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

PD11039 **[Total No. of Pages : 2**

[6423]-9
First Year M. Pharmacy
PHARMACEUTICAL CHEMISTRY
MPAT 101T : Modern Pharmaceutical Analytical Techniques
(2019 Credit Pattern) (Revised) (Semester - I)
(Common Subjects for all Specializations)

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) Give a detailed account on instrumentation of NMR. Add a note on difference in the ^{1}H NMR and ^{13}C NMR. **[15]**

OR

Describe instrumentation and advantages of FTIR. Add a note on reflectance techniques.

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

a) Elucidate the structure of organic compound from the following data Molecular Formula: $C_{10}H_{14}$

IR: 3099-3032cm^{-1}, 2925-2875cm^{-1}, 1500-2000 cm^{-1} overtones, 1465 cm^{-1}, 1506 cm^{-1}, 1614 cm^{-1}, 738 cm^{-1}

PMR: δ 0.8 (d, 6H), δ1.86 (m, 1H), δ2.45 (d, 2H), δ7.28 (s, 5H)

b) Describe factors affecting resolution in chromatography.

c) Elaborate the principle and instrumentation of Differential Scanning Calorimetry.

d) Describe Quadrupole and Time of flight mass analysers.

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

a) Write a note on Electrospray ionization technique.

b) Describe Choice of solvent and solvent effect in UV-Visible Spectroscopy.

c) Explain Capillary electrophoresis.

d) Describe methods used for Production of X-rays.

e) Discuss about Instrumentation of Differential Thermal Analysis.

P.T.O.

Q4) Explain factors affecting separation in Electrophoresis. Add a note on Gel electrophoresis. **[15]**

OR

Describe instrumentation of Ultra High Performance Liquid Chromatography.

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

a) Modulated DSC and Hyper DSC.

b) Instrumentation of Affinity Chromatography.

c) Metastable ions, isotopic and base peaks.

d) Quenching of fluorescence.

e) Coupling constant.

Total No. of Questions : 5]

SEAT No. :

PD11040

[Total No. of Pages : 2

[6423]-10
First Year M. PHARMACY
MRA 101T: GOOD REGULATORY PRACTICES
(Revised 2019 Pattern) (Semester-I) (Credit)

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 questions (Any 1). **[1×15=15]**

a) Explain about Good Automated Laboratory Practices in details.

b) Explain in details about cGMP for Finished Pharmaceuticals.

Q2) Medium length answers (Any 2). **[2×7½=15]**

a) Explain future of GLP regulations.

b) Give Challenges and benefits in implementing electronic documentation systems under GDP.

c) Give the rules of classification under Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

d) Write in detail about analytical method validation.

Q3) Short answers (Any 3). **[3×5=15]**

a) Give details about software evaluation checklist.

b) What do you mean by GDP? Give the principle of GDP for GLP.

c) Write a note on cleaning validation.

d) Give various types of validation along with validation master plan.

e) Give details about laboratory management and personal details under GALP.

P.T.O.

Q4) Long answer questions (Any 1). **[1×15=15]**

a) Describe about USFDA GLP Regulations (Subpart A to Subpart K).

b) Explain in detail 21 CFR part 11.

Q5) Short notes (Any 3). **[3×5=15]**

a) Explain in detail types of qualification.

b) General & documentation requirements in QMS under Schedule M-III.

c) ICH guidelines to establish quality & efficacy of drug substance.

d) Write a note on ISO 13485.

e) Validation of HAVC.

Total No. of Questions : 5]

SEAT No. :

PD-11041

[Total No. of Pages : 2

[6423]-11
F.Y. M. Pharmacy
PHARMACEUTICAL BIOTECHNOLOGY
MPB 102 T : Microbial and Cellular Biology
(Rev. 2019) (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 labelled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Explain in detail applications of industrially important microorganisms with suitable examples. **[15]**

OR

Explain methods of isolation cultivation and preservation of pure cultures. **[15]**

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

a) Write types, purifications and applications of gene mapping of plasmids.

b) Explain structure and types of DNA.

c) What is primary cell culture? Write the applications of cell cultures in research.

d) Explain the process of in-vitro fertilization.

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

a) Embryonic germ cells.

b) Cell division and its regulation.

c) Mutation and lysogeny.

d) Transcription and translation.

e) Eukaryotic cell.

P.T.O.

Q4) Explain the mechanism of microbial pathogenicity and currently recommended therapies for viral infections. **[15]**

OR

Explian anti-tumor and anti-viral assays as in-vitro screening techniques.**[15]**

Q5) **Write a note on (Any Three)** **[15]**

a) Features of pathogenic bacteria.

b) Transformed cell cultures.

c) Cell cycle and apoptosis.

d) Oncogenes.

e) RNA amplification.

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Total No. of Questions : 5]

SEAT No. :

PD-11042

[Total No. of Pages : 2

[6423]-12
M. Pharmacy
PHARMACEUTICAL CHEMISTRY
MPC 102 T: Advanced Organic Chemistry - I
(Rev. 2019) (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.***

Q1) What is multi-component synthesis? Discuss about mechanism and synthetic applications of hantzsch reaction, passerini reaction and strecker synthesis.**[15]**

OR

Discuss reaction mechanism and applications of sandmeyer reaction, Dieckmann reaction and Mannich reaction.

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

a) Explain the phenomenon of protection for the hydroxyl group, including 1,2-diols and 1,3-diols.

b) Explain the preparation, salient features of aluminium isopropoxide and N-uromosucinamide. Explain their applications in organic synthesis.

c) Explain about C-X disconnections and C-C disconnections with respect to alcohols and carbonyl groups.

d) Explain the detailed mechanism and reactions with synthetic applications of mitsunow reaction and Doebner-Miller reaction.

P.T.O.

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

a) Write mechanism and synthetic applications of Ullmann coupling reaction.

b) Describe about method of formation, stability and synthetic applications of carbocations and carbanions as organic reaction intermediates.

c) Discuss about stereochemistry and factors affecting nucleophilic unimolecular and bimolecular reactions.

d) Explain about mechanism and synthetic importance of Biginelli reaction.

e) Write synthesis of Metronidazole and Promazine.

Q4) Discuss about protection for the amino group and amino acids. **[15]**

OR

Describe mechanism and application of Knorr Pyrazole synthesis and pinner pyrimidine synthesis with suitable example of drugs.

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

a) Organic reaction intermediates

b) Mechanism and applications combes quinoline synthesis.

c) Synthetic applications of Dicyclohexylcarbodimide and Diazomethane.

d) Ugi reaction and passerini reaction.

e) Bimolecular elimination reaction.

Total No. of Questions : 5]

SEAT No. :

PD-11043

[Total No. of Pages : 2

[6423]-13

F.Y. M.Pharmacy (Semester - I)

MPG - 102T : ADVANCED PHARMACOGNOSY - I

(Rev. 2019 Pattern) (Credit System)

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

Instructions to the candidates:

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

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

a) What are Marine natural product. Explain in detail about recent advances in research in marine drugs.

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

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

a) Elaborate Medicinal uses and health benefits of Green and Herbal tea.

b) Elaborate detail account of bio drug-drug interactions with examples.

c) Write method of isolation,chemical properties and medicinal and health benefits of Ellagic Acid.

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

Q3) **Write Short Note on (Solve any three).** **[15]**

a) Chemical nature, Medical benefits and health benefits of Spirulina.

b) Isolation of Withanolides

c) Bio drug - food interactions

d) Herbs as functional food

e) Discuss Regulatory aspects of Nutraceuticals.

P.T.O.

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

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

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

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

a) Formulation of neutraceuticals.

b) Ex-situ conservation of medicinal plants.

c) Current Good Collection practices

d) Marine toxins.

e) Medicinal uses and health benefits Ginseng.

Total No. of Questions : 5]

SEAT No. :

PD11044

[Total No. of Pages : 2

[6423]-14

First Year M.Pharmacy

MPH 102T : DRUG DELIVERY SYSTEM

(Revised 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.***
4) ***Do not write anything on question paper except seat number.***

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

a) Describe about various physicochemical and biological approaches for sustained release/controlled release formulations.

b) Discuss in detail about formulation and evaluation of various buccal formulations.

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

a) Compare natural polymers with synthetic polymers Give 5 examples of semisynthetic polymers.

b) Describe different principles behind gastro-retentive drug delivery systems.

c) Define Pharmacogenetics, and give Categories of Patients for Personalized Medicines.

d) Explain in detail about mucosal and transdermal delivery of vaccines.

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

a) Write note on 3D Printing of pharmaceuticals.

b) Give applications and examples of Biodegradable polymers.

c) Describe evaluation of transdermal drug delivery system.

d) Give principle of feedback regulated drug delivery systems with examples.

e) Give importance of % CDR (dissolution) study in evaluation of oral SRDFs.

P.T.O.

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

a) Explain following equations with reference to Oral SRDF-Fick's law of diffusion, Noyes-Whitney equation, Robinson Eriksen equation.

b) Explain Principle, concepts advantages and disadvantages, and principles used for modulation of GI transit time approaches to extend GI transit.

Q5) Answer any 3 out of 5 : **[3×5=15]**

a) Illustrate advantages and disadvantages of different ocular drug delivery systems.

b) Give mechanism of action of penetration enhancers with some examples of commonly used enhancers.

c) Write note on -Evaluation of Pharmaceutical polymers.

d) Explain in brief about customized drug delivery systems.

e) Write note on different types of vaccines.

Total No. of Questions : 5]

SEAT No. :

PD11045

[Total No. of Pages : 2

[6423]-15

First Year M.Pharmacy (Pharmacology)

MPL-102 T : ADVANCED PHARMACOLOGY - I

(Revised 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 diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Define and classify receptors. Explain structural and functional families of receptors with their respective transduction systems. **[15]**

OR

Define hypertension. Classify antihypertensive and discuss the role of ACEI in hypertension.

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

a) Classify anxiolytics. Write mechanism of action and therapeutic uses of Benzodiazepines.

b) Explain the role of Lithium carbonate in the management of mania.

c) Discuss the pharmacology of phosphodiesterase inhibitors in heart failure.

d) Write the pharmacological effects of Morphine.

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

a) Write the factors infusing drug absorption.

b) Explain the significance of Plasma protein binding of drug distribution.

c) Define anesthesia. Discuss the stages of general anesthesia.

d) Explain Enzyme induction and Enzyme inhibition.

e) Write mode of action and therapeutic uses of loop diuretics.

P.T.O.

Q4) Classify anti-hyperlipidemic. Write in brief about mechanism of action, therapeutic uses and adverse effects of HMG-CoA reductase Inhibitors. **[15]**

OR

Define bioavailability and bioequivalence. Write a short note on the various factors affecting absorption and bioavailability of drugs.

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

a) Non adrenergic cholinergic transmission.

b) Quantative aspects of drug effects.

c) Synthesis and storage of catecholamines.

d) Selective serotonin reuptake inhibitors.

e) Anti-platelet drugs.

Total No. of Questions : 5]

SEAT No. :

PD11046

[Total No. of Pages : 2

[6423]-16

First Year M.Pharmacy (Pharmaceutical Quality Assurance)
MQA 102T : QUALITY MANAGEMENT SYSTEMS
(Revised 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 diagrams wherever necessary.***

Q1) Long answer questions (Solve 1 out of 2) : **[1×15=15]**

a) Describe six system inspection model.

b) Explain ICH Q9 in detail.

Q2) Medium length answers (Solve 2 out of 4) : **[2×7½=15]**

a) Give types for benchmarking.

b) Explain statistical process control.

c) Explain CFR-21 part 11.

d) Explain HACCP.

Q3) Short answer questions (Solve 3 out of 5) : **[3×5=15]**

a) Explain customer satisfaction and customer delight.

b) Explain benchmarking.

c) Explain process capability.

d) Principles of six sigma.

e) Operational excellence.

P.T.O.

Q4) Long answer questions (Solve 1 out of 2) : **[1×15=15]**

a) Describe TQM in detail.

b) Explain ICH Q8 guidelines in detail.

Q5) Short notes (Solve 3 out of 5) : **[3×5=15]**

a) Returns and Recalls of pharmaceutical product.

b) Handling of out of Specifications results.

c) Concept of self inspection.

d) Photostability testing.

e) WHO-GMP requirements.

Total No. of Questions : 5]

SEAT No. :

PD11047

[Total No. of Pages : 1

[6423]-17

First Year M.Pharmacy

MRA-102 T : DOCUMENTATION AND REGULATORY WRITING

(Revised 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.***

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

a) Explain in detail modules of CTD.

b) Explain in detail, Site Master File and Drug Master Files (DMF).

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

a) Write a note on post marketing reporting requirements.

b) Write a note on preparation and conduct of audit.

c) Write a note on Product Development Plan (PDP).

d) Explain inspection of manufacturing facilities by regulatory agencies.

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

a) Write a note on post approval labeling changes.

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

c) Write a note on ISO risk management standard.

d) Brief on Prior Approval Supplement (PAS).

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

a) Explain Sugam system of CDSCO in detail.

b) Explain Print Pack specifications and COA.

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

a) Write a note on audit analysis.

b) Write a note on post approval labeling changes.

c) Write a note on seizure and injunctions.

d) Brief on Post Approval Changes (SUPAC).

e) Explain Root cause analysis.

Total No. of Questions : 5]

SEAT No. : [ ]

PD11048

[Total No. of Pages : 2

[6423]-18

First Year M. Pharmacy (Pharmaceutical Biotechnology)

MPB 103T: BIOPROCESS ENGINEERING AND TECHNOLOGY

(Revised 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.***

Q1) Long answer question (Solve 1 out of 2): **[15]**

a) Draw neat and labeled diagram of Bioreactor. Explain various ancillary parts and their functions.

b) Explain basic principles of fermentation. Draw explanatory diagram with necessary parts and their functions.

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

a) Explain various fermentation media along with their advantages and applications.

b) Explain various filtration methods for down streaming process.

c) Explain microbial transformation of alkaloids.

d) Write principle, working and application of metabolic response assay.

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

a) Describe Flow chart for Bioproduction of citric acid.

b) Write applications of liquid sterilization process.

c) Explain batch cultivation process.

d) What are primary culture and secondary culture?

e) Write factors affecting on mass transfer co-efficient.

P.T.O.

Q4) Long answer question (Solve 1 out of 2): **[15]**

a) What is Enzyme Immobilization? Discuss in details about various techniques for enzyme immobilization.

b) Explain in detail about Biotransformation of steroids.

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

a) Airlift Bioreactor.

b) Microbial strain improvement.

c) Computer control of fermentation process.

d) Bioproduction of Vitamin-B12.

e) Bioproduction of Glycerol.

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Total No. of Questions : 5]

SEAT No. :

PD11049

[Total No. of Pages : 2

[6423]-19

First Year M. Pharmacy

MPC 103T: ADVANCED MEDICINAL CHEMISTRY

(Revised 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 number.***

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

Enlist different classes of antihistaminic agents with examples and mode of action. Give an account of ACE blockers with liberal use of examples.

OR

Write a note on Prodrug design and steps involved in prodrug design, Enlist different applications of Prodrugs with suitable examples.

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

a) Describe Antipsychological agents and write note on chemistry of Benzodiazepines.

b) Discuss in details about antiviral agents. And write note on amantadine as antiviral agents.

c) Write comparison between COX-2 and COX-1 Inhibitors with examples.

d) Write detailed note on agents to treat Parkinson disease.

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

a) Enlist different types of stereoisomers suitable example. Discuss E and Z isomers in details with examples.

b) Write chemistry and detailed account of H1 and H2 blockers.

c) Write detailed note on Peptidomimetic agents.

d) Explain various drug-receptor interactions- binding forces with suitable examples.

e) Enantioselectivity influence the drug action and ADMET profile, justify with suitable examples.

P.T.O.

Q4) Classify major tranquilizers agents with examples and mechanism of action of GABA nergic agents. Discuss chemistry of Barbituric acid derivatives. **[15]**

OR

Define resistance, enlist different theories of efflux protein mechanisms. Explain in details drug resistance through mutation.

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

a) Write note on Enzyme inhibitors as source of new drug discovery approach.

b) Explain enzyme kinetics, Differentiate between competitive and non competitive inhibitors.

c) Classify antineoplastic agents and explain mode of action of DHFR inhibitors.

d) Discuss different strategies to combat resistance in anticancer therapy.

e) What is bioisosterism? Explain bio-isosteric replacement strategies as a source of drug discovery with examples.

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Total No. of Questions : 5]

SEAT No. :

PD11050

[Total No. of Pages : 2

[6423]-20
First Year M. Pharmacy
MPG 103T: PHYTOCHEMISTRY
(Revised 2019 Pattern) (Semester - I) (Credit)

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

Instructions to the candidates:

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

Q1) Describe in detail Biosynthesis, isolation, purification, characterization and industrial importance of Sennosides. **[15]**

OR

Describe in detail principle, working, application, of SCFE Techniques along with their advantages and disadvantages.

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

a) Explain in detail isolation, purification, characterization and industrial importance of digitoxin.

b) Explain in detail spectroscopic characterizations for structural elucidation of Luteolin.

c) Explain in detail separation of phytoconstituents by preparative HPLC.

d) Elaborate a detail account of spectroscopic characterization of Glycyrrhizin for structural elucidation.

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

a) Discuss and compare technical advancement of conventional and supercritical fluid method of extraction.

b) Explain in detail isolation, purification and industrial importance of withanolides.

c) Explain isolation, purification and industrial importance of guggulosterone.

d) Explain application of HPTLC in characterization of herbal extracts.

e) Explain in detail drug registration.

P.T.O.

Q4) Elaborate a detail account of phytochemical finger printing in the characterization of herbal extracts using LCMS along with its application in structure elucidation of phytoconsituents. **[15]**

OR

Describe in detail Biosynthesis, isolation, purification, characterization and industrial importance of quinine.

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

a) Microwave assisted extraction.

b) Elaborate recent advances in extraction methods for plant drugs with merits and demerits over conventional methods.

c) Lead structure selection process in drug discovery and development.

d) Umbelliferone

e) Methods of fractionation.

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Total No. of Questions : 5]

SEAT No. :

PD-11051

[Total No. of Pages : 2

[6423]-21
F.Y M. Pharmacy
(Pharmacy)
MPH103T : MODERN PHARMACEUTICS
(Revised 2019) (Semester - I) (Credit System)

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 suitable daigrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) **Attempt any One question of the following:** **[15]**

a) Compare between and propose the significance of Bracketing and matrixing design in ICH Stability studies.

b) Propose various types of excipient interactions with suitable pros and cons and example.

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

a) Define and differentiate between Process and equipment validation

b) Signify the optimization process and reflect various methods of optimization in detail.

c) Explain sales forecasting

d) Draw and interpret various compaction profiles with suitable examples.

Q3) **Attempt any Three questions of the following :** **[15]**

a) Stability guidelines.

b) Statistical design.

c) Preformulation of Suspension.

d) Applications of Optimization in Pharmaceuticals.

e) Lubricant efficiency and force distribution.

P.T.O.

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

a) Define Poison Ratio. Discuss the theories involved in describing the mechanisms of bonding during compression process.

b) Discuss equipment validation, Explain the mixer granulator and dissolution apparatus validation in detail.

Q5) **Write a Short Note on any Three of the following :** **[15]**

a) Compressibility index and its significance

b) Total Quality management

c) Inventory management and control

d) Define and differentiate between Dissolution and Diffusion

e) From the following dissolution data, calculate dissolution efficiency and dissolution rate constant by assuming the drug dissolution follows first order kinetics. Strength of the tablet is 150 mg.

Time (Min)	Amount of Drug Dissolved (mg)
5	20
10	35
15	55
20	75
30	89

Total No. of Questions : 5]

SEAT No. :

PD-11052

[Total No. of Pages : 2

[6423]-22

M. Pharmacy

MPL 103T - Pharmacological and Toxicological Screening Methods - I (Rev. 2019) (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.

P.T.O.

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.

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. :

PD-11053

[Total No. of Pages : 2

[6423]-23

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

MQA - 103T : QUALITY CONTROL AND QUALITY ASSURANCE

(Revised 2019) (Semester - I)

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

Instructions to the candidates:

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

Q1) Define and explain the concept of 'Quality Assurance' in the context of pharmaceutical or manufacturing industries. Provide a summarized overview of the key roles and responsibilities of the Head of the Quality Control (QC) Quality Assurance (QA) Department. **[15]**

OR

Discuss in detail about cGMP guideline as per Schedule M in Pharmaceutical Industry.

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

a) Discuss in detail the concept and evolution of quality control and quality assurance. Enumerate the major responsibilities of the Quality Control department.

b) Discuss in detail the concept, significance and key principle of Good Warehousing Practices(GWP).

c) Explain the requirements related to hygiene and maintenance of personal records as per current Good Manufacturing Practices (cGMP) guidelines.

d) State the principle of Quality Audit and explain the significance of using checklists during audit processes.

P.T.O.

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

a) Discuss the key parameters and procedures involved in IPQC and FPQC for cream formulations, as per Good Manufacturing Practices (GMP).

b) Define the concept of Change Control and explain the structure and essential elements involved in designing Change Control documents.

c) Write about controlled and uncontrolled documents.

d) Explain the purpose, key components and significance of a Batch Manufacturing Record (BMR).

e) Elaborate on the core principles of Good Laboratory Practices. How do these principles contribute to data integrity and regulatory compliance in pharmaceutical laboratories?

Q4) Discuss the ICH QSEM guidelines, outlining the main objectives of each category, with special emphasis on the Quality (Q-series) guidelines. **[15]**

OR

Explain the CPCSEA guidelines in detail, along with the protocol to be followed for conducting nonclinical testing.

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

a) Drug product reprocessing and salvaging.

b) Master Batch Record

c) Mix-ups and cross contamination

d) Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD)

e) Basic principles-How to maintain, retention and retrieval of documents.

Total No. of Questions : 5]

SEAT No. :

PD-11156

[Total No. of Pages : 2

[6423]-24

F.Y. M. Pharmacy

MRA-103T : CLINICAL RESEARCH REGULATIONS

(Rev. 2019) (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) **Long Answer Questions (Solve 1 out of 2) :** **[1 × 15 = 15]**

a) Describe in detail the protocol development process for a clinical trial, including key components and regulatory considerations.

b) Discuss the ICMR Ethical Guidelines for Biomedical Research and their application to vulnerable populations

Q2) **Medium Length Answers (Solve 2 out of 4) :** **[2 × 7½ = 15]**

a) Explain the concept and objectives of Phase II proof-of-concept studies.

b) Write about the FDA IND application process (CFR 21 Part 312)

c) Describe the responsibilities of the sponsor, CRO and investigator in ensuring ethical conduct of clinical research.

d) Give an overview of EU Directive 2001 and its impact on clinical trial conduct in Europe.

Q3) **Short Answer Questions (Solve 3 out of 5) :** **[3 × 5 = 15]**

a) List the key features of GHTF Study Group 5 Guidance.

b) What is an Annual Safety Report (ASR) in the EU context?

c) Define Multi-ethnic and Global Clinical Trials.

d) Give two examples of pediatric study guidelines under ICH E11.

e) Explain the purpose of financial disclosure by Clinical Investigators (CFR 21 Part 54).

P.T.O.

