

Total No. of Questions : 5]

SEAT No. :

PE-4932

[Total No. of Pages : 2

[6570]-45

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) Discuss principle, theory, instrumentation of Nuclear Magnetic Resonance spectroscopy. Draw the possible structure of the compound (Molecular formula C_3H_7Cl) that shows one doublet and one septet in proton NMR spectrum.
- b) Discuss bragg's law, different X-ray methods, types of crystals and applications of X-ray diffraction.

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

- a) Compare proton NMR to C^{13} NMR. Write methods for simplification of complex NMR spectrum.
- b) Why are IR absorption bands inverted compared to those in uv-visible spectra? Why does Hydrogen molecule not give an IR spectrum?
- c) Explain principle, instrumentation and advantages of AAS.
- d) Explain the principle of UV-Visible Spectroscopy. Write the quantitative applications of UV Visible spectroscopy.

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

- a) What is quenching and explain factors affecting fluorescence intensity.
- b) Write a note on Capillary electrophoresis.
- c) Ion exchange chromatography
- d) FT-NMR
- e) Give the fragmentation rules in Mass spectrometry.

P.T.O.

Q4) Long answer questions (solve 1 out of 2) :

[1 × 15 = 15]

- a) Explain modes of molecular vibrations and factors affecting vibrational frequencies. Give applications of IR spectroscopy.
- b) Elucidate the structure of organic compound from the following data.

Molecular formula: $C_9H_{10}O_2$:

UV: λ_{max} 264nm,

MS: m/z = 43 (40%), 65(12%), 76 (27%), 77(14%), 91(50%), 107 (18%), 108 (100%) and 150 (34%).

IR: 1750 (s), 740, 690 cm^{-1}

PMR: δ ppm 19.5 (*singlet*, 6.5 *sq.*); 5.0 (*singlet*, 4.3 *sq.*); 7.28 (*singlet*, 10.9 *sq.*)

Q5) Short notes (Solve 3 out of 5) :

[3 × 5 = 15]

- a) Differentiate between flame emission and Atomic Absorption spectroscopy.
- b) Give the principle and instrumentation of Differential scanning calorimetry (DSC).
- c) What is UPLC? Explain the applications of UPLC.
- d) Explain Moving Boundary Electrophoresis.
- e) Exhaustive note on HPTLC.



Total No. of Questions : 5]

SEAT No. :

PE-4933

[Total No. of Pages : 2

[6570]-46

First Year 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) 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) Stages of Qualification
- b) Importance of documentation of GLP.
- c) Objectives of Six Sigma
- d) Quality Council of India (QCI)
- e) Analytical validation

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.

P.T.O.

Q5) Write short note on (Any three) :

[15]

- a) Types of Validation
- b) Reasons for failure of TQM
- c) Steps in QbD.
- d) GALP and its importance
- e) Enlist subpart A to K of 21 CFR part 211



Total No. of Questions : 5]

SEAT No. :

PE-4934

[Total No. of Pages : 2

[6570]-47

M.Pharmacy

MPB102T : 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.*

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

- a) Explain in detail different methods used for isolation and cultivation of pure cultures.
- b) Explain the central dogma of molecular biology with reference to transcription and translation.

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

- a) What is mutagenesis? Explain the types of mutants and application of mutagenesis in strain improvement.
- b) Write the cultural, physiological and reproductive features of fungi.
- c) Explain in detail structure and types of DNA.
- d) What is RNA splicing and RNA editing? Explain.

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

- a) Explain the mechanism and applications of cell division.
- b) Write the basic aspects of cell regulation and fuelling reactions of aerobics.
- c) What is in-vitro fertilization? Explain the events of fertilization.
- d) Write the procedure, principle and applications of antiviral assays.
- e) Explain mechanism of action of antimicrobial agents and possible sites of chemotherapy.

P.T.O.

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

- a) Write the pathogenicity, etiology, pathology and recommended therapies for common viral infections.
- b) Explain general procedure, nutrient composition, types and applications of cell cultures.

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

- a) Stability and degeneration of microbial cultures.
- b) Tumor cells
- c) Stem cells and its applications
- d) Nuclear receptors
- e) Phage genetics



Total No. of Questions : 5]

SEAT No. :

PE-4935

[Total No. of Pages : 2

[6570]-48

First Year M. Pharmacy (Pharmaceutical Chemistry)
MPC-102T : 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.*

Q1) Explain SN1 and SN2 reactions with their mechanism, Stereochemistry and factors affecting these reactions. **[15]**

OR

Elaborate the term multi-component synthesis. Explain mechanism and synthetic applications of Biginelli reaction and Ugi reaction.

