer questions Solve any three: **[3×5=15]**

a) Importance of clinical Research Organisation.

b) Pharmacoepideniology.

c) Guidelines for ADR reporting.

d) Note on Vaccine Safety Surveillance.

e) Write Roles and responsibilities of sponsor in clinical trial study.

P.T.O.

Q4) Long Answer questions: **[15]**

Define Pharmacovigilance. Explain methods for Pharmacovigilance Study.

OR

Write on basic steps in setting up a pharmacovigilance center and note on clinical research organisation.

Q5) Short notes Any three: **[3×5=15]**

a) Pharmacoeconomics.

b) Reporting process of ADRs.

c) Basics of drug information resources in Pharmacovigilance.

d) Functions of pharmacovigilance system.

e) Explain periodic safety update Reports.

Total No. of Questions : 5]

SEAT No. : [ ]

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[Total No. of Pages : 2

[6020]-2027

F.Y. M.Pharm. (Pharmaceutical Quality Assurance)

MQA-204T: PHARMACEUTICAL MANUFACTURING TECHNOLOGY

(2019 Credit Pattern) (Semester - II) (Theory)

Time : 3 Hours] ***[Max. Marks : 75***

Instruction to the candidates:

All questions are compulsory.

Q1) Discuss legal requirements for API and formulation industry in India. Explain selection of pharmaceutical plant layout with factors influencing plant location and layout. **[15]**

OR

Describe process automation in tablet manufacturing. Add on spheronizers and manumerizers as improved tablet production techniques.

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

a) Problems in coating technology and remedies thereof.

b) Process automation in SVP's and LVP's manufacturing.

c) Area planning in sterile product manufacturing.

d) Manufacturing flow chart and IPQC test for capsules.

Q3) Attempt any three: **[15]**

a) What factors should be considered while selecting closure lining?

b) CIP.

c) Lyophilization technique.

d) IPQC test for sterile emulsion and suspensions.

e) Analytical QbD.

P.T.O.

Q4) Describe QbD in detail with elements and various terminologies with examples. **[15]**

OR

Discuss in detail containers and closures for Pharmaceuticals with their advantages and disadvantages.

Q5) Write short note on any three: **[15]**

a) Stability aspects of packaging material.

b) Form fill seal technology.

c) PAT.

d) Production planning.

e) Drug - plastic interaction.

Total No. of Questions : 5]

SEAT No. : [ ]

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[Total No. of Pages : 2

[6020]-2028

First Year M.Pharmacy

MRA - 204T : REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

(2019 Credit Pattern) (Semester - II)

Time : 3 Hours] ***[Max. Marks : 75***

Instructions to the candidates:

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

Q1) Long Answer Question (Solve 1 out of 2): **[15]**

a) Explain role of NSF in dietary supplement and nutraceutical.

b) Explain US regulation for manufacturing and sale of nutraceutical & dietary supplement.

Q2) Medium length answer (Solve 2 out of 4): **[15]**

a) What is food? Give its type, explain the function of each with example.

b) What information required on label? Give its importance of each other.

c) What is food safety and standard act? Give its composition along with their role.

d) Explain European Regulation on novel food ingredient.

Q3) Short answer question (Solve 3 out of 5): **[15]**

a) What is nutraceutical? Classify them explain any two.

b) Give the importance of confirmation of supplements by health care professional.

c) What is food safety and standard act giving its function.

d) Recommended dietary allowance in europe.

e) Responsibilities of USFDA.

P.T.O.

Q4) Long Answer Question (Solve 1 out of 2): **[15]**

a) European Regulation on Novel Food and Novel Food Ingredients.

b) Explain role of NSF international in dietary supplements and Nutraceutical Industries.

Q5) Short Note (Solve 3 out of 5): **[15]**

a) Role of Probiotics in management of disease.

b) Good manufacturing practices in India.

c) European Nutrition labelling.

d) Occurrence and management of disease due to lack of micronutrients.

e) USFDA Food Safety Modernization Act.