Q4) **Long Answer Questions (Solve 1 out of 2) :** **[1 × 15 = 15]**

a) Elaborate on the regulatory guidance on efficacy and safety as per ICH guidelines E4, E7, E8, E10 and E11.

b) Discuss the ethical considerations and role of placebo controls in randomized clinical trials.

Q5) **Short Notes (Solve 3 out of 5) :** **[3 × 5 = 15]**

a) Volume 9A - Pharmacovigilance for Medicinal Products for Human Use.

b) FDA Safety Reporting Requirements for INDs.

c) Proof of Principle studies to establish efficacy.

d) Informed consent process in illiterate populations.

e) CDSCO guidelines for clinical trials.

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Total No. of Questions : 5]

SEAT No. : ____

PD11054

[Total No. of Pages : 2

[6423]-25
First Year M. Pharmacy
MPC 104T : CHEMISTRY OF NATURAL PRODUCTS
(2019 Credit Pattern) (Semester-I) (Revised)

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

Define Terpenoids. Give Classification and isoprene rule of it. Explain structural elucidation of triterpenoids with examples.

OR

Discuss structural characterization using IR, 1 H-NMR, 13C-NMR and Mass spectroscopy for following natural compounds: Vitamin D and Quercetin.

Q2) Solve any 2 questions out of 4. **[2×7½=15]**

a) Explain Clinical applications and recent advances in gene therapy.

b) Explain Structural characterization of digitalis glycosides using IR, 1H-NMR, 13C-NMR and MS Spectroscopy.

c) Explain development of curare alkaloids as Neuromuscular blocking agents.

d) Give chemistry of contraceptive agents.

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

a) What are vitamins? Discuss the physiological significance of vitamins.

b) Write a note on Oligonucleotide therapy.

c) Give Structural characterization of Camphor using IR, 1H-NMR, 13C-NMR and MS Spectroscopy.

d) Explain Chemistry of β-Lactam antibiotics.

e) Describe structural elucidation of Sterols.

P.T.O.

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

Explain the significance of anticancer drugs developed from plant sources.

OR

Define Flavonoids. Describe isolation and purification of Flavonoids. Explain structural elucidation of Flavonoids with example.

Q5) Answer any 3 questions out of 5. **[3×5=15]**

a) Explain Structural elucidation of carotinoids.

b) Give active constituents of crude drugs used in Indigenous System Diabetic therapy.

c) Elucidate a structure of Morphine using IR, 1H-NMR, 13C-NMR and MS Spectroscopy.

d) Explain Structural elucidation of adrenocorticoids.

e) Describe chemistry of Cardiovascular Drugs.

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Total No. of Questions :4]

SEAT No. :

PD11055

[Total No. of Pages : 2

[6423]-26
First Year M.Pharmacy
MPG 104T : INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY
(2019 Credit Pattern) (Semester - I) (Revised)

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 question paper except seat number.***

Q1) Explain Plant design and lay out for Small-Scale Herbal Industries based on herbal dosage form. **[15]**

OR

Discuss in detail WHO guidelines for quality assessment of herbal drugs.

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

a) Explain basic concepts of quality management relating to ISO-9000.

b) Write note on Concept of GLP in herbal industry.

c) Write note on Examination of patent.

d) What are challenges in stability testing of natural products? Explain importance of stability Testing?

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

a) Describe EXIM policy.

b) Write note on pilot plant scale up for standardised extract.

c) How natural local resources are protected legally?

d) Explain stability protocol for natural product.

e) Write note on "Geographical indication in India".

P.T.O.

Q4) Explain are WHO guidelines on Good Manufacturing Practices (GMP) for the production of herbal dosage forms. **[15]**

OR

Describe the process for obtaining patent for herbal drug formulation or natural product.

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

a) Unani Pharmacopoeia

b) American Herbal Pharmacopoeia

c) TQM

d) Copyright

e) Clinical lab testing.

Total No. of Questions : 5]

SEAT No. : ____

PD11056

[Total No. of Pages : 2

[6423]-27
First Year M. Pharmacy
MPH 104T : REGULATORY AFFAIRS
(2019 Credit Pattern) (Revised) (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) Long Answer questions (Any 1): **[1×15=15]**

a) Explain in details about DMF & MFR.

b) Explain the regulatory requirement for product approval of biologics in order to obtain NDA.

Q2) Medium length answers (Any 2): **[2×7½=15]**

a) Explain in detail scale up process approval changes.

b) Describe general requirements of filling ANDA approval process.

c) Give details of formulation and working procedure of Institutional review board.

d) What is SUPAC? Explain scale-up process in pharmaceutical industry.

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

a) What is CTD? Differentiate between CTD & e-CTD.

b) Regulatory requirements of MHRA and its objectives.

c) What is investigator brochure (IB)? Give the main content of it.

d) Give brief about NDA filling in India.

e) What is significance of post-market surveillance required by the FDA?

P.T.O.

Q4) Long Answer questions (Any 1): **[1×15=15]**

a) Explain how Hutch and Waxman Act strives to strike a balance between the interests of branded drug manufacturers, generic drug manufacturers and the consumers.

b) Describe the regulatory requirements of medical devices for market authorization.

Q5) Short notes (Any 3): **[3×5=15]**

a) HIPAA

b) TGA

c) Investigation of Medicinal Products Dossier (IMPD)

d) CTD organization & its benefits.

e) Types & content of IND.

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Total No. of Questions : 5]

SEAT No. :

PD-11057

[Total No. of Pages : 2

[6423]-28
M. Pharmacy
MPL 104 T : CELLULAR AND MOLECULAR PHARMACOLOGY
(Rev. 2019) (Semester - I) (2019 Credit Pattern)

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 neat labeled diagrams wherever necessary.***

Q1) Discuss in detail molecular physiology of cell cycle and its regulation. **[15]**

OR

Comment on cell death events, apoptosis, autophagy and necrosis.

Q2) **Attempt ANY TWO :** **[15]**

a) How polymorphism affects drug metabolism?

b) Describe JAK/STAT pathway as intracellular signaling pathway.

c) Discuss nitric oxide and Diacyl glycerol as second messengers.

d) Explain cyclic AMP signaling pathway in cells.

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

a) Describe glucose uptake assay.

b) Explain genetic variation in G-protein coupled receptors.

c) Discuss various types of gene transfer techniques.

d) Write the applications of proteomic science.

e) Comment on western blotting technique.

Q4) Describe various types of vectors and applications of DNA recombinant technology. **[15]**

OR

List out various types of cell culture including general procedure for any four types of cell cultures.

P.T.O.

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

a) Microarray techniques

b) Inositol triphosphate (IP3).

c) Importance of Si RNA and Micro RNA.

d) Calcium influx assays.

e) Ligand gated ion channel receptors.

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Total No. of Questions : 5]

SEAT No. :

PD-11058

[Total No. of Pages : 2

[6423]-29

M.Pharmacy (Pharmaceutical Quality Assurance)

MQA - 104T : PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

(Rev. 2019 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) What is technology transfer? Discuss various documents involved in the technology transfer of a dosage form. **[15]**

OR

Discuss in detail various quality control tests for glass and plastic containers.

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

a) What do you mean by drug discovery? Describe clinical research process step by step.

b) What is the importance of crystal properties in preformulation study? Discuss any two techniques for the study of crystal properties & polymorphism.

c) What is Investigational New Drug Application (INDA)? Describe the contents of IND.

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

P.T.O.

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

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

b) Enlist types of pharmaceutical packaging. Discuss any two quality control tests for secondary packaging material.

c) Explain packaging materials used for medical devices.

d) Write short note on CDSCO.

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

Q4) a) Describe large scale manufacturing techniques including formula, equipment, process, stability & quality control of liquid oral dosage forms in detail. **[15]**

OR

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

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

a) Quality control tests for closures.

b) Plastic as a Pharmaceutical Packaging Material.

c) Design of pilot plant.

d) Post marketing surveillance.

e) Qualitative models for technology transfer (any two)

Total No. of Questions : 5]

SEAT No. :

PD-11059

[Total No. of Pages : 2

[6423]-30

M. Pharmacy

MRA 104 T - Regulations & Legislation for Drugs & Cosmetics, Medical Devics, Biologicals & Herbals and Food & Nutraceuticals in India and Intellectual Property Rights (Rev. 2019) (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) Explain guidelines and regulatory requirements for bioequivalence study

b) What is Intellectual Property Rights (IPR)? Discuss various components of IPR

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

a) Give rationale for conducting drug testing on animal

b) Write in brief about Indian Pharmacopoeial Standards

c) Write about composition and functions of Drug Technical Advisory Board

d) Explain ICH guidelines for stability study

Q3) **Answer any three (5 marks each) :** **[15]**

a) Explain in brief the process of obtaining copyright. Differentiate between copyright infringement and Trademark infringement

b) Give format and content of Regulatory Dossier filing

c) Write about ethical guidelines for human participants

d) Give the ICMR-DBT Guidelines for Stem Cell Research

e) Write about schedule M under D & C Act and rules there under

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

a) Give regulatory requirements and approval procedure for drugs & cosmetics

b) Explain rules and guidelines for approval of Food and Nutraceuticals in India

P.T.O.

Q5) **Write Short Notes on any three (5 marks each) :** **[15]**

a) BIS standards

b) Indian Patent Scenario

c) BCS Classification of Drugs

d) Powers of Drug Inspector

e) Schedule X

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Total No. of Questions : 5]

SEAT No. :

PD-11060

[Total No. of Pages : 2

[6423]-31
M. Pharmacy
(Pharmaceutical Biotechnology)
MPB 104 T - Advanced Pharmaceutical Biotechnology
(Rev. 2019) (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) **Long answer question (Solve 1 out of 2) :** **[15]**

a) What are Biosensors? Discuss various mechanism and types of Biosensors.

b) Explain details about various methods for Gene manipulation.

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

a) Discuss Biotransformation of any one steroidal drug.

b) Write detail classification of an Enzymes.

c) Explain microbial production, purification & isolation of Glucose Isomerase enzyme.

d) Discuss in detail about gene therapy.

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

a) What are Enzymes? Write various sources of an enzymes.

b) Write ideal properties of cloning vectors.

c) Write applications of PCR in r-DNA

d) Write applications of microbes in environmental monitoring.

e) Discuss inflammatory responses in cell.

Q4) **Long answer question (Solve 1 out of 2) :** **[15]**

a) Discuss Site Directed Mutagenesis process.

b) Explain detail procedure about extraction and purification of enzymes.

P.T.O.

Q5) **Short notes (solve 3 out of 5) :** **[15]**

a) Microbial production of amylase

b) Biodegradation of xenobiotics

c) r-DNA production of Erythropoietin

d) Gene Library

e) Recombinant DNA production of Interferon.

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Total No. of Questions : 5]

SEAT No. :

PD11061

[Total No. of Pages : 2

[6423]-32
First Year M. Pharm.
MPB 201T: PROTEINS & PROTEIN FORMULATION
(Revised 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 well labelled diagram wherever necessary.***

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

a) Explain in brief different strategies used in the formulation of DNA and proteins.

b) Write a note on Biophysical characterization of proteins.

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

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

b) Explain various approaches of protein engineering based on stability and activity.

c) Write a note on Edman sequencing.

d) Write three distinct steps for protein characterization. Explain protein sequence strategies.

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

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

b) Tryptic peptide Mapping.

c) A note on ACEI inhibitors

d) Explain different types of proteomics.

e) Forced degradation studies of protein.

P.T.O.

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

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

b) Briefly discuss various sequencing methods for protein.

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

a) Write three distinct steps for protein characterization. Explain protein sequence strategies.

b) Describe in brief liposomes in protein formulation.

c) Definition classification & evaluation of Peptidomimetics.

d) What is the purpose of PEGylation?

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

Total No. of Questions : 5]

SEAT No. :

PD11062

[Total No. of Pages : 2

[6423]-33

First Year M.Pharm. (Pharmaceutical Chemistry)
MPC 201T : ADVANCED SPECTRAL ANALYSIS
(Revised 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 side indicate full marks.***
3) ***Draw well labeled diagrams wherever necessary.***

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

OR

Explain Mass fragmentation and its rules. Elaborate Mc-Lafferty rearrangement in Mass Spectroscopy.

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

a) Elaborate NOESY and COSY NMR.

b) Explain instrumentation and applications of GC-AAS.

c) Predict and explain the NMR spectra of following compounds (any three)

i) Methylbenzoate

ii) p-Bromobenzoic acid

iii) 3-Methyl-2-Butanol

iv) Toluene

d) Elucidate the structure of an unknown organic compound from following data.

C_7H_6O

UV : –λmax 255 – 280 mm

IR : –3050, 2900, 2850, 1700, 1600 – 1450, 690, 750 cm^{-1}

NMR : – δ ppm 7.4–7.9m (5H), 9.8s (1H)

P.T.O.

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

a) How will you distinguish between Diethyl ether and Methyl propyl ether by NMR.

b) Enumerate Woodward - Fieser rule for α, β – carbonyl compounds.

c) How will you distinguish between Benzene and Cyclohexane by IR spectroscopy.

d) Elaborate Ring Rule in Mass Spectrometry with examples.

e) Elaborate instrumentation of GC-MS.

Q4) Elaborate the principle, instrumentation and applications of Supercritical Fluid Chromatography. **[15]**

OR

Determine the Probable Structure of compound

MF : $C_{10}H_{14}$

IR (cm^{-1}) : 3102, 2967, 2890. 1590-1601

1 H NMR (δ ppm) : i) δ : 0.88, singlet, 6H

ii) δ : 1.86, multiplet, 1H

iii) δ : 2.45, doublet, 2H

iv) δ : 7.15, singlet, 5H

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

a) ATR-IR

b) Metastable ion peak and isotopic peak in mass spectrometry.

c) Radioimmunoassay of Insulin

d) 2-D NMR

e) Explain instrumentation and applications of DTA

Total No. of Questions : 5]

SEAT No. :

PD11063

[Total No. of Pages : 2

[6423]-34

First Year M.Pharmacy (Pharmacognosy)
MPG-201T : MEDICINAL PLANT BIOTECHNOLOGY
(2019 Credit Pattern) (Revised) (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) What is DNA and RNA? Explain DNA replication and RNA transcription. **[15]**

OR

What are different Gene transfer strategies? Write a detail note on Agrobacterium-mediated gene transfer.

Q2) Attempt any 2 : **[15]**

a) Describe different sterilization methods used in tissue culture and their significance.

b) Explain the process and applications of synthetic seed production.

c) Outline the immobilization techniques for plant cells and their importance in secondary metabolite production.

d) Discuss the applications of transgenic plants in pharmacy.

Q3) Attempt any 3 : **[15]**

a) Define monoclonal variation and its significance in plant tissue culture.

b) What is organogenesis? Explain its role in plant biotechnology.

c) List the advantages and disadvantages of plant cell cloning.

d) Define protoplast fusion and mention its applications.

e) Describe the term "biotransformation' and its importance in plant biotechnology.

P.T.O.

Q4) Explain different methods of cloning with their applications. **[15]**

OR

What are applications of plant biotechnology in pharmacy and allied fields?

Q5) Attempt any 3 : **[15]**

a) Applications of PCR in plant genome analysis.

b) Role of elicitors in the production of secondary metabolites.

c) Transgenic plants : Advantages and challenges.

d) Importance of secondary metabolism in tissue cultures.

e) Biotransformation in plants and its industrial applications.

Total No. of Questions : 5]

SEAT No. :

PD-11064

[Total No. of Pages : 2

[6423]-35

F.Y. M.Pharmacy

MPH 201T : MOLECULAR PHARMACEUTICS

(Nano Tech & Targeted DDS)

(Revised 2019) (Credit System)(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 a neat diagram wherever necessary.***

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

a) Explain in detail the method of preparation and key evaluation parameters for pulmonary drug delivery system.

b) Elaborate on the different methods of nanoparticle preparation and highlight important evaluation parameters for nanoparticles.

Q2) **Medium Length questions (Solve any 2 out of 4)** **[15]**

a) What are the key obstacles in achieving effective brain-specific drug delivery and how can they be addresses?

b) Explain the various preparation techniques for liposomes.

c) Outline the major strategies employed for targeting tumors with therapeutic agents.

d) Highlight about method of preparation for Aquasomes.

Q3) **Short answer questions (Solve any 3 out of 5)** **[15]**

a) What are the different types of containers used in the delivery of pulmonary drugs and how do they impact drug stability?

b) Discuss the potential target diseases for gene therapy and application of gene therapy in treating cancer.

P.T.O.

c) What are the critical factors in formulation of intranasal drug delivery systems?

d) Write a note on Electrosomes.

e) What do you mean by Antisense molecules?

Q4) **Long answer questions (Solve any 1 out of 2)** **[15]**

a) Compare and contrast *ex-vivo* and *in-vivo* gene therapy, focusing on their potential applications and limitations.

b) Describe the formulation process for microspheres and how they can be evaluated for quality control.

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

a) Role of aptamers in drug delivery and diagnostics.

b) Preparation and potential applications of niosomes.

c) Explain dry powder inhalers in respiratory drug delivery.

d) Therapeutic used and advantages of phytosomes.

e) Define biodistribution and explain its importance in designing effective drug delivery systems.

Total No. of Questions : 5]

SEAT No. :

PD-11065

[Total No. of Pages : 2

[6423]-36

M. Pharm.

MPL 201 T: Advanced Pharmacology - II

(Rev. 2019) (Semester - II) (Credit System)

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) Write a comprehensive classification of antiviral agents and construct a detailed explanation on antiretroviral agents.

b) Classify anti-TB drugs, write the mechanism of action, adverse effects, therapeutic uses and interactions of Isoniazid.

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

a) Write the mechanism of action, therapeutic uses and toxicity of Doravirine.

b) Explain Patho-physiological role of thyroid hormones.

c) Write the mechanism of action, spectrum of activity and therapeutic uses of third-generation fluoroquinolones.

d) Explain management of asthma.

P.T.O.

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

a) Enlist source of free radicals. Illustrate mechanism of oxidative stress for diabetic mellitus

b) Summaries role of chronotherapy in Asthma.

c) Categorize antifungal drugs. Write mechanism of action of first line antifungals used.

d) Write mechanism of action of Cyclophosphamide.

e) Write a note on laxatives

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

a) Explain in brief mechanisms of antibiotic resistance with strategies to overcome this challenge.

b) Discuss the classification of contraceptives and elaborate on the pharmacological mechanisms of hormonal contraceptives

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

a) Mechanism of action of Macrolide antibiotics

b) Pharmacology of drugs used in COPD

c) Nitroimidazoles

d) Antioxidants

e) Probiotics in Diarrhea

Total No. of Questions : 5]

SEAT No. :

PD-11066

[Total No. of Pages : 2

[6423]-37

F.Y. M.Pharmacy (Semester - II)

(Pharmaceutical Quality Assurance)

MQA - 201T : HAZARDS AND SAFETY MANAGEMENT

(Revised 2019 Pattern)

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) a) Discuss the ICH guidelines on risk assessment. Explain in details any three risk management tools. **[15]**

OR

b) What is air based hazards. Explain in detail air circulation maintenance in pharmaceutical industry for sterile area.

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

a) Write a note on Factories act.

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

c) Discuss renewable and nonrenewable resources.

d) Write a note on preventive management from fire and explosions.

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

a) Discuss the element of a safety management programme.

b) Explain the sources of fire hazards.

c) Write a note on self-protective measures against workplace hazards.

d) Explain the concept of fire triangle and its requirement to pose a fire hazard.

e) Describe strategies for accident prevention.

P.T.O.

Q4) a) What are the sources of chemical hazards? Explain with suitable examples control measures for management of chemical hazards. **[15]**

OR

b) Elaborate on various parameters of MSDS and its significance.

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

a) Describe the TLC concept and its limits.

b) Explain the strategies for handling flammable solvents hazards.

c) Discuss the storage and disposal of radioactive waste.

d) Describe minerals and forests as natural resources.

e) Explain the concept of an ecosystem with their structure and function.

Total No. of Questions : 5]

SEAT No. :

PD-11067

[Total No. of Pages : 2

[6423]-38
M. Pharmacy
MRA 201 T : Regulatory Aspects of Drugs & Cosmetics
(Revised 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):** **[15]**

a) Explain the Active Substance Master File (ASMF) system in the EU. How does it contribute towards the quality of active pharmaceutical ingradients.

b) Describe the requirements for marketing authorization for drugs in China. Outline the post approval requirements for pharmaceutical companies in china to maintain compliance.

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

a) Explain the role of Federal Register and the Code of Federal Regulation (CFR) in Us regulatory system.

b) Describe the Eudral. ex guidelines for human medicines. What role does it play in ensuring compliance of European pharmacopoea.

c) Discuss the key pharmaceutical laws and regulations governing the approval manufacturing and labelling of pharmaceuticals in Japan.

d) Write about prequalification programme and its importance for healthcare in emerging markets.

Q3) **Attempt any Three (5 marks each) :** **[15]**

a) Write a note on Orange Book.

b) What is the ASEAM Common Technical Dossier (ACTD)?

c) What is copp and how does it facilitate international pharamaceutical trade?

d) Outline the Drug Master File in Japan.

e) Describe the requirements of ANDA in the U.S.

P.T.O.

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

a) Describe the regulations for manufacturing, packaging and labelling of pharmaceuticals in the U.S.

b) Elaborate on the role of EAC and SADC in supporting healthcare infrastructure and regulatory practices in East Africa.

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

a) European Medicine Agency - Structure & Functions.

b) Roles and responsibilities of Qualified person in EU.

c) Post - Approval requirements under WHO prequalification programme.

d) Post Approval requirement compliance in Singapore.

e) Regulation of cosmetics manufacture in Japan.

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Total No. of Questions : 5]

SEAT No. :

PD-11068

[Total No. of Pages : 2

[6423]-39

M. Pharmacy

MPB 202T: IMMUNOTECHNOLOGY

(Rev. 2019) (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) Discuss in detail about primary and secondary lymphoid organs.

b) Explain adaptive immunity. Differentiate between humoral and cell-mediated immunity

Q2) **Attempt Any Two (Solve 2 out of 4) :** **[15]**

a) What are Cytokines? Discuss their biological role.

b) Write the impact of genetic engineering on vaccine technology.

c) Discuss complement activation and types and their biological functions.

d) Explain production and purification of monoclonal antibodies.

P.T.O.

Q3) **Attempt Any Three (Solve 3 out of 5) :** **[15]**

a) Write a note on peptide vaccine.

b) Write examples of various traditional vaccines.

c) Write a note on Western blot analysis.

d) Explain Stem cell technology.

e) Discuss the Tumor Necrosis factor (TNF).

Q4) **Long answer question (Solve 1 out of 2) :** **[15]**

a) Outline different types of vaccines. Discuss on anti-idiotypic vaccine.

b) Explain in detail about recombinant vaccine with suitable example.