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

- a) Describe retrosynthetic analysis of 1,2-disfunctionalized 1,3-disfunctionalized compounds with suitable examples.
- b) What is Witting reagent and Wilkinson reagent? Describe their important synthetic applications.
- c) Describe reaction mechanism and stereochemical aspects in support of E2 elimination reaction.
- d) Briefly describe the methods of formation of carbene and nitrene along with synthetic applications.

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

- a) Explain the mechanism of Pinner pyrimidine synthesis.
- b) Describe Functional group interconversion and addition (FGI and FGA).
- c) Explain the mechanism and synthetic applications of Dieckmann reaction.
- d) Describe synthesis of Metamizole sodium and Ketoconazole.
- e) Highlight on advantages of retrosynthesis and discuss guidelines for good disconnection.

P.T.O.

Q4) Discuss briefly protection of amino group and amino acids for carbamates and amides. **[15]**

OR

Demonstrate mechanism and applications of CombesQuinoline Synthesis and Bernthsen Acridine Synthesis.

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

- a) Rearrangement reactions
- b) Applications of N-bromosuccinamide and osmium tetroxide.
- c) Protection of carboxylic group by amide and hydrazide.
- d) Mechanism and synthetic applications of ozonolysis.
- e) Traube purine synthesis.



Total No. of Questions : 5]

SEAT No. :

PE-4936

[Total No. of Pages : 2

[6570]-49

First Year M. Pharmacy

MPG-102T : ADVANCED PHARMACOGNOSY - I

(Rev. 2019) (Semester - I) (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.*

Q1) Answer the Question (Solve any one) :

[15]

- a) Elaborate detail account of Current Good Cultivation & Collection practices.
- b) Discuss Marine natural product. Give general methods of isolation and purification of marine natural products.

Q2) Answer the Following (Solve any two) :

[15]

- a) Comment on Conservation of medicinal plants.
- b) Write method of isolation, chemical properties and medicinal and health benefits of Taxol.
- c) Write a note on spontaneous reporting schemes for biodrug adverse reactions.
- d) Comment on Regulatory aspects of Nutraceuticals.

Q3) Write Short Note on (Solve any three) :

[15]

- a) Antioxidants as nutraceuticals
- b) Discuss isolation of marine products.
- c) Medicinal & health benefits of Herbal tea.
- d) Occurrence & isolation of alpha & beta carotene
- e) Safety monitoring of natural medicines.

P.T.O.

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

- a) Write in detail about the occurrence, isolation and characteristic feature of Andrographolides and Shatavarins.
- b) Elaborate WHO guidelines for safety monitoring of natural medicines.

Q5) Short Notes (Solve any three) : [15]

- a) Taxonomical identification of Marine drugs.
- b) Discuss importance of Pharmacognosy in herbal drug industry.
- c) Classification of functional food with suitable examples.
- d) FSSAI guidelines.
- e) Current trends and future scope on Nutraceuticals.



Total No. of Questions : 5]

SEAT No. :

PE4937

[Total No. of Pages : 2

[6570]-50

First Year M. Pharmacy

MPH 102T : DRUG DELIVERY SYSTEM

(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 the well labelled diagram wherever necessary.*

Q1) Long answer questions (Answer Any 1) [1×15=15]

- a) Explain the physicochemical and biological factors influencing the approaches of SR/CR formulation.
- b) Enlist various approaches GRDDS. Explain in details floating drug delivery systems.

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

- a) Explain in details barriers for protein and peptide delivery in-vivo.
- b) Describe working along with applications of Franz Diffusion cell apparatus.
- c) Give the principle, advantages and disadvantages of mucoadhesive drug delivery systems.
- d) Discuss the mechanism of drug release from SR/CR formulations.

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

- a) What are biodegradable polymers? Give ideal requirements and its applications.
- b) Describe in brief enzyme activated drug delivery system.
- c) Explain with example pH activated DDS.
- d) What are hydrogels and their applications in DDS?
- e) Give importance and applications of personalized medicines.

P.T.O.