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

a) List out activators for alternative pathway.

b) Immune- electrophoresis.

c) Chemiluminescence assay.

d) ELISA

e) Write basic characteristics of complement system

Total No. of Questions : 5]

SEAT No. :

PD-11069

[Total No. of Pages : 2

[6423]-40

M.Pharmacy

(Pharmaceutical Chemistry)

ADVANCED ORGANIC CHEMISTRY - II

(Rev. 2019) (Semester - II) (MPC - 202T)

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 the question paper except seat number.***

Q1) a) Elaborate on examples of asymmetric synthesis using Chiral pool and Chiral auxiliaries. **[15]**

OR

b) What is solid phase synthesis? Explain various solid supports and linkers used for the solid phase synthesis. Add a note on FMOC strategy for protection. **[15]**

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

a) Elaborate on applications of Phase transfer catalysis.

b) Define optical activity and specific rotation, add a note on D/L notations.

c) Explain the mechanism of cycloaddition-Diels Alder reaction.

d) Explain sequential strategies for solution phase peptide synthesis with suitable examples.

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

a) Deprotection strategies in solid peptide synthesis.

b) Explain [3,3] sigmatropic rearrangement reaction with suitable examples.

c) Briefly describe the mechanism of microwave-assisted synthesis and its effects on reaction rates.

d) Applications of ionic liquids.

e) Write principles of Green chemistry.

P.T.O.

Q4) a) Explain rules for Z/E and cis/trans nomenclature of stereoisomers with suitable examples. Add a note on meso compounds and axis of symmetry. **[15]**

OR

b) Elaborate on homogenous and heterogenous catalysis with examples. Add a note on their advantages and disadvantages. **[15]**

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

a) Examples of Photochemical Reactions

b) Side reactions in peptide synthesis

c) Principle of Continuous flow reactors.

d) Elaborate on applications of Immobilized enzymes in organic reactions.

e) Ultra sound assisted reactions.

Total No. of Questions : 5]

SEAT No. : [ ]

PD11070

[Total No. of Pages : 2

[6423]-41

First Year M. Pharmacy

MPG202T: ADVANCED PHARMACOGNOSY - II

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

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

Instructions to the candidates:

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

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

a) Elaborate detail account of different Pharmacodynamic and Pharmacokinetic issues of Herbal remedies.

b) Comment on Impact of Ethnobotany on traditional medicine and in new drug discovery process.

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

a) Comment on Toxicity of Herbal remedies with suitable examples.

b) Elaborate Role of Ethnopharmacology in drug evaluation.

c) Discuss *in vivo* screening techniques for Antidiabetic drugs.

d) Comment on analytical profile of *Emblica officinalis*.

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

a) Compare and contrast between Herbals and Conventional drugs.

b) Discuss *in vivo* screening techniques for Anti-inflammatory drug.

c) Comment on analytical profile of *Boswellia serata*.

d) Discuss *in vitro* evaluation techniques for Anticancer drugs.

e) Comment on DNA Finger printing techniques in identification of drugs.

P.T.O.

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

a) Elaborate detail analytical profile of *Curcuma longa* along with its Pharmacological significance.

b) Explain in detail different Causes and Measures of Adulteration of Herbal Drugs.

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

a) Reverse Pharmacology

b) Toxicity studies as per OECD Guidelines

c) Analytical Profiles of *Coleus forskholii*

d) Sampling Procedures of crude drugs

e) *In vitro* evaluation techniques for Antioxidants drugs.

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Total No. of Questions : 5]

SEAT No. :

PD11071

[Total No. of Pages : 2

[6423]-42

First Year M. Pharmacy (Pharmaceutics)

MPH202T: ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

(Revised 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 well labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) What are the causes of non linearity in pharmacokinetics? Describe the non linear pharmacokinetics by Michaelis-Menten equation. **[15]**

OR

Enlist the factors affecting drug absorption. Write in detail about pharmaceutical factors affecting drug absorption. **[15]**

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

a) What is dissolution? Explain the process with the help of Noyes-Whitney equation.

b) Enlist and elaborate the approaches used to bioequivalence.

c) Explain methods to calculate K_m and V_{max} for non linear pharmacokinetics.

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

a) Explain pH partition hypothesis.

b) What are drug interactions?

c) Enlist the mechanisms of drug absorption and describe passive diffusion.

d) Explain the method of residuals for calculation of absorption rate constant.

e) What are the factors to be considered in the design of a drug product?

P.T.O.

Q4) Define IVIVC. Explain the different in vitro-in vivo correlation levels used with their applications. **[15]**

OR

Explain one compartment open model for IV infusion administration. **[15]**

Q5) Short notes (Any three): **[15]**

a) Similarity and dissimilarity factors.

b) Approachess used to determine bioequivalence.

c) Modified drug release products.

d) Explain BCS and its importance.

e) Write a note on the types of dissolution test apparatus.

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Total No. of Questions : 5]

SEAT No. :

PD11072

[Total No. of Pages : 2

[6423]-43

First Year M. Pharmacy

MPL202T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - II

(Revised 2019 Credit Pattern) (Semester - II)

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

Instructions to the candidates:

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

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

a) Discuss in detail the ICH guidelines for toxicity studies.

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

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

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

b) Discuss the importance, methodology and limitations of Ames test and Micronucleus test.

c) Describe in detail the Tier 1 and Tier 2 safety pharmacology studies.

d) Discuss in detail about male reproductive toxicity studies.

Q3) Solve any Three (3 out of 5): **[15]**

a) Briefly write about GLP's concept and importance in drug development.

b) Discuss the study design, conduct, and evaluation of ocular toxicity study.

c) Explain the inhalation toxicity studies as per OECD guidelines.

d) Describe in brief genotoxicity studies.

e) Write a note on HERG assay and its importance.

P.T.O.

Q4) Solve any One (1 out of 2): **[15]**

a) Describe in detail acute oral toxicity studies as specified in the OECD guidelines.

b) Discuss various evaluation methods for Toxicokinetics in preclinical studies.

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

a) Importance of IND.

b) Teratogenicity studies.

c) Importance and applications of Toxicokinetic studies.

d) Skin sensitization toxicity studies.

e) Chromosomal aberration studies.

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Total No. of Questions : 5]

SEAT No. : [ ]

PD11073

[Total No. of Pages : 2

[6423]-44

First Year M. Pharmacy

MQA 202T: PHARMACEUTICAL VALIDATION

(Revised 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) Attempt any One question of the following: **[15]**

a) Write in brief about validation of compressed air system in pharmaceutical Industry.

b) Comment on Process validation of coated tablets.

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

a) Discuss Qualification of Tablet Compression Machine.

b) FTIR qualification as per Indian Pharmacopoeia.

c) Discuss process validation for aerosols.

d) Enlist parameters for validation of analytical method. Discuss any two parameters in details.

Q3) Attempt Any Three questions of the following: **[15]**

a) State & compare types of steam.

b) How Validation Master Plan help to establish an effective qualification control programme for equipment.

c) Write short note on Concurrent Validation.

d) Discuss benefits of patents.

e) Elaborate types of analytical methods as per ICH guidelines.

P.T.O.

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

a) Elaborate the OQ and PQ of HPLC.

b) Explain importance of cleaning method validation, various sampling techniques. Discuss MACO calculation.

Q5) Write short note on any Three of the following: **[15]**

a) Qualification of Friability test apparatus and disintegration tester.

b) Elaborate the Pharmaceutical Utility system.

c) What is Qualification? Explain the steps of Equipment qualification.

d) Discuss the stage of "Continuous Process Verification" during process validation.

e) What are types of method precision?

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Total No. of Questions : 5]

SEAT No. : [ ]

PD11074

[Total No. of Pages : 2

[6423]-45

First Year M. Pharmacy

MRA 202T: REGULATORY ASPECTS OF HERBAL & BIOLOGICALS

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

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

Instructions to the candidates:

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

Q1) Describe the regulatory procedure for issuing a marketing authorization of vaccines in the USA. **[15]**

OR

Explain in detail about ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network).

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

a) Describe the CTD module 3 data needs for the Indian market authorization application.

b) Write a note on the plasma master file.

c) Elaborate in details about the laws, safety and quality of herbal goods in India.

d) Write a note on pharmacovigilance.

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

a) According to Indian laws, what data are required for preclinical studies of biologics?

b) Elaborate in detail about distinctions between biosimilars and generic medications.

c) What are the EU's stability requirements for vaccinations?

d) Write about the TSE/BSE assessment.

e) Explain about the guidelines that govern the determination of biosimilarity?

P.T.O.

Q4) Provide a detailed account of the GMP specifications for biologicals in accordance with Indian laws. **[15]**

OR

Describe in detail about the USA BLA application procedure.

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

a) Give in detail about labeling specifications of US legislation stipulate for blood products.

b) Market Authorization Application Data Requirements as per EU.

c) Elaborate about the Herbal medicinal products Regulatory pathway EU.

d) Write a note on European Union advertising regulations.

e) Explain Principles & Procedure for Development of Similar Biologics.

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Total No. of Questions : 5]

SEAT No. :

PD-11075

[Total No. of Pages : 2

[6423]-46

F.Y. M. Pharmacy

PHARMACEUTICAL BIOTECHNOLOGY

MPB 203 T - Bioinformatics & Computer Technology

(Rev.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) **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 × 7.5 = 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) Explain in detail genetic mapping.

b) Write a note on the "Internet and Bioinformatics".

c) What are the components of Bioinformatics?

d) Write application of Bioinformatics.

e) Write about high throughput screening and virtual screening.

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

a) What is Force field methods of protein informatics? Explain in detail protein informatics.

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

P.T.O.

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

a) Discuss methods of protein ligand docking.

b) Enlist methods of alignment. Explain any one method?

c) What is CLUSTALX?

d) What is MUSCLE?

e) Write a note on Nematode biology.

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Total No. of Questions : 5]

SEAT No. : ____

PD-11076

[Total No. of Pages : 2

[6423]-47

M. Pharmacy

MPC 203 T: COMPUTER AIDED DRUG DESIGN

(Rev.2019 Credit Pattern) (Semester - II)

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

Instructions to the candidates:

1) ***All questions are compulsory***
2) ***Figure to right indicate full marks***
3) ***Neat labeled diagram must be drawn wherever necessary***

Q1) a) What is drug likeness. Give detailed account of approaches used predicting ADMET properties of new molecules **[15]**

OR

b) Explain various HIV protease inhibitors with reference to enzyme drug interactions. Give the applications of these agents.

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

a) What is AchE? Giving examples of various AchE inhibitors

b) What is virtual screening in CADD? Explain various approaches and give applications of it.

c) What is global minima? Explain methods of energy minimization.

d) Explain molecular docking. Comment on protein preparation aspect involved in docking

P.T.O.

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

a) Discuss the principle of Free-Wilson analysis. Give its advantages and disadvantages

b) Explain the suitable approach to build the 3D structure of protein in CADD

c) Write a note on Quantum mechanics in drug discovery.

d) Explain approach of conformational analysis in CADD along with suitable example

e) Note on Hammett substitution constant in QSAR

Q4) a) Give principle, methodology of Hansch analysis. How good model can be generated from Hansch analysis. **[15]**

OR

b) What is QSAR? Explain various physicochemical parameters used in QSAR. Give importance of QSAR

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

a) Structured-based drug design approach

b) Fragment based drug design

c) Receptor-drug interactions

d) Pharmacophore mapping and its examples

e) 3-D QSAR

Total No. of Questions : 5]

SEAT No. :

PD-11077

[Total No. of Pages : 2

[6423]-48

M. Pharmacy (Pharmacognosy)

MPG 203 T: INDIAN SYSTEM OF MEDICINE

(2019 Credit Pattern) (Semester - II) (Rev. - 2019)

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) a) Explain basic principles and treatment modalities of naturopathy. **[15]**

OR

b) Explain Quality Assurance in ISM formulations.

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

a) What are the challenges in Safety of Herbal Medicines.

b) Explain in brief about Unani System of Medicine.

c) Explain about Asanas and Pranayam.

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

a) Explain CCRU in Detail

b) Explain about Aromatherapy's oils

c) Explain Geographical Indication Bill.

d) What is Suddhi.

P.T.O.

Q4) **Attempt any One Question of the following :** **[15]**

a) Explain document preparation for new drug application and export registration.

b) Explain Good Manufacturing Practices of Indian System of Medicine.

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

a) TKDL

b) Aromatherapy Tretment

c) GAP

d) Principles of Homeopathy

e) GLP

Total No. of Questions : 5]

SEAT No. :

PD-11078

[Total No. of Pages : 2

[6423]-49

F.Y. M.Pharmacy (Pharmaceutics)

MPH203T : COMPUTER AIDED DRUG DEVELOPMENT

(Rev. 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) **Attempt any one out of two:** **[1 × 15 = 15]**

a) Explain Quality by Design approach in Pharmaceutical Development in light of ICH Q8 (R2).

b) Explain *In vitro* dissolution and *In vitro-In vivo* correlation?

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

a) Explain in brief computational modelling for drug disposition.

b) Explain BCRP and HPEPTI.

c) Explain in detail nucleoside transporter OCT and OATP

d) Write a short note on Legal Protection of Innovative Uses of Computers in R&D.

Q3) **Attempt any Three out of five.** **[3 × 5 = 15]**

a) Explain Descriptive versus Mechanistic Modeling?

b) Write a short note on QbD.

c) Write a short note on BBB-Choline Transporter.

d) Write a detailed account on AI & robotics.

e) Write a short note on Fed Vs Fasted state.

P.T.O.

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

a) Write in detail about the history of Computers in Pharmaceutical Research and development.

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

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

a) Write a short note on development of Pharmaceutical Emulsions.

b) Explain in detail computer simulation in whole organism.

c) Write a note on Parameter estimates for a model and confidence region.

d) Mention the various fields of pharmaceutical automation along with its advantages and disadvantages.

e) Write a short note on ethics of computing in Pharmaceutical Research.

Total No. of Questions :5]

SEAT No. :

PD11079

[Total No. of Pages : 2

[6423]-50
First Year M.Pharmacy
MPL 203T : PRINCIPLES OF DRUG DISCOVERY
(Credit 2019 Pattern) (Revised) (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 Questions. **[15]**

What are the methods for protein structure prediction and give applications of NMR and X-ray crystallography in protein structure prediction?

OR

What are the various types of docking? Describe in brief.

Q2) Medium Length Answer Solve any two: **[2×7½=15]**

a) Describe various lead seeking methods in drug design.

b) Discuss in detail pharmaceutical and pharmacokinetic applications of Prodrugs.

c) Definition of Biomarkers and write down their classification.

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

Q3) Short answer Questions Solve any Three: **[3×5=15]**

a) Role of Enzyme inhibition in Drug Discovery Process.

b) Role of bioinformatics in target identification.

c) What is parallel synthesis? Explain in detail.

d) Discuss how drug targets are assessed for safety during drug discovery.

e) Give the brief account on the Multivariate Statistical Methods.

P.T.O.

Q4) Long Answer Questions. **[15]**

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

OR

Explain G-protein coupled receptor (GPCRs). Note on Pharmacophore based screening.

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

a) What are the detection methods used in HTS? Explain in detail.

b) Write in brief account on types of regression with equations.

c) Write a note on ELISA.

d) Differentiate between combinatorial synthesis and traditional synthesis.

e) Add a note on in silico lead discovery technique.

Total No. of Questions : 5]

SEAT No. : [ ]

PD11080

[Total No. of Pages : 2

[6423]-51
First Year M. Pharmacy
MQA 203T : AUDIT AND REGULATORY COMPLIANCE
(2019 Credit Pattern) (Semester-II) (Revised)

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) What are the objectives of an audit? Explain the various steps involved in the audit process and discuss the planning and information-gathering phases of the audit? **[15]**

OR

What is the significance of an audit checklist? What factors should be considered while designing the checklist? Discuss typical audit checklist for tablet manufacturing processes?

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

a) Comment on bulk pharmaceutical Chemical (drug substance) vendor audit.

b) Give detail account on deficiencies found during regulatory audits.

c) Discuss the role of quality assurance and quality control unit under cGMP regulations.

d) Discuss the auditing of granulation and coating process in dry production department.

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

a) Give detail account on responsibilities of auditors and auditees during regulatory audit.

b) Discuss audit checklist for drug industry.

c) Comment on auditing for dry production.

d) Explain about vendor audit with respect to packaging.

e) Discuss about facilities need to be focused at auditing of sterile production.

P.T.O.

Q4) Describe importance of auditing in quality assurance and engineering department. **[15]**

OR

Explain in detail about auditing of sterile dosage form manufacturing process. Discuss product audit system for sterile dosage form.

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

a) Auditing of water system in Pharmaceutical Industry.

b) Auditing of HVAC system.

c) Process audit.

d) Auditing of pharmaceutical effluent treatment plant.

e) Parameters for an auditing of packaging materials.

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

PD11081 **[Total No. of Pages : 2**

[6423]-52

First Year M.Pharmacy

MRA203T : REGULATORY ASPECTS OF MEDICAL DEVICES

(Revised 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) Answer any one. **[15]**

a) Write introduction, classification, regulatory approval process for medical devices (510k) as per premarket notification.

b) Explain in detail global medical device nomenclature(GMDN).

Q2) Answer Any Two. **[15]**

a) Write in detail of clinical investigation of medical devices.

b) Write in detail of quality risk management of medical devices.

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

d) Write detail on summary technical document.

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

a) Write a note on good clinical practice.

b) Write a note on pre-market approval.

c) Explain medical devices working groups.

d) What are the adverse event reporting of medical device.

P.T.O.

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

a) Write a detail on risk based classification and essential principles of medical devices.

b) Explain in detail quality system requirements and clinical evaluation as per China regulation.

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

a) Write down regulatory registration procedures in Japan.

b) Explain in detail Investigational Device Exemption (IDE) as per USA.

c) Write a note on basics of In vitro diagnostics process of European Union.

d) Write classification, regulatory approval process for Medical Devices as per European Union.

Total No. of Questions : 5]

SEAT No. : ____

PD-11082

[Total No. of Pages : 2

[6423]-53

M. Pharmacy

MPB 204 T : Biological Evaluation of Drug Therapy

(2019 Credit Pattern) (Semester - II) (Rev. 2019)

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 :** **[1 × 15 = 15]**

a) Explain the importance of biological evaluation in drug development. Describe the principles of screening and evaluation, including the development of models for and their application in preclinical testing.

b) Analyze the role of biologic therapies in cancer treatment and related conditions.

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

a) Explain types of microbial assays in detail

b) Explain the OECD guidelines for acute toxicity studies.

c) Describe the main steps involved in pre-clinical testing for a new drug or biologic and the regulatory considerations associated with this phase.

d) Explain hybridoma technology in detail.

P.T.O.

Q3) **Write notes on any three :** **[3 × 5 = 15]**

a) Pyrogen testing of parenteral.

b) Biologics in eye related disorders

c) Subacute and chronic toxicity studies

d) Bioassay of oxytocin

e) Principles and applications of cell line study.

Q4) **Answer any one :** **[1 × 15 = 15]**

a) Summarize the regulatory requirements for bioavailability and bioequivalence studies in biopharmaceuticals. How do these requirements differ for conventional dosage forms versus controlled drug delivery systems?

b) Explain the regulatory framework governing the approval of drugs, biologics, and medical devices.

Q5) **Answer any three :** **[3 × 5 = 15]**

a) Explain 'Wagner Nelson' method.

b) Explain the measurement of bio availability.

c) Describe the importance of safety and efficacy data in the clinical testing phase for medical devices.

d) Explain the objectives of bioavailability studies of biopharmaceuticals.

e) Write a note on bioassay of vitamin B12.

Total No. of Questions : 5]

SEAT No. :

PD-11083

[Total No. of Pages : 2

[6423]-54

F.Y. M.Pharmacy

(Pharmaceutical Chemistry)

MPC204T : PHARMACEUTICAL PROCESS CHEMISTRY

(2019 Credit Pattern) (Semester - II) (Rev. 2019)

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) Explain the importance of material safety data sheet and give an account of the contents of MSDS.

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

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

a) Elaborate on Industrial Reduction Process giving emphasis on use of metal hydrides.

b) Discuss Principle of azeotropic and steam distillation.

c) Write about Fermentation of Statins: Lovastatin, Simvastatin.

d) Explain the Principle and general methods of Preparation of polymorphs and amorphous.

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

a) Comment on families of reagents useful for scale-up process.

b) Explain the equipment used for Nitration process.

c) Define Filtration. Explain Theory of filtration.

d) Explain various sources of Impurities in API.

e) Explain aerobic and anaerobic fermentation with examples.

P.T.O.

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

a) Validation of Pharmaceutical Process is an important criterion for any Pharmaceutical industry. Justify.

b) Define Crystallization. Explain Crystallization from aqueous, non-aqueous solutions. Elaborate Principle and general methods of Preparation of polymorphs.

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

a) Factors affecting scale-up process of APIs

b) Applications of Nonmetallic oxidizing agents

c) Types of evaporators

d) Techniques to handle Fire Hazards in Pharmaceutical Industry

e) Hydrogen transfer reactions

Total No. of Questions : 5]

SEAT No. :

PD-11084

[Total No. of Pages : 2

[6423]-55

F.Y. M.Pharmacy (Pharmacognosy)

MPG 204T : HERBAL COSMETICS

(2019 Rev Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) a) Define and classify Cosmetics. Explain about method of preparation of Lipstick. **[15]**

OR

b) Discuss Preformulation and Compatibility studies in brief.

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

a) Explain Hair growth formulation and Enlist Hair growth promoters.

b) Brief on Formulation and evaluation of Anti sunburn preparation.

c) Describe Formulation and Standardization of Mouth washes.

d) Discuss physiology and chemistry of skin and pigmentation.

Q3) **Answer the following (Any three).** **[15]**

a) Elaborate evaluation of Cleansing cream.

b) Explain toxicity of Cosmetic.

c) Comment on Herbal shampoo.

d) Explain Formulation and evaluation of Vanishing cream.

e) Brief on Surfactant used in cosmetic.

P.T.O.

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

a) Explain import and export of herbal cosmetic and enlist industries involved in production of herbal cosmetic.

b) Explain in detail manufacturing and evaluation of colorants and hair oils.

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

a) Design of herbal cosmetic formulation.

b) Tooth paste.

c) Cosmetic for Nail.

d) Evaluation of Bath soap and baby products.

e) Offenses and penalties to cosmetic.

Total No. of Questions : 5]

SEAT No. :

PD11085

[Total No. of Pages : 2

[6423]-56
First Year M. Pharmacy
MPH 204T : COSMETICS & COSMECEUTICALS
(2019 Credit Pattern) (Semester - II) (Revised)

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 one out of two. **[15]**

a) Describe hair growth cycle and Discuss the problems associated with hairs.

b) Propose building blocks for formulation of shampoo and toothpaste.

Q2) Answer any 2 out of Four. **[15]**

a) State the Indian regulatory requirements for labeling of cosmetics.

b) Predict guidelines for herbal cosmetics by private bodies like cosmos.

c) Write a brief note on the design of cosmeceutical products addressing dry skin and wrinkles.

d) Explain the process of cosmeceuticals designed for addressing Body odor and Dental cavity.

Q3) Write Short Note on any three out of five. **[15]**

a) Classify surfactants and discuss their applications in cosmetics.

b) Write a note on herbal ingredients used in Hair care and Skin care.

c) What is misbranded and spurious drug? Explain penalties for the same as per D & C act.

d) Antimicrobials are used as preservative: Explain along with factors affecting efficacy of microbial preservative.

e) Cosmeceutical formulation of Bleeding gums and sensitive teeth.

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

a) Define Cosmeceuticals. Explain and classify Sunscreen with its regulatory 06 aspects.

b) Explain in detail about challenges in formulating herbal cosmetics.

P.T.O.

Q5) Short Notes (Solve three out of five) **[15]**

a) Conditions to be fulfilled for manufacturing of cosmetics in India.

b) Building blocks for formulation of moisturising cream.

c) Classify the Cosmetics and write about the Face powders.

d) Nail Lacquer.

e) Lipsticks.

Total No. of Questions : 5]

SEAT No. :

PD11086

[Total No. of Pages : 2

[6423]-57
First Year M. Pharmacy
MPL 204T : CLINICAL RESEARCH AND PHARMACOVIGILANCE
(Revised 2019 Credit 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 Questions: **[15]**

Explain in details various Types of ADRs, Mechanism of 'B' and C type ADRs with suitable examples.

OR

Define clinical trial. Explain in detail types and design of clinical trials.

Q2) Medium Length Answers Solve any two: **[2×7½=15]**

a) ScheduleY

b) Explain phase 2 and 3 clinical trials.

c) Note on international classification of diseases.

d) Significance of safety monitoring in pharmacovigilance.

Q3) Short answer Questions Solve any Three: **[3×5=15]**

a) Explain Clinical Research Organization.

b) Note on adverse events (AEs).

c) Roles of ICMR in clinical trial study.

d) Responsibilities of institutional review board.

e) Note on detection of ADRs.

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

Explain history and progress of Pharmacovigilance in India. Note on roles and responsibilities of Pharmacovigilance methods.

OR

Guidelines to preparation of clinical trial documents. Describe component of preparation of clinical trial protocol.

P.T.O.

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

a) Case report forms

b) Pharmacoeconomics

c) Reporting of ADRs

d) Informed consent in clinical trial study

e) Note on Pharmacovigilance center in hospitals and industry.

Total No. of Questions : 5]

SEAT No. :

PD11087

[Total No. of Pages : 2

[6423]-58
First Year M. Pharmacy (Pharmaceutical Quality Assurance)
MQA 204T : PHARMACEUTICAL MANUFACTURING TECHNOLOGY
(Revised 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) Explain in detail about various IPQC test for nonsterile solid dosage form. **[15]**

OR

Discuss various container and closures for pharmaceuticals.

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

a) Explain in process quality control test for SVP and LVP.

b) Discuss granulation and pelletization with equipments.

c) Explain lyophilisation techniques.

d) Describe production planning for pharmaceutical products.

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

a) What are Legal requirements and licenses for API and formulation industry?

b) Discuss about PAT.

c) Stability aspects of packaging.

d) Change room and personnel flow in sterile area.

e) Explain the advantages of Process automation in tablet manufacturing.

P.T.O.

Q4) What is the importance of QbD? Explain advantages and elements of QbD.**[15]**

OR

Discuss process and equipment used in coating technology. What are the problems encountered in coating technology?

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

a) CIP and SIP

b) Form Fill seal technology

c) Area planning and environmental control in sterile product manufacturing.

d) Manufacturing of sterile suspension and emulsion.

e) In process quality control test for sterile dry powder.

* * *

Total No. of Questions : 5]

SEAT No. :

PD11088

[Total No. of Pages : 2

[6423]-59
First Year M. Pharmacy
MRA 204T : REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS
(2019 Credit Pattern) (Semester - II) (Revised)

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) Attempt any 1: **[1×15=15]**

a) Discuss the regulatory framework governing the production of nutraceuticals in India.

b) Describe the regulatory requirements for the production and marketing of nutraceuticals and dietary supplements in the United States.

Q2) Attempt any 2: **[2×7½=15]**

a) Define nutraceuticals and provide two examples of products in this category.

b) Outline the Recommended Dietary Allowances (RDA) established in the United States.

c) Summarize the European regulatory framework for dietary supplements.

d) Explain the impact of the U.S. FDA Food Safety Modernization Act on the regulation of nutraceuticals.

Q3) Attempt any 3: **[3×5=15]**

a) Provide an overview of the Recommended Dietary Allowances in Europe.

b) Describe the core responsibilities of the U.S. FDA.

c) Discuss the significance of nutrition labeling requirements.

d) Name two marketed nutraceutical products produced in India.

e) Explain why healthcare professionals' confirmation of healthcare supplements is important.

P.T.O.

Q4) Attempt any 1: **[1×15=15]**

a) Describe the organization and functions of the European Food Safety Authority (EFSA).

b) Discuss the NSF standards applicable to dietary supplements.

Q5) Short Notes any 3: **[3×5=15]**

a) Explain the European Regulation regarding Novel Foods and Novel Food Ingredients.

b) Discuss the role of probiotics in disease management.

c) Provide an overview of the Food Safety and Standards Authority of India (FSSAI).

d) Summarize the permitted label claims for dietary supplements.

e) Describe the EU directives and regulations that govern the manufacture and sale of nutraceuticals.

Total No. of Questions : 5]

SEAT No. :

PD-2016

[Total No. of Pages : 2

[6423]-168

F.Y M.Pharmacy

MPAT 101T : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(Rev. 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 suitable diagram wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

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

a) Explain principle, instrumentation and applications of IR spectroscopy.

b) Describe spin-spin splitting, coupling constant, chemical shift, relaxation processes, solvents used in NMR and nuclear magnetic double resonance.

Q2) **Medium Length answers (solve 2 out of 4) :** **[2 × 7.5 = 15]**

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

Mol. Formula: $C_4H_6O_2$

IR: 3300 (broad). 2940, 1710cm^{-1}

PMR: δ 1.2 quaret 3H, 2.3 triplet 2H, 10.5 singlet 1H

MS: m/z- 74 (Molecular ion), 73, 57, 45, 29, 28.

b) Discuss factors affecting separation in electrophoresis and elaborate Iso electric focusing.

c) Give principle, instrumentation and advantages of affinity chromatography.

d) Compare proton NMR and C^{13} NMR. Give appliactions of both NMR spectroscopy.

P.T.O.

Q3) **Short answer questions (solve 3 out of 5) :** **[3 × 5 = 15]**

a) FT-NMR

b) Differential Thermal Analysis (DTA)

c) Capillary electrophoresis

d) Flame Emission Spectroscopy

e) Ion exchange chromatography

Q4) **Long answer questions (solve 1 out of 2) :** **[1 × 15 = 15]**

a) Discuss mass fragmentation with its rules in detail. Give appliactions of Mass Spectroscopy.

b) Write principle instrumentation and applications of HPLC.

Q5) **Short notes (solve 3 out of 5) :** **[3 × 5 = 15]**

a) UPLC

b) Different X ray diffraction methods & Bragg's Law

c) DSC

d) Detectors in GC

e) MALDI

Total No. of Questions : 5]

SEAT No. :

PD-2017

[Total No. of Pages : 2

[6423]-169

F.Y M.Pharmacy

MRA 101T : GOOD REGULATORY PRACTICES

(Rev-2019 Pattern) (Semester - I)

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

Instructions to the candidates :

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

Q1) Explain in detail Controlling the GLP inspection process. **[15]**

OR

Write in detail about various aspects of manufacturing process covered by WHO GMP guidelines.

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

a) Methodologies used under Six Sigma

b) Write down general checklist of 2l CFR Part 11.

c) Discuss in detail about the Elements for QbD

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

a) PDCA Cycle

b) Stages of qualification

c) 5Ps of GxP compliance

d) OECD GLP guidelines.

e) Five components of quality management system

Q4) Explain in detail about the Quality management system for HVAC. **[15]**

OR

Explain in detail Current Good Manufacturing Practices.

P.T.O.

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

a) Audit report

b) Implementation roles of six sigma

c) Key principles of GALP

d) Validation Mster Plan

e) Applications of TQM

Total No. of Questions : 5]

SEAT No. :

PD2018

[Total No. of Pages : 2

[6423]-170

First Year M.Pharmacy (Pharmaceutical Biotechnology)
MPB 102T: MICROBIAL AND CELLULAR BIOLOGY
(Revised 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 labelled diagrams wherever necessary.***

Q1) Answer the following (Any one) **[15]**

a) Describe in detail structure, morphology & reproductive features of Bacteria.

b) What is mutagenesis? Explain types of mutants and applications of mutagenesis in strain improvement.

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

a) Explain in detail about RNA editing and amplification.

b) Describe in short methods of isolation and maintenance of pure cultures.

c) Describe basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics.

d) Write in short central dogma of molecular biology with reference to transcription.

Q3) Answer the following. (Any three) **[15]**

a) What is chemotherapy? Explain.

b) Explain in detail cytotoxicity testing.

c) Write the mechanism of microbial pathogencity of viral infections.

d) Elaborate on physical and chemical environments for microbial growth.

e) Write Industrial important microbes with importance.

P.T.O.

Q4) Answer the following. (Any one) **[15]**

a) Explain different types of animal cell cultures. Write the applications of cell cultures in pharmaceutical Industry and research.

b) Write in detail about isolation and applications of embryonic germ cells and stem cells.

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

a) Structure of DNA
b) Transcriptional control and translational control.
c) Tumor cells and carcinogenes.
d) Nuclear receptors.
e) Pathology of Fungal infections

Total No. of Questions : 5]

SEAT No. :

PD2019

[Total No. of Pages : 2

[6423]-171

First Year M.Pharmacy (Pharmaceutical Chemistry)
MPC102T: ADVANCED ORGANIC CHEMISTRY-I
(2019 Credit Pattern) (Revised) (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) Discuss reaction mechanism and applications of Knorr Pyrazole synthesis and Bernthsen Acridine synthesis with suitable example of drugs. **[15]**

OR

Write about role of protection in organic synthesis. Explain mechanism of protection for carbonyl group and carboxyl group.

Q2) Answer any 2 of the following. **[15]**

a) Explain the detailed mechanism and reactions with synthetic applications of Shapiro and Suzuki reaction, Mannich reaction.

b) Explain the phenomenon of protection for the hydroxyl group, including 1,2-diols and 1,3-diols.

c) Explain the preparation and salient features of Wilkinson reagent and Witting reagent. Explain their applications in organic synthesis.

d) Discuss about reaction mechanism, stereochemistry and factors affecting Elimination reactions.

Q3) Attempt any Three of the following. **[15]**

a) Write mechanism and synthetic applications of Sandmeyer reaction and Ozonolysis.

b) Describe about method of formation, stability and synthetic applications of carbocations and carbanions as organic reaction intermediates.

c) Discuss about stereochemistry and factors affecting nucleophilic unimolecular and bimolecular substitution reactions.

P.T.O.

d) Explain about mechanism and synthetic importance of Ugi reaction.

e) Write synthesis of Ketoconazole and Triamterene.

Q4) Discuss about reaction mechanism and applications of Pinner Pyrimidine synthesis and Combes Quinoline synthesis with suitable example of drugs. **[15]**

OR

Explain about C-X disconnections and C-C disconnections with respect to alcohols and carbonyl compounds.

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

a) Functional group interconvertion and addition.
b) Smiles rearrangement.
c) Synthetic applications of N-bromosuccinamide and titanium chloride.
d) Biginelli reaction and Passerini reaction.
e) Carbenes and nitrenes.

Total No. of Questions : 5]

SEAT No. :

PD2020

[Total No. of Pages : 2

[6423]-172

First Year. M. Pharmacy

MPG-102-T: ADVANCED PHARMACOGNOSY-I

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

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) Explain in detail account of, importance of pharmacognosy in herbal drug Industry.

b) Elaborate detail account of current Good Agricultural Practices.

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

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

b) Comment on Polyunsaturtated fatty acids.

c) Write a note on Marine toxins.

d) Elaborate on FSSAI guideline.

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

a) Discuss Health benefits of Turmeric.

b) Regulatory aspects of Nutraceuticals.

c) Describe Herbs as functional food.

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

e) Note on drug-drug interaction with suitable examples.

P.T.O.

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

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

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

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

a) Isolation of Ellagic acid.
b) Objectives and functions of Indian Council of Agricultural Research.
c) Occurrence and isolation of Resveratrol.
d) Current trends and future scope on Neutraceuticals.
e) Medicinal uses and health benefits Ginseng.

Total No. of Questions : 5]

SEAT No. : ____

PD2021

[Total No. of Pages : 2

[6423]-173

First Year M.Pharm (Pharmaceutics)
MPH 102 T: DRUG DELIVERY SYSTEM
(Credit 2019 Pattern) (Revised) (Semester - I)

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

Instructions to the candidates:

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

Q1) Solve 1 out of 2. **[15]**

a) Give principles of sustained release formulations. Explain in detail drug release mechanism through matrix type SR formulations.

b) Discuss various barries of drug permeation to ocular delivery system and methods to overcome them.

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

a) Give an account of porosity osmotic pump drug delivery systems.

b) Give mechanisms of mucoadhesion and evaluation if mucoadhesive patches.

c) Explain the concept and formulation of single-shot vaccine.

d) Explain in detail formulation and evaluation of transdermal gel.

Q3) Write short note on any 3 out of 5. **[15]**

a) Give importance of personalized medicine.

b) Give classification of polymers in sustained release drug delivery systems.

c) Explain the transport of drugs across mucosal membrane and give various types and mechanism of action of penetration enhancers.

d) Buccal drug delivery is faster than oral delivery system, Justify?

e) Write a note on microneedle technology.

P.T.O.

Q4) Solve 1 out of 2. **[15]**

a) Explain drug delivery systems modulated by pH and give account of polymers used.

b) Suggest a suitable drug delivery system for transport of drug having first pass metabolism. Give details of any one type of formulation dosage form.

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

a) 3 D printed formulations.
b) Drug candidate selection for buccal drug delivery.
c) Gastric retentive floating drug delivery systems.
d) Telepharmacy.
e) Mucosal vaccine.

Total No. of Questions : 5]

SEAT No. : [ ]

PD2022

[Total No. of Pages : 2

[6423]-174

First Year M.Pharmacy (Pharmacology)
MPL102T: ADVANCED PHARMACOLOGY-I
(2019 Credit Pattern) (Revised) (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.***
4) ***Do not write Anything on question paper except seat number.***

Q1) Explain the mechanism of action, pharmacological action, therapeutic uses and adverse effects of atropine. **[15]**

OR

Write about various physiological barriers to drug distribution. Explain the significance of plasma protein binding during drug distribution.

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

a) Write the structure and physiological role of ion channel receptors.

b) Discuss the pharmacology of phosphodiesterase inhibitors in heart failure.

c) Explain the mechanism of action and therapeutic uses of organic nitrates.

d) Define parkinsonism, classify drug used in parkinsonism. Discuss the rational for combination of levodopa and carbidopa.

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

a) Write the H_1 and H_2 receptor mediated actions of histamine.

b) Explain the pharmacology of acetazolamide.

c) Write the role of bile acid binding resins in hyperlipidemia.

d) Write a note of MAO Inhibitors.

e) Discuss the pharmacological effects of Morphine.

P.T.O.

Q4) Define and classify receptors. Discuss in detail molecular structure and signal transduction via GPCRs. **[15]**

OR

Define bioavailability and bioequivalence. Discuss in brief various factors influencing absorption and bioavailability of Drug.

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

a) Role of GABA in central nervous system.
b) Angiotensin converting enzyme inhibitors.
c) Steps involved in neurotransmission.
d) D-tubocurarine.
e) Physiological role of nuclear receptor.

Total No. of Questions : 5]

SEAT No. :

PD2023

[Total No. of Pages : 2

[6423]-175

First Year M.Pharmacy (Pharmaceutical Quality Assurance)
MQA102T: QUALITY MANAGEMENT SYSTEM
(Revised 2019 Pattern) (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.***

Q1) Long Answer questions (Solve 1 out of 2) **[1×15=15]**

a) What are objectives of pharmaceutical Quality Management-ICH Q10? How continual improvement of process performance and product quality can be achieved using ICH Q 10 guidelines?

b) Explain in detail six system inspection model.

Q2) Medium length answers (Solve 2 out of 4) **[2×7.5=15]**

a) Explain ISO 9001:2008.

b) What is objective of pharmaceutical development? Elaborate in detail different elements of quality by design.

c) Explain Statistical control charts. Give its concept and general aspects.

d) Define Quality Management. Give objectives and principles of ISO.

Q3) Short answer questions (Solve 3 out of 5) **[3×5=15]**

a) Elaborate Photostability testing of drug and drug products.

b) Define benchmarking. Give reasons for benchmarking.

c) Explain the concept of vendor qualification.

d) Write a note on Out of specifications (OOS) and Out of Trend (OOT)

e) Elaborate risk assessment, risk control and risk management tools as per ICH Q9 guidelines.

P.T.O.

Q4) Long answer questions (Solve 1 out of 2) **[1×15=15]**

a) Elaborate principles of quality risk management. Explain HACCP (Hazard analysis and critical control points) in detail.

b) Describe types of benchmarking and provide overview of benchmarking process. Give advantages and limitations of benchmarking.

Q5) Short notes (Solve 3 out of 5) **[3×5=15]**

a) Principles of six sigma.
b) Significance of statistical process control methods in pharmaceutical manufacturing.
c) Concept of IPQC.
d) McKinsey 7 S Model.
e) Vision and Mission statement.

Total No. of Questions : 5]

SEAT No. :

PD2024

[Total No. of Pages : 2

[6423]-176

First Year M.Pharmacy

MRA 102 T: DOCUMENTATION AND REGULATORY WRITING

(Revised 2019 Pattern) (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.***

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

a) Elaborate on the contents and details of Module 3 of the Common Technical Document. (CTD)

b) Explain the process of preparation and conduct of audits.

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

a) Explain in detail site master file.

b) Write a note on ISO risk management standard.

c) Explain in detail internal and external audits.

d) What is significance of Prior Approval Supplement (PAS) in the regulatory process for pharmaceutical products.

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

a) Explain Corrective and Preventive action (CAPA)

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

c) Explain root cause analysis.

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

e) Elaborate Exploratory Product Development Brief (EPDB)

P.T.O.

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

a) Explain post-approval changes related to SUPAC (Scale-Up and Post-Approval Changes)
b) What is the Asian Common Technical Dossier (ACTD), and what are its key components and significance in regulatory submissions?

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

a) Explain product development report.
b) Write a note EIR and warning letter.
c) Explain Batch manufacturing record and its calculations.
d) Explain CTD Model 1.
e) Explain ISO 1348.

Total No. of Questions : 5]

SEAT No. :

PD-2025

[Total No. of Pages : 2

[6423] - 177
F.Y. M. Pharmacy
MPB103T: BIOPROCESS ENGINEERING AND TECHNOLOGY
(Rev.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 labelled diagram wherever necessary.***

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

a) Write principle of working, construction, advantages and application of CSTR.

b) Explain various theories associated with scale down process.

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

a) Explain theories associated with mass transfer with respect to fermentation.

b) Explain diffusional resistance to oxygen requirements of microorganisms

c) Discuss various principles for process scale up of fermentation.

d) Discuss theory of Mass transfer during Bioprocess.

P.T.O.

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

a) Discuss synchronous culture.

b) Differentiate batch cultivation and Continuous cultivation system

c) Discuss regulatory aspects of biological products.

d) Outline Bio autographic technique.

e) Describe various techniques used for cell disruption.

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

a) Explain Biosynthetic pathways for any one secondary metabolite.

b) Discuss important regulation governing the manufacturing of biological products.

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

a) Computer control in Bioprocess.

b) Immobilization of enzyme.

c) Bubble column bioreactor.

d) Cell disruption techniques.

e) Determination of KLa value.

Total No. of Questions : 5]

SEAT No. :

PD-2026

[Total No. of Pages : 2

[6423] - 178
First Year M. Pharmacy
MPC 103T: ADVANCED MEDICINAL CHEMISTRY
(Rev. 2019) (Semester - I)

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

Instructions to the candidates:

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

Q1) Explain the chemistry of histamine and its interaction with Hl/H2 receptors. Give an account of design of H1 receptor antagonist with its chemical classification, SAR and therapeutic uses. Explain the advanta**ge of Second** generation H1 antagonists. **[15]**

OR

Explain mechanisms involved in enzyme inhibition with the kinetics. Discuss the design of reverse transcriptase inhibitors with examples.

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

a) Define Prodrugs .Enlist different types of Prodrugs with suitable examples and their uses.

b) Explain Bioisosterism with examples. Elaborate the design ofAngiotensin blockers.

c) Explain Sterochemistry, elaborate different stereoisomers ,its importance in drug action with suitable examples.

d) Discuss the chemistry, SAR and MOA of benzodiazepines with examples.

P.T.O.

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

a) Explain the MOA of anti-inflammatory drugs and their design as COX I/II inhibitors with examples.

b) What is analog design. Elaborate on the design of Beta blockers.

c) Write detailed note on Peptidomimetic agents with examples.

d) Discuss drug-receptor interactions with comparative analysis of binding forces and suitable examples.

e) Discuss purine and pyrimidine analogues as anticancer drugs with detail MOA.

Q4) Classify anticonvulsants with MOA and examples. Discuss GABA agonists. Add note on chemistry of barbiturates. **[15]**

OR

Explain the different stages of drug discovery. Enlist and elaborate process of lead discovery. Explain with minimum one case study.

Q5) Write short notes on (Any 3) : **[15]**

a) Write note on plant products used in cancer treatment.

b) Discuss the chemistry of prostaglandins with examples and therapeutic use.

c) Discuss the targets for Alzheimers Disease. Elaborate reversible cholinesterase inhibitors.

d) Elaborate on the Leukotriene inhibitors.

e) Discuss the alkylating agents as anti cancer drugs.

Total No. of Questions : 5]

SEAT No. :

PD-2027

[Total No. of Pages : 2

[6423]-179

First Year M. Pharmacy (Pharmacognosy)

MPG 103T: Phytochemistry

(Rev. 2019) (Semester - I)

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) Describe in detail Biosynthesis, isolation, purification, characterization, and industrial applications of Vinca Alkaloids. **[15]**

OR

Describe in detail principle, working, application, of SCFE Techniques along with their advantages and disadvantages.

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

a) Explain Structural elucidation of Caffeine.

b) Explain Flash Column Chromatography in detail.

c) Explain Microwave Assisted Extraction in detail.

d) Explain isolation, purification, characterization and industrial importance of Guggulsterone.

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

a) Elaborate in detail applications of HPTLC in characterization of herbal extracts.

b) Structural Elucidation of Glycyrrhizin.

c) Elaborate Explain isolation, purification, characterization and industrial importance of Piperine.

d) Explain detail spectroscopic characterization for structural elucidation of Carvone.

e) Write about Preparative HPLC.

P.T.O.

Q4) **Attempt any One Question of the following :** **[15]**

a) Describe in detail Biosynthesis, isolation, purification, characterization, and industrial applications of Quercetin.

b) Write in detail about Drug Discovery with special reference to Natural Products.

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

a) GCMS

b) CCCET

c) Successive and Exhaustive Extractions

d) Methods of Fractionation

e) Berberine

Total No. of Questions : 5]

SEAT No. :

PD-2028

[Total No. of Pages : 2

[6423]-180

M.Pharmacy

MPH103T: MODERN PHARMACEUTICS

(Rev. 2019) (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 suitable diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) **Solve on out of two :** **[15]**

a) Explain in detail Physics of tablet compression.

b) Define and differentiate between Process and equipment validation.