Q4) Long answer questions (Answer Any 1)

[1×15=15]

- a) Justify SR drug delivery system differ from conventional drug delivery. Discuss in details prerequisites of drug candidate for development into SRDF.
- b) Explain in details formulation for delivery systems of proteins and other macromolecules.

Q5) Short notes (Answer Any 3)

[3×5=15]

- a) Feedback regulated drug delivery systems.
- b) Single shot vaccine.
- c) Penetration enhancers in transdermal drug delivery systems.
- d) Telepharmacy and its applications.
- e) Buccal tablet.



Total No. of Questions : 5]

SEAT No. :

PE4938

[Total No. of Pages : 2

[6570]-51

First Year M. Pharmacy (Pharmacology)

MPL - 102T : ADVANCED PHARMACOLOGY - I

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

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

- 1) All questions are compulsory.*
- 2) Figures to the right indicate full marks.*
- 3) Draw well labeled diagrams 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 non - narcotics analgesics. Explain the pharmacology of salicylates in detail.

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

- a) Write the mechanism of action and therapeutic uses of cardiac glycoside.
- b) Write a note on 5HT₃ antagonists.
- c) Write the mechanism of action, therapeutic uses and adverse effects of spironolactone.
- d) Classify anti-depressant. Write the pharmacology of atypical antidepressant.

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) Explain the role of organic nitrates in ischemic heart disease.

P.T.O.

Q4) Enlist the receptors of cholinergic system. Discuss the actions of acetylcholine on various cholinergic receptors. **[15]**

OR

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

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

- a) Dopamine neurotransmitter.
- b) Drugs affecting neuromuscular junction.
- c) Steps involved in neurotransmission.
- d) Physiological role of prostaglandins.
- e) Anticoagulant Heparin.



Total No. of Questions : 5]

SEAT No. :

PE4939

[Total No. of Pages : 2

[6570]-52

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

MQA 102 T : QUALITY MANAGEMENT SYSTEM

(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 questions (Solve 1 out of 2)

[1×15=15]

- a) Discuss the principles of Quality Risk Management (QRM) in depth and critically evaluate the application of Hazard Analysis and Critical Control Points (HACCP) in pharmaceutical manufacturing, highlighting its role in preventing contamination and ensuring patient safety.
- b) List the types of benchmarking and give a brief overview of the benchmarking process.

Q2) Medium Length answers (Solve 2 out of 4)

[2×7½=15]

- a) Explain the principles of Six Sigma with suitable examples from manufacturing or service industries.
- b) What is objective of Pharmaceutical development? Elaborate in detail different elements of quality by design.
- c) Explain applicability of CAPA in Pharmaceutical industry.
- d) Evaluate the effectiveness of ISO 9001 principles in ensuring long-term customer satisfaction in the service sector.

P.T.O.

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

- a) Define Statistical Process Control (SPC) and tools used in pharmaceutical manufacturing.
- b) Evaluate the role of IPQC in reducing production wastage and ensuring regulatory compliance, with reference to cGMP guidelines.
- c) Explain Statistical control charts. Give its concept and general aspects.
- d) Differentiate between OOS and OOT with examples.
- e) Explain each dimension of quality with a suitable example from the pharmaceutical industry.

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

- a) Using ICH Q10 guidelines, illustrate with an example how a pharmaceutical company can achieve continual improvement in both process performance and product quality.
- b) Explain in detail the Six Sigma Inspection Model used by regulatory agencies during GMP inspections.

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

- a) A pharmaceutical manufacturing company wants to implement ISO 9001 : 2008. Describe the steps they should take to meet its requirements.
- b) Explain the principle of photostability testing and describe the conditions used as per ICH Q1B guidelines.
- c) Given a scenario where a new supplier is offering a critical API, outline the vendor qualification process you would follow.
- d) Write a note on McKinsey 7 S Model.
- e) Formulate a Vision and Mission Statement for a newly established Pharmaceutical manufacturing company.

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Total No. of Questions :5]

SEAT No. :

PE4940

[Total No. of Pages : 2

[6570]-53

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 indicate full marks.*

Q1) Answer any one. [15]

- a) Describe the preparation of a Master Formula Record and its relationship to GMP compliance.
- b) Explain in detail the different types of audits with examples.