Q2) **Answer any 2 out of Four :** **[15]**

a) Explain compaction, consolidation, and compression in tablet formulation.

b) Describe Kawakita plots and Heckel plots

c) Write the full factorial design for the 3-factor 3 level experiment.

d) Discuss various dissolution models in the interpretation of release profile of drug.

Q3) **Write Short Note on any three out of five:** **[15]**

a) Suggest a method of validation in the following case:

Paracetamol IP 650 mg tablet was manufactured at ORBITS Pharma, Mumbai in Jan. 2024. The same formulation with the same formula was shifted to a loan license at ZEMBA Pharma. Baddi in Dec. 2024. The manufacturing variables include batch size, compression machine, operator, and location.

P.T.O.

b) Explain validation protocol for process validation with suitable example.

c) Explain Significance of force distribution in tablet compression and its impact on tablet quality.

d) Technology transfer in pharmaceuticals.

e) Write in detail Validation master plan for any one process, give its significance and parts.

Q4) **Solve one out of two:** **[15]**

a) Define Poison Ratio. Give equations for calculation of Net force for compaction along with significance of lubricant in compaction process.

b) Explain the need and concept of Preformulation and discuss the Preformulation studies of suspension and emulsion.

Q5) **Short Notes (Solve three out of five)** **[15]**

a) Write a note on Budget and cost control

b) Industrial & Personal relationships.

c) Role of statistical design in pharmaceutical formulation optimization.

d) Inculcate new technologies and recent developments in optimization during formulation development

e) Signify the need of validation along with role of each personnel involved in validation.

Total No. of Questions : 5]

SEAT No. :

PD-2029

[Total No. of Pages : 2

[6423]-181
M. Pharmacy
PHARMACOLOGY
MPL 103 T : Pharmacological & Toxicological Screening Methods - I
(Rev. 2019 Pattern) (Semester - I)

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) ***Figures to the right indicate full marks.***

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

a) Explain the in vivo and in vitro screening methods for antiepileptic agents,

b) List the methods to screen antifertility agents. Describe any four methods to screen a potential antifertility agent.

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

a) Explain principle, procedure and evaluation parameters for the following methods: (i) Cotton pallet Granuloma (ii) Writing Test (iii) Tail immersion test.

b) Describe different in-vivo preclinical screening models of anxiety.

c) Discuss Good laboratory Practices of experimental animals.

d) What are diabetogens? Name four diabetogens used for animal experimentation. Differentiate between MOA of two prototype diabetogens used for screening purposes.

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

a) Explain Morris water maze test assessment of memory related tasks.

b) Describe various models for screening of antipyretic activity in experimental animals.

c) Discuss in detail about the pylorus ligation model and NSAIDs induced ulcers.

d) How would you estimate first in human dose based on preclinical data?

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

P.T.O.

Q4) **Attempt any One :** **[15]**

a) Enlist different in-vivo preclinical screening models of nootropics. Explain any four in-vivo screening models.

b) Discuss in detail various in vitro and in vivo screening methods used in evaluation of anti-cancer agents.

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

a) Principle and types of immunoassays.

b) Limitations of animal experimentations.

c) Methods of euthanasia used for experimental animals.

d) Screening of anti - anginals.

e) Evaluation of hepatoprotective activity.

Total No. of Questions : 5]

SEAT No. :

PD-2030

[Total No. of Pages : 2

[6423]-182
M. Pharmacy
(Pharmaceutical Quality Assurance)
MQA 103 T : QUALITY CONTROL AND QUALITY ASSURANCE
(Rev. 2019) (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 labeled daigrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Discuss in detail the cGMP guidelines according to Schedule M for personnel, location design and plant layout of pharmaceutical industry.**[15]**

OR

Explain in detail the concept of Three tier documentation in pharamaceutical industry. Write a note on Common Technical Document.

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

a) Explain the In process quality control and finished products tests for capsules.

b) Write in detail about Good Warehousing Practice.

c) Elaborate about maintenance of distribution records.

d) Explain about scope and importance of Good laboratory practices. Summarize the responsibilities of Quality assurance unit.

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

a) Explain the concept of process deviation and charge-in of components in Pharamaceutical industry.

b) Discuss about Master Batch Record.

c) Comment on regulated and non-regulated markets concept in Pharamaceuticals.

d) Discuss in brief the validation of analytical procedures [Q2 (R1)] ICH guidelines.

e) Explain about mix-ups and cross contamination.

P.T.O.

Q4) Explain in detail the IPQC and FPQC for parenteral dosage form in Pharamaceutical Industry according to Indian Pharmacopoeia. **[15]**

OR

Explain why it is essential to follow cGMP during manufacturing operations and control. Discuss about sanitation of manufacturing premises, mix-ups and cross contamination.

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

a) Expiry date calculation and calculation of yields.

b) Environmental control in sterile areas.

c) Difference between Quality control and Quality assurance.

d) CPCSEA guidelines for physical facilities for laboratory animals.

e) IPQC and FPQC of ointments.

Total No. of Questions : 5]

SEAT No. :

PD-2031

[Total No. of Pages : 2

[6423]-183

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) Discuss the composition, role and responsibilities of Institutional Review Board. Explain in brief about review and approval process and ongoing monitoring of safety data.

b) Discuss in brief about important features of Good Clinical Practice Guidelines (ICH GCP E6).

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

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

b) Explain about E7 guidelines on studies in support of General Geriatrics Population.

c) Write about FDA guidance for Industry-Acceptance of Foreign Clinical Studies.

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

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

a) ANDA regulations, governing clinical trials.

b) Provide the details about ISO 14155.

c) Explain EU Annual Safety Report (ASR).

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

e) Explain the different types of clinical Studies.

P.T.O.

Q4) **Attempt Any One :** **[15]**

a) Discuss in brief about various phases of clinical research. Write a note on informed consent and its importance in clinical research.

b) Discuss in brief about ICMR Ethical Guidelines for Biomedical Research.

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

a) Discuss format used for application for approval of a new drug.

b) Write a note on Nuremberg code.

c) Discuss on EU Directives 2001.

d) Discuss the purpose, scope and recordkeeping in context of CFR 21 part 54.

e) Write short note on clinical research regulations in European Union.

Total No. of Questions : 5]

SEAT No. :

PD-2032

[Total No. of Pages : 2

[6423]-184

M.Pharmacy (Pharmaceutical Chemistry)

MPC 104T : CHEMISTRY OF NATURAL PRODUCTS

(Rev. 2019 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) **Attempt Any One :** **[15]**

a) Discuss in detail about methods of isolation & purification, and the biological activity of flavonoids. Add a note on structural elucidation of quercetin.

OR

b) Explain the development of drugs affecting central nervous system, from natural sources as lead examples.

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

a) Discuss chemistry and physiological significance of Vitamin B_1 and Vitamin B_{12}.

b) Discuss structural characterization of Vitamin D using IR, ^{1}H-NMR, ^{13}C-NMR and Mass Spectroscopy.

c) Explain development of new drugs with lead paclitaxel.

d) Explain the stereochemistry and nomenclature of reserpine.

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

a) How will you do structural elucidation of monoterpenoids?

b) Explain the stereochemistry of quercetine.

c) What are β-lactam antibiotics? Give chemistry of Cephalosporins.

d) Write the active constituents present in the following crude drugs: *Gymnema sylvestre and Salacia reticulate* for diabetic therapy.

e) Explain the stereochemistry and nomenclature of progesterone.

P.T.O.

Q4) **Attempt Any One :** **[15]**

a) Explain rDNA and hybridoma technology in brief.

OR

b) Define Terpenoids and classify it. Discuss isolation of Terpenoids. Explain structural elucidation of diterpenoids with examples.

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

a) Structural elucidation of one example of Digitalis glycosides.

b) Structural elucidation of carotinoids (β carotene).

c) Classification and general structural determination of alkaloids.

d) Oligonucleotide therapy.

e) Characterization details of Camphor.

Total No. of Questions : 5]

SEAT No. :

PD-2033

[Total No. of Pages : 2

[6423] - 185

F. Y. M. Pharmacy (Pharmacognosy)

MPG 104T: INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

(Rev.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.***

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

Discuss Indian and international patent laws. Describe amendments applicable to natural products.

OR

Explain current challenges in upgrading and modernization of herbal formulations.

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

a) Discuss WHO guidelines in quality assessment of herbal drugs.

b) Explain provisional and complete specifications in application of Indian patent.

c) Describe Pilot plant scale up techniques in connection with herbal drugs.

d) What is ISO-9000? Explain its significance in herbal drug quality

P.T.O.

Q3) Short answer question (Any Three) : **[15]**

a) What is 'TRIPS'? Elaborate its understanding for regulatory of herbal industry.

b) Discuss clinical laboratory testing of herbal drugs.

c) What is role and responsibilities of controller of patents?

d) Which are non-patentable inventions?

e) Discuss project selection and project report requirement in herbal industry.

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

a) Describe in detail about the Good Manufacturing Practices (GMP) for the production of herbal formulations.

b) Explain requirements of herbal industry involved in production of standardized extracts and various dosage forms.

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

a) Comparative study of British Herbal Pharmacopoeia and Ayurvedic Pharmacopoeia

b) Enablement and best mode in case of patent

c) Total Quality Management

d) Stability testing of herbal drugs

e) Good Laboratory practices

Total No. of Questions : 5]

SEAT No. :

PD-2034

[Total No. of Pages : 2

[6423] - 186

F. Y. M. Pharmacy (Pharmaceutics)

MPH 104T: REGULATORY AFFAIRS

(Revised 2019) (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) Attempt any one : **[1 × 15 = 15]**

a) Explain the steps involved in carrying out a clinical trial. Write the responsibilities and functional modalities for the institutional review board.

b) Explain in detail regulatory requirements for product approval with special emphasis on NDA and ANDA.

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

a) Explain in-vivo drug product assessment and Bioequivalence studies.

b) Write a note on chemistry, manufacture and control in pharmaceutical industry.

c) Explain the ways and means of US registration for foreign drugs.

d) Write a note on the investigation of medicinal products dossier (IMPD) and Investigator brochure.

P.T.O.

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

a) What is the significance of post-market surveillance required by the FDA?

b) What is CFR? Explain 21 CFR 210 and 21 CFR 211.

c) Discuss about Health Insurance Portability and Accountability Act.

d) What is the importance of CTD &e-CTD in regulatory application submission?

e) What are the various regulatory requirements of TGA?

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

a) Explain the importance of documentation and documents to be maintained in the pharmaceutical industry.

b) Explain the regulatory requirements of medical devices for market authorization.

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

a) Guidelines ICH-E

b) Generic drugs product development

c) Regulatory requirements of ROW and its objectives

d) Pharmacovigilance in safety monitoring

e) Investigator brochure

Total No. of Questions : 5]

SEAT No. :

PD-2035

[Total No. of Pages : 2

[6423]-187
M. Pharmacy
MPL 104 T : CELLULAR AND MOLECULAR PHARMACOLOGY
(Rev.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 side indicate full marks.***
3) ***Draw well labeled daigrams wherever necessary.***

Q1) What do you mean by Pharmacogenomics? How gene variation can help in treatment of diseases and maintenance of health. **[15]**

OR

Discuss the principles and apllications of DNA recombinant technology.

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

a) Discuss the role of caspases family of enzymes in apoptosis.

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

c) How cell signaling and communication takes place between cells?

d) Explain in detail, principles and applications of flow cytometry.

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

a) Describe basic equipments used in cell culture laboratory.

b) Describe the types of immunotherapeutics.

c) Explain principle and applications of flow cytometry.

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

e) What is DNA electrophoresis? Give its applications.

P.T.O.

Q4) Describe structure and functions of human cells in detail. **[15]**

OR

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

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

a) JAK/STAT signaling pathway.

b) SDS PAGE

c) Gene sequencing.

d) General procedure for cell culture.

e) Cryopreservation technique and its applications.

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Total No. of Questions : 5]

SEAT No. :

PD-2036

[Total No. of Pages : 2

[6423]-188

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA 104 T : PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

(2019 Revised) (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 labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Describe large scale manufacturing techniques including formula equipment, process, stability and quality control for solid dosage forms in detail. **[15]**

OR

Discuss in detail stability testing during product development as per ICH guidelines.

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

a) What do you mean by drug discovery? Describe Clinical Research Process step by step.

b) Write in detail about medical Device packing.

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

d) Give a detailed account of BACPAC.

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

a) Describe the registration guidelines for dosage forms as per USFDA.

b) Enlist types of Pharmaceutical Packaging. Discuss any two Quality control tests for secondary packing material.

c) Discuss various issues faced in modern drug packaging.

d) Describe various steps involved in Technology transfer.

e) Write a short note on Polymorphism.

P.T.O.

Q4) Explain the concept of solubility of drugs? Explain the methods to enhance the solubility in detail. **[15]**

OR

What is technology transfer? Discuss various documents involved in technology transfer of a dosage form.

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

a) Significance and need of preformulation studies.

b) Post marketing surveillance.

c) SUPAC

d) Design of Pilot.

e) Aseptic packaging system.

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Total No. of Questions : 5]

SEAT No. :

PD-2037

[Total No. of Pages : 2

[6423]-189
F.Y.M. Pharmacy
(PHARMACEUTICS)
MRA 104 T : Regulations & Legislation For Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food and Nutraceuticals in India and Intellectual Property Rights (Rev. 2019) (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 :** **[1 × 15 = 15]**

a) Write about Indian patent Scenario.

b) Give regulatory requirements and approval procedures for drugs and cosmetics, medical devices, biologicals & herbals & food & nutraceuticals.

Q2) **Attempt any Two :** **[2 × 7.5 = 15]**

a) Mention the conditions of import license for schedule C and shedule X drugs.

b) Give the constitution of Drug Technical Advisory Board (DTAB) & its functions.

c) What is Berne Convention for the protection of Literary & Artistic works?

d) Offences & Penalties in narcotic drugs & psychotropic substances.

Q3) **Attempt any Three :** **[3 × 5 = 15]**

a) Write a brief note on schedule M framed under D & C act rules there under.

b) Guidelines for approval of drugs and cosmetics.

c) Comment on prohibition of misleading advertisement relating to drugs under drugs & magic remedies act 1955.

d) What international conventions protect patent rights?

e) Give regulatory requirements of Bioequivalence study.

P.T.O.

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

a) What is IPR? Discuss various components of IPR.

b) Patent Act 1970 & its amendments.

Q5) **Answer any three :** **[3 × 5 = 15]**

a) Explain the powers of drug Inspecter.

b) What are the conditions for grant of license for manufacture of Ayurvedic and Unani Drugs.

c) What are geographical indications? Write its function.

d) Discuss Schedule X.

e) Define

i) Spurious drug ii) Misbranded drug

iii) Drug iv) Cosmetics

v) Registered Medical Practitioner.

Total No. of Questions : 5]

SEAT No. :

PD-2038

[Total No. of Pages : 2

[6423]-190
F.Y.M. Pharmacy
PHARMACEUTICAL BIOTECHNOLOGY
MPB 104 T : Advanced Pharmaceutical Biotechnology
(Revised 2019) (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.***

Q1) **Answer any One out of two :** **[1 × 15 = 15]**

a) Discuss detail classification and general properties of enzymes.

b) Explain various drug delivery approaches for therapeutic proteins.

Q2) **Attempt any Two out of four :** **[2 × 7.5 = 15]**

a) Write the principle of genetic engineering. Discuss various applications of genetic engineering.

b) Explain microbias productions, purification & isolation of glucose isomerase enzyme.

c) Explain biotransformation process for chiral drugs.

d) Briefly explain role of various oncogenes proteins.

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

a) Write ideal properties of cloning vectors.

b) Discuss various sources of enzymes.

c) Write the applications of biotransformation

d) What are restriction endonuclease enzymes? Write their various classes.

e) Write the significant of human genome project.

P.T.O.

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

a) What are transgenic animals? Write their applications in production of Therapeutic proteins.

b) What are biosensors? Discuss various mechanisms and types of biosensors.

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

a) Production of Trypsin.

b) Xenobiotics.

c) Production of single cell protein.

d) r-DNA production of Hepatitis - B vaccine.

e) Therapeutic and clinical applications of enzymes.

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Total No. of Questions : 5]

SEAT No. : ____

PD-5718

[Total No. of Pages : 2

[6423]-191

F.Y. M.Pharmacy

(MPB201T) : Proteins & Protein Formulation

(Rev.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) Briefly discuss various sequencing methods for protein.

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

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

b) Explain various approaches of protein engineering based on stability and activity.

c) Write a note on Edman sequencing.

d) Write three distinct steps for protein characterization. Explain protein sequence strategies.

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

a) Write three distinct steps for protein characterization. Explain protein sequence strategies.

b) Describe in brief liposomes in protein formulation.

c) Definition classification & evaluation of Peptidomimetics.

d) What is the purpose of PEGylation?

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

P.T.O.

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

a) Explain in brief different strategies used in the formulation of DNA and proteins.

b) Write a note on Biophysical characterization of proteins.

Q5) **Write short notes on (any 3) :** **[15]**

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

b) Tryptic Peptide Mapping.

c) A note on ACEI inhibitors.

d) Explain different types of proteomics.

e) Forced degradation studies of protein.

Total No. of Questions : 5]

SEAT No. :

PD5719

[Total No. of Pages : 2

[6423]-192
First Year M. Pharmacy (Pharmaceutical Chemistry)
ADVANCED SPECTRAL ANALYSIS
(Revised 2019 Credit Pattern) (Semester - II) (MPC 201T)

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

Instructions to the candidates:

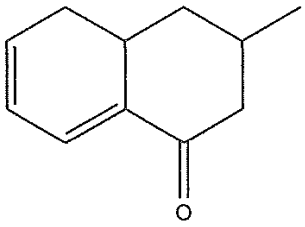
1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Draw a neat diagrams wherever necessary.***

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

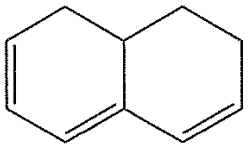
OR

Explain Woodward - Fieser rule for assessment of λmax for 1,3 - butadienes and α, β - carbonyl compounds.

Predict the λmax of the following compound (ANY ONE)



(I)



(II)

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

a) Explain the mass fragmentation patterns of following class of organic compounds

   i) Amines

   ii) Aliphatic and aromatic acids

b) Explain principle and instrumentation of Supercritical Fluid Chromatography.

P.T.O.

c) Predict and explain the NMR spectra of following compounds (Any Three)

i) *p* - toluidine

ii) 1 - nitropropane

iii) *p*-hydroxyacetophenone

iv) *t*- butyl chloride

d) Explain Mc-Lafferty rearrangement with suitable example.

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

a) Discuss Attenuated Total Reflectance (ATR).

b) How will you differentiate ethyl acetate and methyl acetate by NMR.

c) Explain instrumentation of CE-MS.

d) What is an ortho effect in Mass Spectrometry? Explain with example.

e) Elaborate Ring Rule in Mass Spectrometry with examples.

Q4) Determine the probable structure of compound from the following data **[15]**

MF : $C_9H_{10}O$

UV : 280 nm (ethanol)

IR(cm^{-1}) : 1715, 1590, 1550

^1H NMR (δ ppm) : a) δ : 2.09, singlet, 3H

b) δ : 3.65, singlet, 2H

c) δ : 7.29, singlet, 5H

OR

Elaborate the principle, instrumentation and applications of Flash Chromatography.

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

a) LC-FTIR

b) Radioimmunoassay of Digitalis.

c) ELISA

d) Explain instrumentation and applications of TGA.

e) Metastable ion peak and Isotopic peak in Mass Spectrometry.

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Total No. of Questions : 5]

SEAT No. :

PD-5720

[Total No. of Pages : 2

[6423]-193

F.Y. M.Pharmacy (Pharmacognosy)

MPG201T : Medicinal Plant Biotechnology

(Rev.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.***
4) ***Do not write anything on question paper except seat number.***

Q1) a) Explain the methods of manipulation of production of secondary metabolities in plant cell culture. **[15]**

OR

b) What are different types of bioreactors used for fermentation for production of secondary metabolities? **[15]**

Q2) **Attempt any 2.** **[15]**

a) Explain the process of DNA replication.

b) Define monoclonal variation and its significance in plant tissue culture.

c) Describe the methods and significance of plant cell cloning.

d) Explain the production of ergot alkaloids through fermentation technology.

Q3) **Attempt any 3.** **[15]**

a) What is concept of cellular totipotency?

b) Discuss the applications of transgenic plants in pharmacy.

c) Describe the term "biotransformation" and its importance in plant biotechnology.

d) Define hairy root culture and its applications.

e) What is the importance of precursor feedings in secondary metabolite production?

P.T.O.

Q4) a) Discuss the historical perspective of plant biotechnology and explain its potential as a source of medicinal agents. **[15]**

OR

b) Explain the structure and complexity of the genome and the regulation of gene expression in plants. **[15]**

Q5) **Attempt any 3 :** **[15]**

a) Immobilization of enzyme and its application.

b) What is protoplast? Define protoplast fusion and mention its applications.

c) Gene transfer techniques in plants.

d) Role of elicitors in the production of secondary metabolites.

e) Write note on Cryopreservation.

Total No. of Questions : 5]

SEAT No. :

PD5721

[Total No. of Pages : 2

[6423]-194
First Year M. Pharmacy
MOLECULAR PHARMACEUTICS (Nano Tech & Targeted DDS)
(Revised 2019 Credit Pattern) (Semester - II) (MPH 201T)

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 a neat diagram wherever necessary.***

Q1) Long answer question (Solve any 1 out of 2) **[15]**

a) Explain the challenges and advanced approaches in the development of tumour targeting drug delivery systems.

OR

b) Explain the design, preparation, and evaluation of nanoparticles for controlled drug delivery, highlighting their advantages and limitations.

Q2) Medium Length questions (Solve any 2 out of 4) **[15]**

a) What are Microspheres and Microcapsules. Explain preparation methods

b) Elaborate in detail on electrosomes

c) Write a detailed note on preparation and evaluation of niosomes

d) Write in detail about the preparation and evaluation of dry powder inhalers.

Q3) Short answer questions (Solve any 3 out of 5) **[15]**

a) Define and discuss applications of Antisense molecules

b) What are niosomes and write the advantages of Niosomal drug delivery systems

c) Define and differentiate between active and passive targeting.

d) What are phytosomes? and what are their benefits in drug delivery?

e) Give detailed classification of liposomes along with diagram.

P.T.O.

Q4) Long answer question (Solve any 1 out of 2). **[15]**

a) Elaborate on the importance and role of gene therapy in drug delivery along with major events in gene delivery.

OR

b) Discuss the preparation methods of liposomes and add a note on evaluation parameters.

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

a) Explain about propellants and evaluation of Aerosols.

b) Write an account on aptamers as therapeutic agents.

c) Explain in brief the basic concept and objectives of drug targeting.

d) Write short note on metered dose inhalers.

e) Explain the concept of Biodistribution.

Total No. of Questions : 5]

SEAT No. : ____

PD-5722

[Total No. of Pages : 2

[6423] - 195
M.Pharm. (Theory)
MPL-201T: Advanced Pharmacology-II
(Rev.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 neat labeled diagram wherever necessary.***

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

a) What are Corticosteroid drugs? Discuss the pharmacological actions, mode of action, adverse effects and therapeutic applications of Corticosteroids

b) Classify Beta lactams and write a brief account on Penicillin and Cephalosporins

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

a) Classify antiulcer drugs. Explain pharmacology of Pantoprazole.

b) Classify immunosuppressant drugs. Explain their mechanisms of action.

c) Critically discuss the biochemical mechanisms by which bacteria acquire resistance to antibiotics.

d) Write the pharmacology of Anti-thyroid drugs belongs to the class thioamide derivatives.

P.T.O.

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

a) Summaries Rational approach to treat Diarrhoea.

b) What is tuberculosis, classify and justify first line drugs used in tuberculosis therapy.

c) Conclude chronopharmacology applications in various diseases.

d) Discuss the pharmacological treatment options for Irritable Bowel Syndrome.

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

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

a) Classify antiasthamatics. Explain pharmacology of glucocorticoids and bronchodilators in asthma.

b) Describe the different classes of aminoglycosides, their mechanisms of action, spectrum of activity, resistance issues, and therapeutic indications.

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

a) Adverse effects profile of anticancer drugs.

b) Mechanism of Insulin & its preparations

c) Lipoic acid as an antioxidant

d) Mechanism of Antithyroid drugs

e) Prokinetics

Total No. of Questions : 5]

SEAT No. :

PD5723

[Total No. of Pages : 2

[6423]-196

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

HAZARDS AND SAFETY MANAGEMENT

(Revised 2019 Credit Pattern) (Semester - II) (MQA 201T)

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 air circulation in pharmaceutical industry for non-sterile area. Write a note on the HVAC system. **[15]**

OR

Explain components of Fire triangle and classification of Fire. Add a note on the preventive and protective management from fire and explosions.

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

a) Discuss in detail on control strategies for handling of toxic gases and oxygen displacing gases.

b) Discuss the ICH guideline on risk assessment.

c) Explain the control measures while handling flammable material, dust explosions and pyrophoric material.

d) Describe strategies for accident prevention.

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

a) Explain in brief the various hazards which can occur due to air and water and suitable measures to prevent them.

b) Write in short about critical training for risk management.

c) Add a note on Preliminary Hazard analysis.

d) Elaborate on Management of over exposure to chemicals and significance of various Threshold limits.

e) Write a note on Factories act.

P.T.O.

Q4) Define industrial hazards? Classify types of chemical hazards and discuss its influence on environment. Add a note on MSDS. **[15]**

OR

Describe in detail various risk management tools used in industry.

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

a) Explain the concept of ecosystem with its structure and function.

b) Write in brief about BOD and COD.

c) Discuss disposal of hazardous material.

d) Enlist and explain renewable and non-renewable natural resources.

e) Explain the Elements of Safety Management Programme

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Total No. of Questions : 5]

SEAT No. : [ ]

PD5724

[Total No. of Pages : 2

[6423]-197
First Year M. Pharmacy
REGULATORY ASPECTS OF DRUGS AND COSMETICS
(Revised 2019 Credit Pattern) (Semester - II) (MRA 201T)

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) Explain the purpose of PAMDRH. How does it work towards regulatory hormonization in Latin America.

b) Describe the organisational structure and primary functions of the U.S. Food and Drug administration (USFDA) and its role in public health.

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

a) Compare the legislation governing the import, manufacturing, distribution and sale of cosmetics in Brazil and CIS countries.

b) Write about CoPP in South Africa & Egypt.

c) Enlist and elaborate the documentation requirement for Drug Master File (DMF) submission in Japan.

d) Describe the purpose and structure of EudraLex and its role in medicine regulation in EU.

Q3) Answer any three (5 marks each) **[15]**

a) Define emerging market. Why are they crucial for global economic growth.

b) Discuss the post marketing serveillance (PMS) in Japan.

c) Describe centralized Marketing Authorization.

d) Comment on supplemental new drug Application (SNDA) in the U.S. regulatory process?

e) Outline the post approval requirements for drugs in Saudi Arabia.

P.T.O.

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

a) Outline the key steps in the drug registration process in Philippines and ASEN guidelines.

b) Discuss the organisational structure and functions of EMA and EDQM.

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

a) Comment on significance of Hatch-Waxman Act in the U.S. Pharmaceutical industry.

b) Responsibilities for a Qualified Person (QP) in ensuring batch release in the EU.

c) Types of registration application.

d) Enlist five major emerging markets with their significance in the global economy.

e) Regulatory requirements for registration of drugs in Brazil.

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Total No. of Questions : 5]

SEAT No. : [ ]

PD5725

[Total No. of Pages : 2

[6423]-198
First Year M. Pharmacy
IMMUNOTECHNOLOGY
(Revised 2019 Credit Pattern) (Semester - II) (MPB 202T)

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) What is RIA? Write principle, procedure and application of RIA.

OR

b) Explain cytokines and their role in immune response.

Q2) Attempt Any Two (Solve 2 out of 4) **[15]**

a) Explain various types of Hypersensitivity reactions.

b) Write a note on MHC.

c) Explain structure and properties of immunoglobulin classes.

d) Describe advantages and drawbacks of live attenuated vaccines.

Q3) Attempt Any Three (Solve 3 out of 5) **[15]**

a) Write a note on ELISA.

b) Enlist subunit vaccine with suitable example.

c) Write functions of different types of T-cells.

d) Discuss anatomy of immune response.

e) Describe the Autoimmune disorders and their types.

P.T.O.

Q4) Long answer question (Solve 1 out of 2) **[15]**

a) Write structure and general functions of Antibody.

OR

b) Explain the Discuss on attenuated and inactivated viral vaccines.

Q5) Write short notes on (Solve 3 out of 5) **[15]**

a) Conjugate vaccine.

b) Western blot analysis.

c) DNA Vaccine

d) Primary lymphoid organ

e) Antigen presenting cells (APC)

x x x

Total No. of Questions : 5]

SEAT No. :

PD5726

[Total No. of Pages : 2

[6423]-199
First Year M. Pharmacy (Pharmaceutical Chemistry)
ADVANCED ORGANIC CHEMISTRY - II
(Revised 2019 Credit Pattern) (Semester - II) (MPC 202T) (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) Explain the concept of Green chemistry with suitable examples? Describe the principle and examples of Microwave assisted and ultrasound assisted reactions. **[15]**

OR

What are pericyclic reactions? Explain with suitable example, cycloaddition reaction and sigmatropic rearrangement.

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

a) Explain about different types of catalysis. Explain their advantages and disadvantages.

b) Explain the stereoselective synthesis with examples.

c) Describe Transition metal and organo-catalysis with suitable examples?

d) Elaborate on uses of enzymes in organic synthesis.

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

a) Discuss principle and applications of continuous flow reactors

b) Explain reactions with Wilkinson and Ziegler-Natta catalyst.

c) Write in detail about heterogenous catalysis.

d) Write note on photo- oxidation and Photo-addition reaction.

e) Explain CIP sequence rule for stereoisomers with suitable examples.

P.T.O.

Q4) What are recemates? Explain in detail about different methods used for resolution of racemic mixture. **[15]**

OR

Explain with example solid phase peptide synthesis with respect to procedure, resins and linkers.

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

a) Describe principle and applications of Phase transfer catalysis.

b) Application of Chiral auxiliaries.

c) Applications of Ionic Liquids and Solvent free reactions.

d) Write a note on t-BOC and FMOC protocols in peptide synthesis.

e) Write note on electrocyclic reactions.

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

PD-5727 **[Total No. of Pages : 2**

[6423]-200
M. Pharmacy
MPG 202 T : ADVANCED PHARMACOGNOSY - II
(Rev. 2019 Pattern) (Semester - II)

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 labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Explain biological screening of herbal drugs for anti-oxidant and antidiabetic activities. **[15]**

OR

Explain analytical profile of following herbal drugs

i) *Embelica officinalis*

ii) *Psoralea corylifolia*

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

a) Explain pharmacokinetic and pharmacodynamic issues related to herbal remedies.

b) Describe *In vivo* evaluation methods for anti-inflammatory activities.

c) Write analytical profile of *Andrographis paniculata.*

d) Explain DNA finger printing technique in idntification of herbal drugs.

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

a) Explain new strategies for evaluating natural products.

b) Describe evaluation of heavy metals and pesticide residues in herbs and their formulations.

c) Explain impact of ethnobotany in traditional medicine.

d) Give analytical profile of *Coleus forkholii*.

e) Write about new development in herbals in brief.

P.T.O.

Q4) Define adulteration and deterioration. Explain various methods of adulteration with examples. Give sampling procedures. **[15]**

OR

Explain toxicity studies as per OECD guidelines.

Q5) **Write a short note on the followings (Any Three) :** **[15]**

a) Role of ethnopharmacology in drug evaluation.

b) *In vivo* evaluation technique for hepatoprotective activity.

c) Determination of Phycotoxin

d) Analytical profile of *Boswellia serata*

e) Bioprospecting tools for drug discovery.

Total No. of Questions : 5]

SEAT No. :

PD-5728

[Total No. of Pages : 2

[6423]-201

F.Y. M.Pharmacy (PHARMACEUTICS)

MPH202T : Advanced Biopharmaceutics & Pharmacokinetics

(Rev. 2019 Pattern) (Semester - II)

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

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***The 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) a) Describe in detail factors affecting drug absorption from gastroinstestinal tract. **[15]**

OR

b) What are the causes of non linearity in pharmacokinetics? Describe the non linear pharmacokinetics by Michaelis-Menten equation.

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

a) Enlist and elaborate the approaches used to bioequivalence.

b) Describe cytochrome P450 drug interactions.

c) Explain the basis of BCS classification. Discuss different models for the determination of permeability.

Q3) **Answer the following (Any three).** **[15]**

a) Enlist the mechanisms of drug absorption and describe passive diffusion.

b) Explain pH partition hypothesis.

c) What are modified release drug products?

d) Write a note on non compartmental methods of pharmacokinetic analysis.

e) Write a note on biowaivers.

P.T.O.

Q4) a) What are the pharmacokinetics parameters? Describe one compartment open model for extravascular administration. **[15]**

OR

b) Explain various bioequivalence study designs.

Q5) **Short notes (Any three):** **[15]**

a) Similarity and dissimilarity factor.

b) IVIVC.

c) Compendial methods of dissolution.

d) Write a note on in vitro methods of calculating drug permeability.

e) Factors to be considered in the design of a drug product.

Total No. of Questions : 5]

SEAT No. :

PD5729

[Total No. of Pages : 2

[6423]-202
First Year M. Pharmacy
PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II
(Revised 2019 Credit Pattern) (Semester - II) (MPL202T)

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

Instructions to the candidates:

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

Q1) **Solve any one (01 out of 02)** **[15]**

a) Discuss in detail OECD principles of GLP.

b) Define safety pharmacology? Explain the scope, importance and principles of safety pharmacology.

Q2) **Solve any Two (02 out of 04)** **[15]**

a) Write a note on in *vitro* and in *vivo* studies for genotoxicity.

b) How are inhalational products tested for their toxic effects?

c) Discuss the concept of GLP and its importance in New Drug Development Process.

d) Discuss the importance of male reproductive toxicity studies.

Q3) **Solve any Three (03 out of 5)** **[15]**

a) Write about ICH guidelines for toxicity studies.

b) Discuss acute eye irritation toxicity studies.

c) Explain in detail about carcinogenicity studies.

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

e) Write the alternative methods to animal toxicity studies.

P.T.O.

Q4) **Solve any one (01 out of 02)** **[15]**

a) Define acute, subacute and chronic toxicity studies. Explain the process of determining LD50 in acute toxicity testing of drugs as per OECD guidelines.

b) Explain in brief the importance and applications of toxicokinetic studies write a note on toxicokinetic evaluation of preclinical studies.

Q5) **Write a short note on any Three (03 out of 5)** **[15]**

a) Skin sensitization toxicity studies

b) Chromosomal aberration studies

c) Schedule Y

d) Significance of IND

e) HERG assay

Total No. of Questions : 5]

SEAT No. : [ ]

PD5730

[Total No. of Pages : 2

[6423]-203
First Year M. Pharmacy
MQA202T : PHARMACEUTICAL VALIDATION
Pharmaceutical Quality Assurance
(Revised 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 indicates full marks.***
3) ***Draw suitable diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

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

a) Give detail protocol for process Validation of Capsule.

b) State the applications of Steam in Pharmaceutical industry. How is Steam system validated?

Q2) **Medium Length answers (Solve 2 out of 4)** **[2×7.5=15]**

a) Provide framework for Computer System Validation.

b) Describe the sampling techniques in Cleaning Validation.

c) Summarize the content of Validation Master Plan.

d) Explain Qualification of Autoclave.

Q3) **Short answer questions (Solve 3 out of 5)** **[3×5=15]**

a) Infer the economic importance of IPRs.

b) Provide URS for Dissolution test apparatus.

c) Describe Qualification of Tablet Compression machine.

d) Mention advantages and scope of validation.

e) Distinguish Calibration, Qualification and Validation.

P.T.O.

Q4) **Long answer questions (Solve 1 out of 2)** **[1×15=15]**

a) Enlist various mechanisms of protection of Intellectual Property. State the content of Form 2 for patent application.

b) Discuss general principles for Validation of Analytical method as per ICH Guidelines.

Q5) **Short notes (Solve 3 out of 5)** **[3×5=15]**

a) IPR and Ethics

b) Maximum Allowable Carryover

c) Retrospective Validation

d) Qualification of Hardness tester.

e) Validation of UV-Visible spectrophotometer

Total No. of Questions : 5]

SEAT No. :

PD-5731

[Total No. of Pages : 2

[6423]-204

M.Pharmacy

MRA202T : Regulatory Aspects of Herbals & Biologicals

(Rev. 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) a) Describe in detail how the European Union's biosimilarity or comparability examination is done. **[15]**

OR

b) Describe the safety, quality, and legal framework for herbal goods in India.

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

a) Elaborate in detail the EU's criteria for the quality of herbal products.

b) Examine the term pharmacovigilance.

c) Describe the laws, safety, and quality of herbal goods in India.

d) Write a note on EU advertising regulations.

Q3) **Attempt (Any Three).** **[15]**

a) Describe in detail about the guidelines govern the determination of biosimilarity.

b) According to Indian laws, what data are required for preclinical studies?

c) Write distinctions between biosimilars and generic medications.

d) What are the EU's stability requirements for vaccinations?

e) Write about the TSE/BSE assessment.

P.T.O.

Q4) a) Elaborate in detail about ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network). **[15]**

OR

b) Explain the data requirements for preclinical studies and clinical trial applications as per India regulations.

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

a) Write note on plasma master file.

b) Describe quality control tests required for herbal product in India.

c) What are the European Union's vaccination safety regulations?

d) Write a note on Pharmacovigilance.

e) Explain about the US Blood and Blood Products Regulations additional requirements.

Total No. of Questions : 5]

SEAT No. :

PD-5732

[Total No. of Pages : 2

[6423]-205
F. Y. M. Pharmacy
PHARMACEUTICAL BIOTECHNOLOGY
MPB 203 T : Bioinformatics & Computer Technology
(Rev. 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) **Attempt any one out of two :** **[1 × 15 = 15]**

a) What are bioinformatics databases? Discuss five major types of bioinformatics databases.

b) Explain in detail sequence Analysis.

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

a) What is data mining. Give its applications.

b) What is FASTA and BLAST?

c) What is drug designing? Explain its principle.

d) Write about pattern of nucleotide.

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

a) Write a note on protein databases.

b) Write a note on the "Internet and Bioinformatics".

c) Write a note on Nucleic acid databases.

d) Write application of Bioinformatics.

e) Write about high throughput screening and virtual screening.

P.T.O.

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

a) What is force Field methods, of protein informatics? Explain in detail protein informatics.

b) What is lead discovery? Explain application of bioinformatics in microarray analysis.

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

a) What is CLUSTALX?

b) What is MUSCLE?

c) Enlist methods of alignment. What is multiple sequence alignment?

d) Write a short note on protein ligand docking.

e) What is the importance of nucleotide sequence.

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Total No. of Questions : 5]

SEAT No. :

PD5733

[Total No. of Pages : 2

[6423]-206
First Year M. Pharmacy
COMPUTER AIDED DRUG DESIGN
(Revised) (Credit 2019 Pattern) (Semester - II) (MPC 203T) (Theory)

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 labeled diagram be drawn wherever necessary.***

Q1) a) Give principle, applications and limitations of Hansch analysis. Give at least two examples. **[15]**

OR

b) Explain various DHFR inhibitors with reference to enzyme drug interactions. Give the applications of these agents.

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

a) Give detail account on Hydrogen-bond and Hydrophobic interactions in drug-receptor interaction.

b) Discuss concept of QSAR and explain steric parameter in QSAR.

c) Explain Ligand & Structure-based pharmacophore modeling and virtual screening.

d) Write a detail account of energy minimization methods for small molecules.

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

a) Explain different minima in energy minimization of compounds.

b) Write in detail about molecular docking.

c) Explain molecular mechanics.

d) Explain hydrophobic parameters used in QSAR with examples.

e) Write a note on Homology modeling.

P.T.O.

Q4) a) Explain role of CADD in drug discovery process. Give its history and applications drug discovery. **[15]**

OR

b) Write in detail about ADME properties of new molecules and give its significance in drug discovery.

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

a) Write about statistical methods used in QSAR. State its importance in QSAR

b) Explain methods of receptor/enzyme cavity size prediction

c) Explain 3D-QSAR techniques. Give importance of contour maps in 3D-QSAR

d) Enlist methods in Quantum Mechanics. Discuss any one of them.

e) Explain Free-Wilson analysis. Give its advantages & disadvantages.

Total No. of Questions : 5]

SEAT No. :

PD5734

[Total No. of Pages : 2

[6423]-207
First Year M. Pharmacy (Pharmacognosy)
INDIAN SYSTEM OF MEDICINE
(Revised 2019 Credit Pattern) (Semester - II) (MPG 203T) (Theory)

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) Explain principle and treatment of ayurvedic system of medicine. **[15]**

OR

Explain in detail "Schedule T".

Q2) Answer the Following (Any Two) **[15]**

a) Elaborate Government Bill in ISM.

b) Discuss the importance of Asanas, Pranayam, Meditation in Yoga.

c) Explain Ayurvedic Pharmacopoeia in detail.

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

a) Discuss Unani System of Medicine.

b) Explain Aromatherapy.

c) Explain Purification Process in Siddha system.

d) Write about GAP.

P.T.O.

Q4) Attempt any One Question of the following. **[15]**

a) Explain in detail about Analysis of Formulations.

b) Write in detail about Different Types of Formulations in Ayurvedic System of Medicine.

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

a) TKDL

b) Shelf Life and Stability studies of ISM formulations

c) CCRH

d) Raw Drug in Siddha System

e) Carrier Oils

Total No. of Questions : 5]

SEAT No. :

PD5735

[Total No. of Pages : 2

[6423]-208
First Year M. Pharmacy
PHARMACEUTICS
Computer Aided Drug Development
(Revised 2019 Credit Pattern) (Semester - II) (MPH 203T)

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 out of two. **[1×15=15]**

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

b) Explain in detail clinical data collection and management add a short note on Regulation of Computer System.

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

a) Define quality, Quality by Design (QbD) and Quality Target Product Profile (QTPP).

b) Explain in detail artificial intelligence.

c) Explain BCRP and HPEPTL.

d) Write a note on comparison between Descriptive and mechanistic models.

e) Explain in detail computer simulation in isolated tissue & organ.

P.T.O.

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

a) Explain in detail fed Vs. fasted state and biowaiver considerations.

b) Write the significance of In-Vitro-In-vivo correlation.

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

a) Mention the various fields of pharmaceutical automation.

b) Write short note on use of computers in marketing analysis.

c) What are Robotics, Give its applications.

d) Define modelling and enlist various modelling techniques.

e) Compare population and non-population PK/PD.

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Total No. of Questions : 5]

SEAT No. :

PD-5736

[Total No. of Pages : 2

[6423]-209

M. Pharmacy

MPL 203 T : PRINCIPLES OF DRUG DISCOVERY

(Rev. 2019 Pattern) (Semester - II)

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

Instruction to the candidates:

All questions are compulsory and carry equal marks.

Q1) **Long Answer Questions :**

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

OR

What is regression analysis? Give an account on important uses of regression analysis.

Q2) **Medium Length Answers (Solve any two) :** **[2 × 7.5 = 15]**

a) Describe various lead seeking methods in drug design.

b) Explain in brief the role of bioinformatics in target identification.

c) Definition of Biomarkers and write their classification.

d) Explain enzymes and enzymes Inhibition process in drug discovery.

Q3) **Short answer questions (Solve any Three) :** **[3 × 5 = 15]**

a) Describe molecular docking.

b) Explain in brief the role of protein microarrays.

c) Describe types of protein structure.

d) Discuss how drug targets are assessed for safety during drug discovery.

e) Note on ELISA.

P.T.O.

Q4) **Long answer questions :** **[1 × 15 = 15]**

i) Explain Ion Channels, Membrane Transport Proteins (Transporters). **[15]**

OR

i) Write on Biomarkers versus Surrogate End Points. **[8]**

ii) Write in details about application of NMR in Protein structure prediction. **[7]**

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

a) Write electrophysiological patch clamp process.

b) Explain biomarkers for diabetes.

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

d) Note on Radioligand Assay Systems (RIA).

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

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Total No. of Questions : 5]

SEAT No. :

PD-5737

[Total No. of Pages : 2

[6423]-210

M.Pharmacy

MQA 203T : AUDIT AND REGULATORY COMPLIANCE

(Rev. 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) a) Explain about scope, objective, advantages and disadvantages of audit in pharmaceutical industry. Comment on internal and external audits. **[15]**

OR

b) Discuss quality assurance functions and quality system approach in pharmaceutical industry in detail.

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

a) Give detail account on regulatory requirements of granulation and tableting.

b) Discuss an internal audit checklist for the stores and warehouse department?

c) Describe management responsibilities under cGMP regulations.

d) What are the responsibilities of auditors and auditees?

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

a) Discuss deficiencies found in external audit.

b) Outline the duties of Quality control unit under cGMP regulations.

c) Discuss steps for auditing of Warehouse stocks.

d) Explain in brief about auditing of capsule department.

e) Comment on auditing of packaging material vendor.

P.T.O.

Q4) a) What is the need of auditing Water for injection system. Discuss the layout and steps involved in auditing Water for injection system. **[15]**

OR

b) What are the importance of raw material specification and certificate of analysis in regulatory compliance? Explain general areas OF interest in the building and premises?

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

a) General area of interest for cleaning of equipment

b) Process audit

c) Environmental monitoring in sterile dosage forms

d) Auditing by pollution control authorities

e) Regulatory compliance of chemicals

Total No. of Questions : 5]

SEAT No. : [ ]

PD5738

[Total No. of Pages : 2

[6423]-211
First Year M. Pharmacy
REGULATORY ASPECTS OF MEDICALDEVICES
(2019 Credit Pattern) (Revised) (Semester - II) (MRA 203T)

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) Explain in detail about clinical investigation of medical devices as per China Regulation.

b) Explain in detail about regulatory registration process of USA.

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

a) Write detail history of medical device regulation.