Q2) Answer any two. [15]

- a) Describe the structure and modules of CTD and their significance in dossier submission.
- b) Explain the concept and application of CAPA in regulatory inspections.
- c) Write a note on preparation and conduct of Audit.
- d) Write a note on Product Development Plan (PDP).

Q3) Answer any three. [15]

- a) Write the importance of Distribution Records in pharmaceutical industry.
- b) Explain the purpose and significance of a model certificate of GMP.
- c) Differentiate between eCTD and NeeS Submissions.
- d) Brief on Prior Approval Supplement (PAS).
- e) Explain inspection of manufacturing facilities by regulatory agencies.

P.T.O.

Q4) Answer any one.

[15]

- a) Describe the various enforcement actions taken by the FDA following inspections.
- b) Explain submission via the Sugam system of CDSCO with process flow, Preparation, and validation.

Q5) Answer any three.

[15]

- a) Describe the concept of GMP compliance auditing in the pharmaceutical Industry.
- b) Write a note on ISO risk management standard.
- c) Write a note on COA.
- d) Write a short note on the preparation of an inspection report.
- e) Describe the Asian Common Technical Document (ACTD) format.



Total No. of Questions : 5]

SEAT No. :

PE-4941

[Total No. of Pages : 2

[6570]-54

First Year M. Pharmacy

**MPB-103 T : BIOPROCESS ENGINEERING AND
TECHNOLOGY**

(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 diagram wherever necessary.*

Q1) Attempt any one from the following :

[15]

- a) Discuss various Bioreactors used for immobilized Bioprocess.
- b) Explain in detail about the effects of aeration and agitation on mass transfer during fermentation.

Q2) Attempt any two from the following :

[15]

- a) Briefly discuss various media for fermentation.
- b) Discuss in detail about working and application of Fluidized Bed Reactor.
- c) Discuss various techniques used for preservation of stock culture.
- d) Discuss various cultivation systems in fermentation scale up process.

Q3) Attempt any three from the following :

[15]

- a) Discuss significant of rheological properties in Bioprocess.
- b) Enlists various methods to preserve stock culture.
- c) Write principle of Bioautography technique.
- d) Explain Continuous culture.
- e) Write advantages and drawbacks of Batch fermentation process.

P.T.O.

Q4) Attempt any one from the following :

[15]

- a) Explain various sterilization methods for fermentation media.
- b) Discuss in detail about various chromatographic techniques used in down streaming process.

Q5) Write short note on (Any 3)

[15]

- a) Immobilization of whole cell.
- b) Fed Batch Cultivation.
- c) Preservation of stock culture of microbes.
- d) HTST sterilization.
- e) Bioproduction of Vitamin C.



Total No. of Questions : 5]

SEAT No. :

PE-4942

[Total No. of Pages : 2

[6570]-55

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

Q1) What is neoplasm? Classify anti neoplastic agents with suitable examples and their mechanism of action. Elaborate on cell cycle dependent anticancer drugs. [15]

OR

Give the rationale of prodrug design and stages involved in prodrug design. Enlist different types of prodrugs with suitable examples. Discuss the applications of prodrugs.

Q2) Answer any 2 of the following : [15]

- a) Enlist the various classes of drugs available for psychoses. Discuss the chemistry, SAR and MOA of phenothiazines.
- b) Explain the design of protease inhibitors as Anti HIV drugs.
- c) Discuss the conformational analysis in specific drug actions with examples
- d) What are classical and non classical bioisosteric replacement strategies? Explain their application in analog design.

Q3) Answer any three of the following : [15]

- a) Discuss the COX-LOX pathway and its importance in inflammatory conditions. Explain leukotriene inhibitors with therapeutic uses.
- b) Give an account of Histamine H₂ antagonists
- c) What are the approaches to combat the drug resistance in antibiotics? Elaborate
- d) Discuss acetylcholinesterase inhibitors used in the treatment of Alzheimer's disease.
- e) Write the chemistry, SAR and MOA of Calcium channel blockers

P.T.O.

Q4) Explain the enzyme kinetics and principle of enzyme inhibitors. Give the strategies for rational design of non-covalently and covalently binding enzyme inhibitors with suitable examples. **[15]**

OR

Discuss the chemistry, SAR and mechanisms of action of drugs used in the treatment of Parkinson's disease

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

- a) Elaborate on the Design of peptidomimetics.
- b) Explain in brief genetic principles of drug resistance.
- c) Explain the chemistry and therapeutic uses of Selective COX-2 inhibitors.
- d) Illustrate with examples concept and process of Lead identification and optimization.
- e) Discuss the mechanisms involved in Enzyme inhibition. Illustrate with ACE inhibitors.



Total No. of Questions : 5]

SEAT No. :

PE-4943

[Total No. of Pages : 2

[6570]-56
M.Pharmacy
PHARMACOGNOSY
MPG103T : Phytochemistry
(Revised 2019) (Semester - I)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

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

OR

What are clinical trials? Elaborate phases of clinical trials and protocol for clinical studies used for drug discovery and development process. **[15]**

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

- a) Describe spectroscopic characterization for structural elucidation of nicotine
- b) Explain history of herbs as a source of drugs and drug discovery
- c) Explain Flash Column Chromatography in detail.
- d) Elaborate structural elucidation of Kaempferol

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

- a) Elaborate Explain isolation, purification, characterization and industrial importance of guggulsterone.
- b) Elaborate principle and working of CCCET.
- c) Describe lead structure selection process and structure development in drug discovery
- d) Describe principle and working of preparative HPLC.
- e) Discuss about selection of methods and choice of solvent for extraction.

P.T.O.

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

- a) Elaborate a detail account of spectroscopic characterization for structural elucidation of Glycyrrhizin.
- b) Describe in detail biosynthesis, isolation, purification, characterization, industrial production of quinine.

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

- a) Microwave Assisted Extraction
- b) CCCET
- c) GCMS Fingerprinting
- d) Radiotracer techniques
- e) With anolides



Total No. of Questions : 5]

SEAT No. :

PE-4944

[Total No. of Pages : 2

[6570]-57

F.Y. M. Pharmacy

MPH-103T : 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) Attempt any One question of the following : [1 × 15 = 15]

- a) Classify types of process validation explain any one with suitable example.
- b) Differentiate and discuss the formulation strategies between Suspensions and emulsion based on its stability.

Q2) Attempt any Two questions from the following : [2 × 7½ = 15]

- a) Discuss equipment validation with suitable example.
- b) Describe Kawakita plots and Heckel Plots.
- c) Define and Differentiate between Bracketing and matrixing.
- d) Explain Significance of force distribution in tablet compression and its impact on tablet quality.

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

- a) Optimization techniques.
- b) Similarity Factor.
- c) Preformulation of Parenterals.
- d) Define and differentiate between compaction, compression and consolidation with suitable example.
- e) Total Quality management.

P.T.O.

Q4) Attempt any One question of the following : **[1 × 15 = 15]**

- a) Discuss c-GMP and outline various formats maintained during manufacturing of dosage forms.
- b) Discuss factors affecting Dissolution and solubility and give significance of different dissolution models.

Q5) Write a Short Note on any Three of the following : **[3 × 5 = 15]**

- a) Diffusion
- b) Kinetics of stability studies
- c) Factorial design
- d) Compressibility index give its significance
- c) Tech transfer and scale up



Total No. of Questions : 5]

SEAT No. :

PE4945

[Total No. of Pages : 2

[6570]-58

First Year M. Pharmacy

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

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

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]

- a) Describe the methods of production, maintenance and breeding of transgenic animals. Add their major applications.

OR

- b) Write on the experimental models for screening analgesic, anti-inflammatory and antipyretic agents.

Q2) Medium Length Answer Solve any two :

[2×7.5=15]

- a) Discuss immunoassay methods used for insulin estimation.
- b) Outline experimental models used for anti-atherosclerotic drugs.
- c) Write a note on models for screening antipsychotic drugs.
- d) Screening of anti-diarrhoeal agents.
- e) Screening of diuretic agents.

Q3) Short answer questions Solve any three :

[3×5=15]

- a) Tail suspension test for antidepressants.
- b) Principles of immunoassay optimization.
- c) Screening models for anti-COPD agents.
- d) Diarrhea models in preclinical testing.
- e) Anti-cancer drug screening methods.

P.T.O.

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

- a) Explain preclinical screening of immunosuppressants and immunomodulators.

OR

- b) Discuss the preclinical evaluation of drugs for Parkinsonism disease.