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

c) Write a note on investigation device exemption and in vitro diagnostics.

d) Write a note on regulatory registration procedures as per China.

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

a) Write a note on clinical investigation plan for medical devices as per Japan regulation.

b) Write a note on Pre-market approval as per Europe.

c) Explain global medical devices nomenclature.

d) Explain medical devices working groups.

e) What are the quality system requirements for medical devices as per JAPAN?

P.T.O.

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

a) Write a note on regulatory approval process for medical Devices (510k) pre-market notification.

b) Explain in detail about approval process for medical devices and write its classification as per European Union.

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

a) Write down differences between medical devices and pharmaceutical.

b) Explain in detail investigational device exemption (IDE) as per USA.

c) Write a note on summary technical document.

d) Define and classify medical devices as per Indian regulations.

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Total No. of Questions : 5]

SEAT No. :

PD5739

[Total No. of Pages : 2

[6423]-212
First Year M. Pharmacy
BIOLOGICAL EVALUATION OF DRUG THERAPY
(Revised 2019 Credit Pattern) (Semester-II) (MPB204T)

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: **[1×15=15]**

a) Define bioassay and describe its scope and limitations. Provide examples of bioassays for some commonly used official drugs.

b) Explain current advancements and limitations in using gene therapy and other biologics to target genetic mutations.

Q2) Answer any Two: **[2×7½=15]**

a) Discuss the official tests used to detect pyrogens, highlighting the principles, procedures, and relevance of each test in pharmaceutical applications.

b) Discuss the role of biologics in diabetes treatment.

c) Explain the concept of an Investigational New Drug (IND) application and its significance in drug development.

d) Discuss the concept and importance of novel drug delivery systems in biopharmaceuticals. How do these systems enhance therapeutic outcomes?

Q3) Write notes on any three: **[3×5=15]**

a) Role of cell lines in drug discovery and development.

b) Biologics in blood disorders.

c) Regulatory aspects of bioavailability and bioequivalence studies.

d) Bioassay of Antibiotics.

e) Teratogenicity toxicity studies.

P.T.O.

Q4) Answer any One: **[1×15=15]**

a) Explain the concepts of ED and LD in preclinical drug evaluation. How are these values determined and why are they important for assessing drug safety?

b) Discuss the key documents and processes involved in the approval of a new drug.

Q5) Answer any Three: **[3×5=15]**

a) Describe the use of recombinant hormones in therapy and give an example of a condition treated with recombinant hormone therapy.

b) Describe the importance of safety and efficacy data in the clinical testing phase for medical devices.

c) Differentiate between *in vivo* and *in vitro* models in drug evaluation.

d) Explain the purpose of pre-clinical testing in the regulatory process for new drugs.

e) Write a note on PBPK modeling.

Total No. of Questions : 5]

SEAT No. :

PD5740

[Total No. of Pages : 2

[6423]-213

F.Y.M. Pharmacy (Pharmaceutical Chemistry)

MPC-204-T : PHARMACEUTICAL PROCESS CHEMISTRY (PHARMCHEMISTRY)

(Revised 2019 Credit Pattern) (Semester-II)

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

Instructions to the candidates:

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

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

a) Explain importance of IPCS in various stages of processing of API and describe various types of In-process controls in API manufacturing.Highlight on validation of large scale process.

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

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

a) Elaborate on equipments used for industrial nitration process.

b) Discuss principle and general methods of Preparation of polymorphs.

c) Write about Fermentation of Vitamins: B2 and B12.

d) Discuss the techniques for effluent minimization and control in API manufacturing.

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

a) Define extraction. Write about types of extraction.

b) Explain aerobic and anaerobic fermentation with examples.

c) Write the process involved in Industrial Halogenation.

d) Justify the importance of route selection in reaction optimization.

e) What are different labels used in a Pharmaceutical industry?

P.T.O.

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

a) Define Crystallization. Explain Crystallization from aqueous, non- aqueous solutions. Elaborate factors affecting crystallization.

b) How do you justify the importance of MSDS? Explain with example.

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

a) Types of evaporators.

b) Hydrogen transfer reactions.

c) Factors affecting scale-up process of APIs.

d) Genotoxic impurities in APIs.

e) Discuss in detail types of fire & fire extinguishers.

Total No. of Questions : 5]

SEAT No. :

PD-5741

[Total No. of Pages : 2

[6423]-214
F. Y. M. Pharmacy
MPG 204 T : HERBAL COSMETICS
(Rev. 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) ***Figures to the right indicate full marks.***

Q1) Discuss export and import of herbal cosmetics. Brief on regulatory aspects related herbal cosmetics. **[15]**

OR

Define and classify Cosmetics. Describe the formulation approaches of dentifrices.

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

a) Explain toxicity screening of cosmetics

b) Explain preparation and evaluation of herbal shampoo.

c) Explain physiology and chemistry of skin and pigmentation.

d) Evaluation of Herbal cream.

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

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

b) Write note on soaps and baby product.

c) Economic aspects of natural cosmetics.

d) Brief on Preformulation studies in herbal cosmetics

e) Brief on natural colorants in cosmetic.

P.T.O.

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

a) Outline the structure of Hair and hair growth cycle. Discuss in detail about formulation and evaluation of various Hair care preparations.

b) Explain in detail preservatives and humectants used in herbal cosmetics.

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

a) Overview on the challenges in formulating herbal cosmetic.

b) Tooth paste.

c) Lipsticks as herbal cosmetic.

d) Surfactants in cosmetics.

e) Sunscreen and Anti-ageing preparations.

Total No. of Questions : 5]

SEAT No. :

PD-5742

[Total No. of Pages : 2

[6423]-215
F. Y. M. Pharmacy
PHARMACEUTICS
MPH 204 T : Cosmetics and Cosmeceuticals
(Rev. 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) **Solve one out of two.** **[15]**

a) State the Indian regulatory requirements for labeling and import of cosmetics.

b) Cosmeceuticals.

Q2) **Answer any 2 out of Four.** **[15]**

a) Write a brief note on the design of cosmeceutical products addressing dry skin and wrinkles.

b) Write a brief note on pigmentation disorders and cosmeceuticals used for amelioration of same.

c) Discuss about building blocks for formulation of shampoo and toothpaste.

d) Explain functions and disorders of skin. Draw and explain labeled structure of skin.

Q3) **Write Short Note on any three out of five.** **[15]**

a) What is misbranded and spurious drug? Explain penalties for the a same as per D & C act.

b) Acne.

c) Give classification of surfactants used in cosmetics with suitable examples.

d) Mention principle behind the preparation of vanishing creams.

e) Give a brief note on eye lashes and mascaras.

P.T.O.

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

a) Describe conditions for obtaining cosmetic manufacturing licence in India. Also describe offences and penalties under it.

b) Give classification and applications of emollients in cosmetic products. Add a note on rheological additives.

Q5) **Short Notes Solve three out of five.** **[15]**

a) Problems associated with oral cavity

b) Prickly heat and formulations used for cure.

c) Hair growth cycle and cosmetics influencing it.

d) Building blocks for formulation of moisturizing cream.

e) Explain structure of Hair and Hair growth Cycle with diagram.

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Total No. of Questions : 5]

SEAT No. :

PD-5743

[Total No. of Pages : 2

[6423]-216
F. Y. M. Pharmacy
MPL 204 T : CLINICAL RESEARCH AND PHARMACOVIGILANCE
(Rev. 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) ***Figures to the right indicate full marks.***

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

Define adverse drug reactions and adverse event; Explain various Types of ADRs, Mechanism of type 'A' ADRs with suitable examples.

OR

Describ ICH-GCP guidelines for clinical trials. Write on clinical trial phases.

Q2) **Medium Length Answers Solve any two:** **[2 × 7.5 = 15]**

a) Importance and details of Schedule Y.

b) Clinical trial phase 3 and placebo effect.

c) Clinical trial investigator.

d) Clinical trial monitoring.

Q3) **Short answer Questions Solve any Three:** **[3 × 5 = 15]**

a) Responsibilities of Clinical Research Organization (CRO).

b) Roles and Responsibilities of clinical trial study team.

c) ICMR in clinical trial study.

d) Naranjo's causality ADR assessment scale.

e) Writes on suspected adverse drug reaction with two examples.

P.T.O.

Q4) **Long answer Questions:** **[1 × 15 = 15]**

Explain history and progress of Pharmacovigilance.Note responsibilities and key roles of Pharmacovigilance.

OR

Guidelines to preparation of clinical trial documents. Describe component of preparation of clinical trial protocol.

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

a) Case report forms.

b) Methods of detection of ADRs.

c) Clinical trial monitoring.

d) Significance of safety monitoring.

e) Institutional review board in clinical trial.

Total No. of Questions : 5]

SEAT No. : ____

PD-5744

[Total No. of Pages : 2

[6423]-217

F.Y. M.Pharmacy

(PHARMACEUTICAL QUALITY ASSURANCE)

MQA204T : Pharmaceutical Manufacturing Technology

(Rev. 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) a) Discuss in detail about PAT as a driver for improving quality and reducing costs. **[15]**

OR

b) What IPQC test are carried out for tablets and capsule?

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

a) Outline Sterile and aseptic area layout for manufacturing of parenteral products.

b) Describe environmental control, wall and floor treatment in parenteral manufacturing plant.

c) Elaborate primary and secondary drying with application in lyophilisation.

d) List the problems encountered in tablet coating and provide solution to each problem.

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

a) Illustrate manufacturing flowchart for sterile ointment.

b) Discuss IPQC tests for sterile suspensions and emulsions.

c) Explain about granulation and pelletization equipments.

d) Comment on scheduling and production planning.

e) Elaborate manufacturing of capsules with flowchart.

P.T.O.

Q4) Describe in detail containers and closures for sterile and non sterile pharmaceuticals. **[15]**

OR

Explain about legal requirements and licences for APL and for formulation industry. Discuss about plant location and factors affecting it.

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

a) SVP and LVP

b) CIP and SIP

c) Stability aspects of packaging

d) Elements of QbD

e) Requirements of advanced sterile product manufacturing technology.

Total No. of Questions : 5]

SEAT No. : ____

PD-5745

[Total No. of Pages : 2

[6423]-218

M.Pharmacy

MRA204T : Regulatory Aspects of Food & Nutraceuticals (Rev. 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.***
4) ***Do not write anything on question paper except seat number.***

Q1) **Attempt any 1 out of 2.** **[1 × 15 = 15]**

a) Explain the scope and opportunities in the nutraceutical market, highlighting the role of functional foods, dietary supplements, and medical foods.

b) Discuss the history and regulatory evolution of food and nutraceuticals, emphasizing the significance of dietary supplements and functional foods in public health.

Q2) **Attempt any 2.** **[2 × 7.5 = 15]**

a) Outline the organization and functions of the Food Safety and Standards Authority of India (FSSAI) and describe its role in regulating nutraceuticals in India.

b) Summarize the NSF International's role of the dietary supplements and nutraceuticals industry, including NSF standards and certification.

c) Describe the Food Safety Modernization Act and Dietary Supplement Health and Education Act of the USA, highlighting their implications for the nutraceuticals industry.

d) Explain the European Union's directives for the manufacture and sale of nutraceuticals and dietary supplements, and the role of the European Food Safety Authority (EFSA).

P.T.O.

Q3) **Attempt Any 3.** **[3 × 5 = 15]**

a) Define medical foods and explain how they differ from functional foods.

b) What are Recommended Dietary Allowances (RDA) and their importance in nutritional guidelines?

c) List the key labelling requirements for dietary supplements in the USA.

d) Explain Good Manufacturing Practices (GMP) for nutraceuticals.

e) Describe the significance of novel food regulations in the European Union.

Q4) **Attempt Any 1.** **[1 × 15 = 15]**

a) Discuss WHO guidelines on nutrition and their impact on global nutraceuticals standards.

b) Compare and contrast the Recommended Dietary Allowances (RDA) across India, the USA, and the European Union.

Q5) **Short Notes (Any 3).** **[3 × 5 = 15]**

a) Role of FSSAI in the import, manufacture, and sale of nutraceutical products in India.

b) NSF Certification: Standards and benefits in the nutraceutical industry.

c) Overview of European regulation on novel food ingredients.

d) Important of nutritional labelling for dietary supplements in the EU.

e) Key aspects of the Food Safety and Standards Act in India.

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

PD-5746

[Total No. of Pages : 2

[6423]-1001

First Year M. Pharmacy

MPAT-101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(Rev. 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 suitable diagram wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) **Long answer questions (solve 1 out of 2) :** **[1 × 15 = 15]**

a) Enlist ideal properties of detector. Describe various pumps and detectors used in high performance Liquid chromatography.

b) Explain modes of molecular vibrations and factors affecting vibrational frequencies. Give applications of IR spectroscopy.

Q2) **Medium Length answers (Solve 2 out of 4) :** **[2 × 7.5 = 15]**

a) Discuss various Ionization used in Mass spectroscopy and give fragmentation rules. Mass spectrum of pentane produced a molecular ion peak at m/e 72. It also showed peaks at m/e 57. 43 and 29. Identify these possible fragments of pentane.

b) Describe various sample introduction techniques and detectors used in Gas chromatography.

Elucidate the structure of organic compound from the follwoing data.

c) Molecular formula: $C_9H_{10}O$

IR: 3015 cm^{-1}. 1720 cm^{-1}

PMR : δ 7.9 (m, 10mm). δ 3.65 (s,4 mm). δ 2.2 (S.6 mm)

d) Describe Time of Flight and Magnetic sector mass analyzers.

P.T.O.

Q3) **Short answer questions (solve 3 out of 5) :** **[3 × 5 = 15]**

a) Write principle, instrumentation and advantages of UPLC.

b) Discuss on quenching and factors affecting fluorescence intensity.

c) Principle and Instrumentation of Thermogravimetric analysis.

d) Atomic absorption spectroscopy.

e) Principle and Applications Ion exchange chromatography.

Q4) **Long answer questions (solve 1 out of 2) :** **[1 × 5 = 15]**

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

b) Explain EI, APCI, FAB and ESI. Add a note on metastable ion and isotopic peaks.

Q5) **Short note (any 3 out of 5) :** **[3 × 5 = 15]**

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

b) Instrumentation of X–ray diffraction techniques.

c) Describe Instrumentation of Flame Emission Spectroscopy.

d) Affinity chromatography.

e) Write a note on Capillary electrophoresis.

Total No. of Questions : 5]

SEAT No. :

PD-5747

[Total No. of Pages : 2

[6423]-1002
F.Y. M. Pharmacy
(MRA101T): GOOD REGULATORY PRACTICES
(Rev. 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,***
4) ***Do not write anything on question paper except seat number.***

Q1) Discuss in detail about the eight principles of TQM. **[15]**

OR

What do you mean by Good Distribution Practices? Explain in detail about WHO-GDP and USP-GDP guidelines.

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

a) GLP inspection process.

b) EC principles of GMP (Directive 91/356/EEC).

c) Failure Mode and Effects Analysis (FMEA) and its types.

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

a) Reasons for failure of TQM

b) GALP and its importance

c) Objectives of Six Sigma

d) Steps in QbD.

e) Analytical validation

P.T.O.

Q4) Explain in detail about ICH guidelines to establish quality, safety and efficacy of drug substances and products. **[15]**

OR

Discuss about Current Good Manufacturing Practices for Medical device and IVDs Global Harmonization.

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

a) Types of Validation

b) Stages of Qualification

c) Quality Council of India (QCI)

d) Importance of documentation of GLP.

e) Enlist subpart A to K of 21CFR part 211

Total No. of Questions : 5]

SEAT No. : ____

PD-5748

[Total No. of Pages : 2

[6423]-1003

M.Pharmacy (Pharmaceutical Biotechnology)

MPB 102T : Microbial and Cellular Biology

(Rev. 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 labelled diagrams wherever necessary.***

Q1) **Answer the following (Any One).** **[15]**

a) Explain different methods of isolation and maintenance of pure cultures.

b) Write different type of animal cell culture with applications in industry and research.

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

a) Explain the structure and types of DNA.

b) Explain in detail different models for DNA replication.

c) Write morphology, cultural and physiologicals Features of actinomycetes.

d) Explain types of mutants. Write different applications mutangenesis in strain improvement.

Q3) **Answer the following (Any Three).** **[15]**

a) Explain the process and applications of gene mapping of plasmids.

b) Explain different factors affects the Microbial Growth.

c) Write the principle and method of Cytotoxicity as in-vitro screening technique.

d) Write different pharmaceutical important microorganisms with applications.

e) Explain identifying features of pathogenic fungi.

P.T.O.

Q4) **Answer the following (Any One).** **[15]**

a) Explain in detail mechanism of microbial pathogenicity, etiology, pathology and recommended therapies for common viral infections.

b) Write the events of Fertilization with in-vitro Fertilization technique.

Q5) **Write a note on (Any Three).** **[15]**

a) RNA amplification.

b) Basic aspects of cell regulation and aerobics.

c) Apoptosis and Oncogenes.

d) G- protein coupled receptors.

e) Cytoskeleton and cell movements.

Total No. of Questions : 5]

SEAT No. :

PD5749

[Total No. of Pages : 2

[6423]-1004
First Year M. Pharmacy (Pharmaceutical Chemistry)
ADVANCED ORGANIC CHEMISTRY - I
(Revised 2019 Credit Pattern) (Semester - I) (MPC 102T)

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

Instructions to the candidates:

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

Q1) Write about role of protection in organic synthesis. Explain mechanism of protection for the hydroxyl group and carboxyl group. **[15]**

OR

What is Multi-component synthesis'? Discuss about mechanism and synthetic applications of Ugi reaction, Biginelli reaction and Passerini reaction.

Q2) Answer any 2 of the following **[15]**

a) Write mechanism and synthetic applications of Ullmann coupling reaction and Michael addition reaction

b) Explain the preparation, salient features of Aluminium Isopropoxide and Osmium tetroxide Explain their applications in organic synthesis

c) Discuss about reaction mechanism, stereo chemistry and factors affecting Elimination reactions.

d) Explain in detail mechanism and applications Combes Quinoline Synthesis and Pinner Pyrimidine Synthesis.

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

a) Write mechanism and synthetic applications of Doebner-Miller reaction.

b) Give highlight on types of reaction mechanisms and methods of determining them.

c) Explain about mechanism and synthetic importance of Sandmeyer reaction and Mannich reaction.

d) Write synthesis of Antipyrine and Metronidazole.

e) Give advantages of retrosynthesis and guidelines for dissection of molecules.

P.T.O.

Q4) Explain about C-X disconnections and C-C disconnections with respect to alcohols and carbonyl group containing compounds. **[15]**

OR

Describe mechanism and application of Knorr Pyrazole Synthesis and Traube purine synthesis with suitable example of drugs.

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

a) Organic reaction intermediates.

b) Hantzsch reaction and its synthetic applications.

c) Hoffman & Saytzeff's rules of elimination reaction.

d) Ozonolysis.

e) Wilkinson and Wittig reagent.

Total No. of Questions : 5]

SEAT No. :

PD-5782

[Total No. of Pages : 2

[6423]-1005

First Year M. Pharmacy

MPG-102 T : ADVANCED PHARMACOGNOSY - I

(2019 Rev. Pattern) (Semester - I) (Credit System)

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) ***Figures to the right indicate full marks.***
4) ***Do not write anything on question paper except seat number.***

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

a) Elaborate detail account of Current Good Agricultural Practices.

b) Elaborate in detail 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 method of isolation, chemical properties and medicinal and health benefits of Vasicine.

c) Comment on Classification of Functional Food with suitable examples.

d) Elaborate detail account of Marine toxins.

Q3) **Write Short Note on (Solve any three).** **[15]**

a) Discuss Regulatory aspects of Nutraceuticals.

b) Health benefits of Resveratrol.

c) Bio drug - drug interactions.

d) Medicinal uses and health benefits of Flax seeds.

e) Current trends and future scope of Nutraceuticals.

P.T.O.

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

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

b) Elaborate detail account of Pharmacovigilance of drugs Natural origin.

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

a) Bio drug - food interactions with examples.

b) Dietary fibres.

c) Conservation of medicinal plants.

d) Write a note on Garlic.

e) Chemical screening of Marine products.

Total No. of Questions : 5]

SEAT No. : ____

PD5750

[Total No. of Pages : 2

[6423]-1006
First Year M. Pharmacy (Pharmaceutics)
DRUG DELIVERY SYSTEM
(2019 Credit Pattern) (Revised) (Semester - I) (MPH 102T)

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

Instructions to the candidates:

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

Q1) Solve one out of two. **[15]**

a) What are controlled release formulations. Explain reservoir type of drug delivery systems.

b) Discuss various current strategies towards enhancement of oral absorption of protein and peptide delivery.

Q2) Answer any two out of Four : **[15]**

a) What is advantage and principle of osmotic drug delivery system.

b) Give account of polymers used in formulation of sustained release drug delivery.

c) Explain in detail about iontophoresis and sonophoresis.

d) What is 3 D printed technology. Write its applications in pharmaceutical field.

Q3) Write Short Notes on any three out of five: **[15]**

a) Explain principle of sustained release delivery using ion exchange.

b) Approaches used for modulation of GI transit time.

c) Write a note on personalized medicine.

d) Discuss the criteria for drug selection to transport the formulation through buccal delivery system.

e) Classify ocular drug delivery system and add a note on bioadhesive polymers used in ocular drug delivery.

P.T.O.

Q4) Solve one out of two : **[15]**

a) Explain principles, mechanism and types of gastric retentive drug delivery systems.

b) Explain the concept of vaccine and give brief account on single-shot vaccine.

Q5) Short Notes (Solve three out of five) : **[15]**

a) Evaluation of mucoadhesive drug delivery.

b) Telepharmacy.

c) Novel ocular drug delivery system.

d) Enhancement in transdermal delivery via external stimuli.

e) Transdermal delivery of vaccines.

Total No. of Questions : 5]

SEAT No. :

PD-5751

[Total No. of Pages : 2

[6423]-1007
F.Y. M. Pharmacy (PHARMACOLOGY)
MPL 102T: Advanced Pharmacology - I
(Rev.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 diagram wherever necessary,***
4) ***Do not write anything on question paper except seat number.***

Q1) Discuss in detail molecular structure and signal transduction via G-Protein coupled receptors. **[15]**

OR

Classify anti-hypertensives. Discuss the role of beta blockers in the management of hypertension.

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

a) Write the mechanism of action and therapeutic uses of cardiac glycoside.

b) Discuss linear and non linear component model.

c) Write the mechanism of action, therapeutic uses and adverse effects of spironolactone.

d) Classify anti-depressant. Write the pharmacology of a typical antidepressant.

P.T.O.

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

a) Write the significance of plasma protein binding.

b) Mechanism of action and therapeutic uses of HMG-CoA reductase inhibitors.

c) Define Parkinsonism. Discuss the rational for combination of levodopa and carbidopa.

d) Explain the role of Lithium carbonate in the management of mania.

e) Write mode of action and therapeutic uses of loop diuretics.

Q4) Enlist the receptors of cholinergic system. Discuss the actions of acetylcholine on various cholinergic receptors. **[15]**

OR

Define and classify receptors. Discuss in detail molecular structure and signal transduction via GPCRs.

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

a) Dopamine neurotransmitter.

b) Drugs affecting neuromuscular junction.

c) Anti-platelet drugs

d) Physiological role of prostaglandins.

e) Anticoagulant Heparin.