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

- a) Transgenic zebrafish in pharmacology.
- b) Pyrogen testing alternatives
- c) Animal models for hypertension
- d) Anti-emetic drug screening
- e) Limitations of animal experimentation



Total No. of Questions : 5]

SEAT No. :

PE4946

[Total No. of Pages : 2

[6570]-59

First Year M. Pharmacy (Pharmaceutical Quality Assurance)
MQA-103-T : QUALITY CONTROL AND QUALITY ASSURANCE
(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) Neat diagrams must be drawn wherever necessary.*

Q1) Describe in detail the in-process and finished product quality control tests performed for solid oral dosage forms. Discuss the significance of these tests in ensuring product quality and regulatory compliance. **[15]**

OR

Explain CPCSEA guidelines and protocol for non-clinical (preclinical) testing of pharmaceuticals.

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

- a) Briefly explain the importance of hygiene practices and maintenance of personal records in a pharmaceutical manufacturing unit.
- b) Explain the cGMP guidelines as per Schedule M of the Drugs and Cosmetics Act for pharmaceutical manufacturing.
- c) Elaborate about maintenance of distribution records.
- d) Discuss about material management including raw material analysis and finished products.

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

- a) Differentiate between regulated and non-regulated markets in the pharmaceutical industry and discuss their significance.
- b) Discuss importance electronic data handling and explain the purpose and types of Drug Master Files (DMFs).
- c) Differentiate in between Quality control and Quality assurance department.
- d) Explain the importance and procedures involved in the analysis of raw materials and finished pharmaceutical products.
- e) Describe the roles and responsibilities of major global regulatory agencies: CDER, CBER, and EMA in pharmaceutical regulation.

P.T.O.

Q4) What is documentation in the pharmaceutical industry? Explain the three- tier documentation system and the concept of a Master Batch Record (MBR).

[15]

OR

Discuss in detail about Quality control of parenteral dosage form.

Q5) Write short note on any three :

[15]

- a) Importance of SOP in pharmaceutical quality systems and outline the key elements of a well-designed SOP.
- b) Pharmaceutical Inspection Convention.
- c) CPCSEA guidelines.
- d) Quality audit plan and reports.
- e) Quality certifications applicable to pharmaceutical manufacturing (e.g., WHO-GMP, USFDA, EMEA).



Total No. of Questions : 5]

SEAT No. :

PE4947

[Total No. of Pages : 2

[6570]-60

F.Y. M. Pharmacy

MRA 103T : CLINICAL RESEARCH REGULATIONS

(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 Questions (Solve 1 out of 2) [1×15=15]

- a) Explain the different phases of clinical trials in detail with examples.
- b) Discuss the ethical principles governing the informed consent process, including patient information sheet, informed consent form and documentation.

Q2) Medium Length Answers (Solve 2 out of 4) [2×7.5=15]

- a) Describe Phase I clinical trial designs including single ascending dose, multiple ascending dose, and food effect studies.
- b) Explain the historical perspectives of ethics in clinical research citing examples like the Nuremberg Code and Tuskegee Syphilis Study.
- c) Outline the role and responsibilities of the Institutional Review Board in clinical research.
- d) Write a note on FDA's NDA 505 (b) (1) and 505 (b) (2) approval pathways.

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

- a) What is Phase 0 studies?
- b) Define PSUR and its importance in Phase IV studies.
- c) List any four ICH efficacy guidelines and their scope.
- d) What is the purpose of a Data Safety Monitoring Board?
- e) Give two examples of drug-drug interaction studies and their significance.

P.T.O.

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

- a) Discuss in detail the clinical investigation and evaluation process for medical devices and in-vitro diagnostics (IVDs) with reference to ISO 14155.
- b) Explain EU and US regulations for conducting clinical trials, highlighting key differences.

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

- a) Schedule Y guidelines in India.
- b) The role of placebo in randomized controlled trials.
- c) EudraLex and its role in EU clinical research.
- d) Good Pharmacovigilance Practices.
- e) Bioavailability and bioequivalence requirements under CFR 21 Part 320.



Total No. of Questions : 5]

SEAT No. :

PE-4948

[Total No. of Pages : 2

[6570]-61

First Year M. Pharmacy

PHARM CHEMISTRY

MPC-104T : Chemistry of Natural Products

(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) Solve any 1 question out of 2 :

[15]

Give principles of RNA & DNA estimation and describe active constituent of *Gymnema sylvestre*.

OR

Explain in detail about Structural characterization of Penicillin and Vit.D using IR, ¹H-NMR, ¹³C-NMR and MS Spectroscopy.

Q2) Solve any 2 questions out of 4 :

[2 × 7½ = 15]

- a) Give Structural elucidation of citral.
- b) Write a note on Oligonucleotide therapy.
- c) Explain development of Curare alkaloids as a neuromuscular Blocking agent.
- d) What are Flavonoids? Describe isolation and purification of flavonoids.

Q3) Answer any 3 questions out of 5 :

[3 × 5 = 15]

- a) Discuss Chemistry and Physiological significance of Vitamin A.
- b) Write a note on hybridoma technology,
- c) Give Structural characterization of Morphine using IR, ¹H-NMR, ¹³C-NMR and MS Spectroscopy.
- d) Explain Chemistry of Erythromycin.
- e) Describe chemistry of Testosterone male sex hormone.

P.T.O.

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

Explain how CNS drug development has progressed from plant products.

OR

Define Alkaloids and give its classification, isolation, purification, molecular modification and biological activity of alkaloids.

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

- a) Explain Structural elucidation of carotinoids.
- b) Give Clinical application and recent advances in gene therapy.
- c) Elucidate a structure of Camphor using IR, ¹H-NMR, ¹³C-NMR and MS Spectroscopy.
- d) Explain development of Lovastatin as a Cardiovascular Drug.
- e) Describe chemistry of sterols.



Total No. of Questions : 5]

SEAT No. :

PE-4949

[Total No. of Pages : 2

[6570]-62

First Year M. Pharmacy (Pharmacognosy)
MPG-104T : INDUSTRIAL PHARMACOGNOSTICAL
TECHNOLOGY
(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]

What are the infrastructural requirements for a herbal industry engaged in the production of standardized extracts and various dosage forms? Discuss in detail the facilities, equipment and regulatory compliance needed.

OR

Elaborate on the concepts and principles used in quality assurance of natural products, explaining the methods, standards and regulatory guidelines involved.

Q2) Attempt any Two :

[15]

- a) What are WHO guidelines for assessing quality of herbal medicines with Reference to Heavy metals and Pesticide residues?
- b) Describe the procedure of Indian patent filling?
- c) Describe the guidelines applicable to the herbal drug industry, highlighting the regulatory, quality and safety requirements.
- d) Discuss clinical laboratory testing of herbal drugs.

Q3) Short answer question (Any Three) :

[15]

- a) Design a herbal drug industry plant and discuss its layout.
- b) Describe parameters given in 'Indian herbal pharmacopoeia'.
- c) Explain the process of examination of a patent application under the Indian Patents Act.
- d) Describe significance of Capital venture requirement in herbal industry.
- e) What is the 'right of patents'?

P.T.O.

Q4) Attempt any one :

[15]

How is stability testing of natural products performed? Explain the procedures involved, the parameters evaluated, and the significance of stability testing in ensuring product quality and determining shelf life.

OR

Describe in detail about the Good Manufacturing Practices (GMP) for the production of herbal formulations.

Q5) Write short note (any three) :

[15]

- a) Global marketing management.
- b) Opposition and revocation of patents.
- c) TRIPS.
- d) Comparative study of Indian Pharmacopoeia and Ayurvedic Pharmacopoeia.
- e) Good laboratory practices.



Total No. of Questions : 5]

SEAT No. :

PE-4950

[Total No. of Pages : 2

[6570]-63

F.Y. M.Pharmacy

MPH104T : REGULATORY AFFAIRS

(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) Explain in detail scale up process approval in pharmaceutical industry.
- b) Write in Hatch Waxman Act with implementation examples

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

- a) Give detail about master formula record.
- b) Write NDA regulatory approval process
- c) Describe CMC.
- d) What is informed consent? Write its procedures.

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

- a) Explain a note on 21 CFR.
- b) Write a short note on outsourcing BA & BE to CRO.
- c) Explain Industry & FDA liaison.
- d) Describe post marketing surveillance.
- e) Write a short note on regulation of medical devices.

P.T.O.

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

- a) Describe ANDA and regulatory approval process.
- b) Write in details about Investigational Medical Products Dossier (IMPD).

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

- a) Describe ICH-Q guidelines.
- b) Write in short about CTD & ECTD formats.
- c) Write short note on safety monitoring in clinical trials.
- d) Write in short on development of clinical trial protocols
- e) Explain regulatory requirements of EU countries.