Total No. of Questions : 5]

SEAT No. :

PD-5752

[Total No. of Pages : 2

[6423]-1008

F.Y. M. Pharmacy (PHARMACEUTICAL QUALITY ASSURANCE)

MQA102T: Quality Management System

(Rev.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) **Long answer question (Solve 1 out of 2) :** **[1 × 15 = 15]**

a) What are quality management principles of ISO 9001? Explain different clause of ISO 9001:2015 involved in quality management system.

b) Explain the concept of knowledge management, quality matrices and operational excellence and quality management review.

Q2) **Medium Length answers (Solve 2 out of 4) :** **[2 × 7.5 = 15]**

a) Explain the importance of CA PA (Corrective Action and Preventive action) in pharmaceutical industries

b) Explain statistical control charts. Give its concept and general aspects.

c) State meaning of Quality. Explain Dimensions of Quality.

d) Explain concept of risk assessment and risk control as per ICH Q9.

P.T.O.

Q3) **Short answer questions (solve 3 out of 5) :** **[3 × 5 = 15]**

a) Explain WHO GMP requirements

b) Provide details on Change control, deviations and out of trends with respect to quality systems

c) Briefly explain concept of IPQC

d) Elaborate the concept of self inspection

e) Explain makinsey 75 model

Q4) **Long answer questions (solve 1 out of 2)** **[1 × 15 = 15]**

a) Give significance of drug stability testing. Elaborate ICH guidelines for stability testing of drug substances.

b) Discuss the process of handling customer complaints of Pharmaceutical products.

Q5) **Write short note on (Solve 3 out of 5) :** **[3 × 5 = 15]**

a) Benchmarking process

b) QbD

c) TQM

d) NABL certification and accreditation.

e) OSHAS Guidelines

Total No. of Questions : 5]

SEAT No. : [ ]

PD5753

[Total No. of Pages : 2

[6423]-1009
First Year M. Pharmacy
DOCUMENTATION AND REGULATORY WRITING
(Revised 2019 Credit Pattern) (Semester - I) (MRA 102T)

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) What are the steps involved in submitting applications through the Sugam system of the Central Drugs Standard Control Organization (CDSCO)?

b) Describe the types of audit and its GMP compliance.

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

a) Write a note on Product Development Plan (PDP)

b) Write a note on post marketing reporting requirements.

c) Describe compilation and review of dossier.

d) Explain inspection of manufacturing facilities by regulatory agencies.

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

a) Write a note on ISO risk management standard.

b) Write a note on seizure and injunctions.

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

d) Write a note on post approval labeling changes.

e) Write a note on corrective and preventive action.

P.T.O.

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

a) What is a Site Master File, and what are its key components and functions?

b) Describe the various models of the CTD (Common Technical Document)?

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

a) Describe the establishment inspection report (EIR).

b) Discuss GHTF study group 4 guidance document.

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

d) Write a note on root cause analysis.

e) Write a note on ACTD Format.

x x x

Total No. of Questions : 5]

SEAT No. :

PD5754

[Total No. of Pages : 2

[6423]-1010
First Year M. Pharmacy
BIOPROCESS ENGINEERING AND TECHNOLOGY
(2019 Credit Pattern) (Revised) (Semester - I) (MPB 103T)

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) Draw neat and labeled diagram of Bioreactor. Explain various ancillary parts and their functions.

b) Explain basic principles of fermentation. Draw explanatory diagram with necessary parts and their functions.

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

a) Explain various fermentation media along with their advantages and applications.

b) Explain various filtration methods for down streaming process.

c) Explain microbial transformation of alkaloids.

d) Write principle, working and application of metabolic response assay.

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

a) Describe Flow chart for Bioproduction of citric acid.

b) Write applications of liquid sterilization process.

c) Explain batch cultivation process.

d) What are primary culture and secondary culture?

e) Write factors affecting on mass transfer co-efficient.

P.T.O.

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

a) What is Enzyme Immobilization? Discuss in details about various techniques for enzyme immobilization.

b) Explain in detail about Biotransformation of steroids.

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

a) Airlift Bioreactor.

b) Microbial strain improvement.

c) Computer control of fermentation process.

d) Bioproduction of Vitamin-B12.

e) Bioproduction of Glycerol.

Total No. of Questions : 5]

SEAT No. :

PD-5755

[Total No. of Pages : 2

[6423]-1011

F.Y. M.Pharmacy

MPC 103T : ADVANCED MEDICINAL CHEMISTRY

(Rev. 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) ***Do not write anything on question paper except seat number.***

Q1) a) Explain the biosynthesis pathway involved in synthesis of Prostaglandin and leukotrienes, thromboxanes. Elaborate on anti-inflammatory agents as COX/LOX inhibitors with their MOA. **[15]**

OR

b) Explain the drug resistance mechanism. Discuss the various mechanism involved in drug resistance.

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

a) Classify antipsychotic drugs with their structural requirement. Explain atypical antipsychotics.

b) Discuss the design of stereo isomers and geometric isomers with examples.

c) Discuss Chemistry of drugs used in the treatment of Alzheimer's disease with its MOA.

d) Discuss Prodrug concept for improving the taste and solubility of drugs.

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

a) Explain peptidomimetics with example of Saquinavir.

b) Explain the design of ACE inhibitors.

c) Explain allosteric modulation of enzyme with nonnucleoside analogs.

d) What are drug receptor interactions. Explain the energeties involved.

P.T.O.

Q4) a) Discuss the Cancer cell cycle and elaborate chemistry, MOA of antibioties used in the treatment of cancer with examples. **[15]**

OR

b) Classify anticonvulsants. Elaborate the chemistry of Barbituric acids and GABA A antagonists.

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

a) Explain the analog design with examples using Folate Reductase enzyme inhibitors.

b) Explain rational drug design for H2 antagonists.

c) Discuss the diastereoisomerism with examples.

d) Elaborate on Genetic principles of drug resistance.

e) Explain the design of calcium channel blockers and its therapeutic uses.

Total No. of Questions : 5]

SEAT No. :

PD-5756

[Total No. of Pages : 2

[6423]-1012

F.Y. M.Pharmacy (PHARMACOGNOSY)

MPG 103T : Phytochemistry

(Rev. 2019 Pattern) (Semester - I)

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) a) Describe in detail Biosynthesis, isolation, purification, characterization and industrial applications of Strychnine. **[15]**

OR

b) Explain in detail about Drug Discovery Process with special reference to Andrographolides.

Q2) **Anwer the Following (Any Two):** **[15]**

a) Explain Structural elucidation of Nicotine.

b) Explain Successive Solvent Extraction in detail.

c) Explain Microwave Assisted Extraction in detail.

d) Explain isolation, purification, characterization and industrial importance of Hecogenin.

Q3) **Solve Any Three.** **[15]**

a) Elaborate in detail applications of LCMS in characterization of herbal extracts.

b) Explain in detail the lead structure selection process and structure development in drug discovery and development.

c) Elaborate Clinical studies emphasing on phases of clinical trials.

d) Explain detail spectroscopic characterization for structural elucidation of Menthol.

e) Write about SCFE Technique.

P.T.O.

Q4) **Attempt any One Question of the following.** **[15]**

a) Explain in detail about preparative HPLC and Flash Chromatographic Techniques for Separation of Phytoconstituents.

b) Write in detail about HPTLC in Phytochemical Finger printing.

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

a) Structural elucidation of Kaempferol

b) CCCET

c) Structural elucidation of Phytoconstituents

d) Methods of Fractionation

e) Sennosides

Total No. of Questions : 5]

SEAT No. :

PD5757

[Total No. of Pages : 2

[6423]-1013
First Year M. Pharmacy
MODERN PHARMACEUTICS
(Revised 2019 Credit Pattern) (Semester - I) (MPH 103T)

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 suitable diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Solve one out of two : **[15]**

a) Differentiate and discuss the formulation strategies between Suspensions and emulsion based on its stability.

b) Propose various types of excipient interactions with suitable pros and cons and example.

Q2) Answer any 2 out of Four **[15]**

a) Compare between and propose the significance of Bracketing and matrixing design in ICH Stability studies.

b) Signify the optimization process and reflect various methods of optimization in detail.

c) Explain Inventory management and control.

d) Discuss the theories involved in describing the mechanisms of bonding during compression process.

Q3) Write Short Note on any three out of five : **[15]**

a) ICH stability guidelines.

b) Factorial design.

c) Preformulation of Parentrals.

d) Applications of optimization in Pharmaceuticals.

e) Compressibility index give its significance.

P.T.O.

Q4) Solve one out of two **[15]**

a) Explain models applied to study the release from matrix and reservoir type of controlled release dosage form.

b) Discuss equipment validation. Explain the mixer granulator and dissolution apparatus validation in detail

Q5) Short Notes (Solve three out of five) **[15]**

a) Similarity Factor

b) Total Quality management

c) Sales forecasting

d) Factors affecting Dissolution and Diffusion

e) From the following dissolution data, calculate dissolution efficiency and dissolution rate constant by assuming the drug dissolution follows first order kinetics. Strength of the tablet is 150 mg.

Time (Min)	Amount of Drug Dissolved (mg)
5	40
10	70
15	90
20	96
30	98

Total No. of Questions : 5]

SEAT No. :

PD5758

[Total No. of Pages : 2

[6423]-1014
First Year M. Pharmacy
PHARMACOLOGY
Pharmacological & Toxicological Screening Methods - I
(Revised 2019 Credit Pattern) (Semester - I) (MPL 103T)

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 labeled diagrams must be drawn wherever necessary.***

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

a) Discuss different preclinical pharmacological screening models for antihypertensive agents.

b) Explain the various screening methods of immunosupressants and immunostimulants.

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

a) Enumerate hepatoprotective screening methods. Describe in detail paracetamol induced hepatotoxicity and CC14 induced hepatotoxicity.

b) Describe different in-vivo preclinical screening models of antiatherosclerotic agents.

c) Write scientific names, description, handling and applications of common laboratory animals.

d) Name some convulsants and anticonvulsants. Design any two experiment to screen a compound for anticonvulsant activity.

P.T.O.

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

a) What are phlogistic agents? How will you screen a compound for acute inflammatory condition?

b) What is Ulcer Index? Give the formula used to calculate ulcer index. Discuss a method used to screen a compound for stress induced ulceration.

c) Explain the principle, procedure and evaluation criteria of acetic acid-induced pain in animals.

d) Describe the principles and types of immunoassays.

e) Explain the principle, procedure and assessment parameters of any two models for evaluation of anti-parkinsonian drug.

Q4) Attempt any One : **[15]**

a) Discuss in detail general principles of preclinical screening. Add detailed note on functional observation battery test.

b) List the methods to screen anti-arrhythmic agents. Describe any four methods to select a potential anti-arrhythmic agent.

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

a) Immunoassay of insulin.

b) Methods to screen for antidiarrheal activity.

c) Animal models of anxiety.

d) Good laboratory Practices of experimental animals.

e) Breeding of laboratory animals.

Total No. of Questions : 5]

SEAT No. :

PD-5759

[Total No. of Pages : 2

[6423]-1015

M. Pharmacy

PHARMACEUTICAL QUALITY ASSURANCE

MQA 103T: Quality Control and Quality Assurance

(Revised 2019) (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 labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Discuss in brief technology transfer in pharmaceutical industry. **[15]**

OR

Explain in detail the concept of Three tier documentation in pharmaceutical industry. Write a note on Common Technical Document.

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

a) Explain In process quality control and finished products quality control for tablet dosage forms in Pharma industry according to Indian pharmacopoeias:

b) Elaborate about maintenance of distribution records.

c) Write in detail about Good Warehousing Practice.

d) Explain the in process quality control and finished products tests for capsules.

P.T.O.

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

a) Explain the concept of process deviation and charge-in of components in Pharmaceutical industry.

b) Discuss in brief protocol for conduct of non clinical testing.

c) Explain about mix-ups and cross contamination.

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

e) Comment on regulated and non-regulated markets concept in Pharmaceuticals.

Q4) Discuss in detail preparation of Standard operating procedures. **[15]**

OR

Explain why it is essential to follow cGMP during manufacturing operations and control. Discuss about sanitation of manufacturing premises, mix-ups and cross contamination

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

a) Difference between Quality control and Quality assurance

b) Master Batch Record

c) Expiry date calculation and calculation of yields

d) IPQC and FPQC of ointments

e) Good Laboratory Practices

Total No. of Questions : 5]

SEAT No. :

PD-5760

[Total No. of Pages : 2

[6423]-1016

M. Pharmacy

MRA 103T: Clinical Research Regulations

(Revised 2019) (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) ***Figures to the right indicate full marks.***

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

a) Discuss in brief about important features of Good Clinical Practice Guidelines (ICH GCP E6).

b) Define clinical research. Explain in brief about various phases of clinical research. Write a note on dose escalation method.

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

a) Write about the Good Pharmacovigilance Practices (USA).

b) Describe briefly biostatistics applied in clinical research.

c) Write the responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research.

d) Explain about E7 guidelines on Studies in support of General Geriatrics Population.

P.T.O.

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

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

b) Provide the details about ISO 14155.

c) Write the principles of Nuremberg Code.

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

e) ANDA regulations, governing clinical trials.

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

a) Discuss Bioavailability and Bioequivalence requirements according to CFR 21 Part 320.

b) Discuss in brief about ICMR Ethical Guidelines for Biomedical Research.

Q5) **Write short note on anyThree :** **[15]**

a) Write short note on clinical research regulations in European Union.

b) Add a note on FDA Med Watch.

c) Discuss the purpose, scope and recordkeeping in context of CFR 21 part 54.

d) Data safety monitoring boards.

e) Define Placebo, write the role of placebo in clinical trials.

Total No. of Questions : 5]

SEAT No. : [ ]

PD5761

[Total No. of Pages : 2

[6423]-1017
First Year M. Pharmacy
PHARMACEUTICAL CHEMISTRY
MPC - 104T : Chemistry of Natural Products
(Revised 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.***

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

a) Classify alkaloids. Discuss in detail the general methods of isolation & purification of alkaloids. Add a note on the stereochemistry of ephedrine.

OR

b) Explain the development of anticancer drugs from natural sources as lead giving examples.

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

a) Discuss chemistry and physiological significance of Vitamin A and Niacin.

b) Explain development of antimalarial drugs from natural leads.

c) Explain the stereochemistry of Vit. D. and cortisone.

d) Write the active constituents present in the following crude drugs: *Swertia chirata* for diabetic therapy; *Phyllanthus niruri* in liver dysfunction; *Curcuma longa* in antitumor activity.

P.T.O.

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

a) Discuss hybridoma technology in detail.

b) Define and classify Terpenoids. Comment on isoprene rule.

c) Explain the stereochemistry and nomenclature of progesterone.

d) Elucidate the structure of Citral and Taxol.

e) What are macrolide antibiotics? Give chemistry of azithromycin.

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

a) What is Gene therapy? Discuss clinical applications and recent advances in gene therapy.

OR

b) Discuss structural characterization using IR, ^{1}H-NMR, ^{13}C-NMR and Mass Spectroscopy for following compounds: Camphor and Quercetin.

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

a) Methods of structural determination of flavonoids.

b) Principles of RNA and DNA estimation.

c) Structural characterization of Penicillin.

d) Chemistry of female sex hormones.

e) Structural characterization of Morphine.

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Total No. of Questions : 5]

SEAT No. :

PD5762

[Total No. of Pages : 2

[6423]-1018
F.Y. M. Pharmacy
PHARMACOGNOSY
MPG 104T : Industrial Pharmacognostical Technology
(Revised 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.***

Q1) What are regulatory requirements to assure the quality in herbal/natural Products? **[15]**

OR

Explain comparative study of monographs in Pharmacopoeia.

Q2) Answer 2 out of 4 **[15]**

a) Describe formulation and production management of any one herbal drugs.

b) Discuss WHO guideline for standardization of herbal drugs.

c) Describe protocol for stability testing of herbal drugs.

d) What is ISO-9000? Explain its significance in herbal drug quality.

Q3) Answer 3 out of 5 **[15]**

a) What is role and responsibilities of controller of patents?

b) Discuss few methods for clinical laboratory testing of herbal drugs.

c) Describe Export policies in herbal drug market.

d) Which are non-patentable inventions?

e) Explain importance of standardized extracts in herbal formulation.

P.T.O.

Q4) Explain requirements of herbal industry involved in production of phytomedicines. **[15]**

OR

What are important parameters need to be satisfied for patenting of herbal drugs? Explain with suitable examples. **[15]**

Q5) Write short note on (Answer any 3) **[15]**

a) Parameters of Monographs of the herbal drugs.

b) Indian Patent law.

c) Standardization of Herbal extracts.

d) Global marketing management of herbal drugs.

e) Quality control and quality assurance of herbal drugs.

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Total No. of Questions : 5]

SEAT No. : [ ]

PD5763

[Total No. of Pages : 2

[6423]-1019
First Year M. Pharmacy
PHARMACEUTICS
MPH - 104T : Regulatory Affairs
(Revised 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.***

Q1) Attempt any one: **[1×15=15]**

Explain the regulatory requirements of medical devices for market authorization.

OR

Discuss the following:

a) NDA regulatory approval process.

b) Drug Master File (DMF)

Q2) Attempt Any Two: **[2×7.5=15]**

a) Explain the importance of documentation and documents to be maintained in the pharmaceutical industry.

b) Discuss the role of pharmacovigilance in safety monitoring.

c) Describe the objectives of harmonization guidelines. Enlist ICH quality guidelines.

d) Discuss the distribution Records in Pharmaceutical Industry.

P.T.O.

Q3) Attempt any Three: **[3×5=15]**

a) Give details of formulation and working procedure of Institutional review board.

b) Write a note on Regulations for combination products.

c) Explain Hatch-Waxman Act and its role in generic drug approval.

d) Explain the ways and means of US registration for foreign drugs.

e) What are the various regulatory requirements of EU?

Q4) Attempt any one: **[1×15=15]**

Discuss about

a) Health Insurance Portability and Accountability Act.

b) Informed Consent Process.

OR

Explain the regulatory requirement for product approval of biologics to obtain NDA.

Q5) Attempt any three: **[3×5=15]**

a) Scale up process and its significance.

b) Code of Federal Regulation.

c) Master Formula Record (MFR).

d) Investigational Medicinal Product Dossier.

e) Investigator Brochure.

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Total No. of Questions : 5]

SEAT No. :

PD5764

[Total No. of Pages : 2

[6423]-1020
First Year M. Pharmacy
MPL - 104T : CELLULAR AND MOLECULAR PHARMACOLOGY
(Revised 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 neat labeled diagrams wherever necessary.***

Q1) Write detail account of gene therapy and its clinical applications. **[15]**

OR

Explain in detail, Polymerase chain reaction and its applications.

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

a) What do you mean by DNA recombinant technology? Discuss its applications.

b) Explain the mechanism of apoptosis.

c) How cell cycle is regulated?

d) Write note on gene transfer techniques.

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

a) Describe inter cellular signaling.

b) Explain the principle and applications of cell viability assay.

c) Discuss the role of genetic variation in drug transporters.

d) Explain mitogen activated protein kinase signaling.

e) Differentiate between necrosis and apoptosis.

P.T.O.

Q4) What are second messengers? Explain role of Cyclic AMP, Calcium ion and Nitric oxide as second messengers. **[15]**

OR

Define and classify receptors. Discuss in detail molecular structure and signal transduction via GPCRs.

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

a) Protein engineering.

b) DNA based diagnosis of diseases.

c) Applications of biosimilars.

d) Nuclear receptors.

e) Cellular aging and death.

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Total No. of Questions : 5]

SEAT No. :

PD5765

[Total No. of Pages : 2

[6423]-1021

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

MQA 104T : PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

(Revised 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 diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) How is technology transferred from R & D to production? Give detail overview of various quantitative models in technology transfer. **[15]**

OR

Describe in details steps involved in drug discovery. Explain procedure and challenges in clinical trial study.

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

a) Discuss the quality control tests for plastic and rubber container-closure system.

b) What is the concept of solubility (1.5)? Explain any three techniques used to improve solubility of BCS Class II drugs.

c) What is purpose of stability testing of pharmaceutical products? Explain stability testing methods.

d) What do you mean by Pilot plant scale up? Give its significance. How does it differ from large scale manufacturing?

P.T.O.

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

a) Write a note on aseptic packaging systems.

b) Write a note on product registration guidelines as per CDSCO.

c) Define Polymorphism and discuss methods for its detection.

d) Discuss the development and information content for ANDA.

e) Explain the various issues facing modern drug packaging.

Q4) Discuss in detail process of pre-formulation studies in Tablet dosage forms. **[15]**

OR

Describe large scale manufacturing techniques including formula equipment, process, stability and quality control for semi-solid dosage forms in detail.

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

a) Bulk active chemical Post approval changes (BACPAC).

b) Qualitative models for technology.

c) Medical device packaging.

d) Technology Transfer Plan.

e) Post marketing surveillance.

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Total No. of Questions : 5]

SEAT No. : ____

PD-5766

[Total No. of Pages : 2

[6423]-1022

F.Y. M. Pharmacy

MRA104T: Regulations & Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals and Food and Nutraceuticals in India and Intellectual Property Rights (Rev.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 :** **[1 × 15 = 15]**

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

b) Give regulatory requirement & approval procedure for drug & cosmetics and medical devices.

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

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) Discuss guidelines for drug testing in animals along with CPCSEA guidelines.

P.T.O.

Q3) **Answer any Three :** **[3 × 5 = 15]**

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 :** **[1 × 15 = 15]**

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

b) Explain rules schedules and guidelines of Narcotics Drugs and Psychotropic Substances Act.

Q5) **Answer any three :** **[3 × 5 = 15]**

a) How retail price of formulation is calculated? As per drug price control order 1995.

b) Describe copyright & work protected under copyright act.

c) Write in brief about Patent Act 1970 & its ammendments.

d) Give rules, regulations, guidelines & standards for regulatory filing of biological and herbals.

e) What is trademark? Explain the different types of trademarks with examples.

Total No. of Questions : 5]

SEAT No. :

PD-5767

[Total No. of Pages : 2

[6423]-1023
F.Y. M. Pharmacy
PHARMACEUTICAL BIOTECHNOLOGY
MPB 104 T: Advanced Pharmaceutical Biotechnology
(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 diagram wherever necessary.***

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

a) Discuss various sources of enzymes and their therapeutic and clinical applications.

b) What are biosensors? Discuss various mechanisms and types of biosensors.

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

a) Discuss Biotransformation of any one steroidal drug.

b) Explain techniques of gene cloning.

c) Briefly discuss various cell signaling pathways

d) Discuss in detail about gene therapy.

P.T.O.

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

a) Biodegradation of xenobiotics

b) Write applications of microbes in environmental monitoring.

c) Discuss principle and applications of PCR

d) Write flow chart for production of Insulin by r-DNA technology

e) Write a note on Restriction endonuclease enzymes

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

a) Discuss the production of therapeutic protein from transgenic animals.

b) Explain detail procedure about extraction and purification of enzymes.

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

a) Explain various methods for gene manipulation

b) Oncogenes.

c) Xenobiotics.

d) Human Genome Project.

e) Transgenic animals.