Total No. of Questions : 5]

SEAT No. :

PE4951

[6570]-64

[Total No. of Pages : 2

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.

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.

P.T.O.

Q5) Write short note 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.



Total No. of Questions : 5]

SEAT No. :

PE4952

[6570]-65

[Total No. of Pages : 2

**First Year M. Pharmacy (Pharmaceutical Quality Assurance)
MQA104T : 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.*

Q1) Discuss in detail the steps and guidelines for product registration as per CDSCO. **[15]**

OR

Discuss in detail various quality control tests for glass & Plastic containers.

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

- a) What is Investigational New Drug application? Describe the content of IND.
- b) Discuss the concept of Preformulation studies and explain in detail about various preformulation parameters of drug substance.
- c) Discuss cosolvency. Explain the role of surfactants in solubility enhancement with suitable examples.
- d) Discuss in detail guidelines for product registration as per USFDA.

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

- a) Explain the role of particle size & shape, surface area in product development.
- b) Explain the importance of Medical device packaging material.
- c) Explain the key elements of documentation in technology transfer
- d) Explain about preformulation protocol.
- e) Explain in detail the quality control tests for closures.

P.T.O.

Q4) Discuss in detail manufacturing flowcharts, large scale manufacturing and in-process quality control tests for semisolids. **[15]**

OR

Give the objective of & Significance of pilot plant scale up. Explain the concept of pilot plant scale up.

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

- a) Write a note on supplemental new drug application (SNDA).
- b) Write a note on issues facing modern drug packaging.
- c) Write a note on secondary packaging material used in Pharmaceutical industry.
- d) Write a note on NDA.
- e) Write a note on qualitative technology models.



Total No. of Questions : 5]

SEAT No. :

PE4953

[Total No. of Pages : 2

[6570]-66

F.Y.M. Pharmacy

**MRA 104T : REGULATIONS & LEGISLATION FOR DRUGS &
COSMETICS, MEDICAL DEVICES, BIOLOGICALS &
HERBALS AND FOOD AND NUTRACEUTICALS IN
INDIA AND INTELLECTUAL PROPERTY RIGHTS
(2019 Revised 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) Write about Indian patent Scenario.
- b) Give regulatory requirements and approval procedures for drugs and cosmetics, medical devices, biologicals & herbals & food & Nutraceutical.

Q2) Answer any two. [15]

- a) Mention the conditions of import license for schedule C and schedule 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) Answer any three. [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) Answer any one.

[15]

- a) What is IPR? Discuss various components of IPR.
- b) Patent Act 1970 & its amendments.

Q5) Answer any three.

[15]

- a) Explain the powers of drug Inspector.
- 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. :

PE4954

[Total No. of Pages : 2

[6570]-67

First Year M. Pharm

**MPB104T : ADVANCED PHARMACEUTICAL BIOTECHNOLOGY
(Revised 2019 Credit Pattern) (Semester - I)**

Time : 3Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) Attempt any one out of two. [15]

- a) Differentiate somatic cell line and germ line gene therapy. Elaborate on any two physical and chemical methods to achieve gene delivery. Add a note on the advantages and disadvantages of gene therapy.
- b) Discuss various sources of enzymes and their therapeutic & clinical applications. Explain in brief about kinetics of enzyme activity.

Q2) Attempt any two out of four. [15]

- a) Explain role of various oncogenes proteins.
- b) What are restriction endonucleus enzymes? Write their various classes.
- c) Explain Biotransformation process for chiral drugs.
- d) Explain Recombinant DNA production of hepatitis -B Vaccine.

Q3) Answer the following questions in brief. (Solve 3 out of 5) [15]

- a) Describe Production of Trypsin
- b) Explain site directed mutagenesis
- c) Explain the Biodegradation of xenobiotic
- d) Write the significance of human genome project.
- e) Discuss inflammatory responses in cell.

P.T.O.

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

- a) Define Biosensors? Discuss various concept in construction of different types of Biosensors and their applications.
- b) Explain various drug delivery approaches for therapeutic proteins.

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

- a) Principle and applications of PCR
- b) Production of interferon
- c) Extraction and purification of Enzymes
- d) Gene library
- e) Applications of microbes in environmental monitoring



Total No. of Questions : 5]

SEAT No. :

PE-4955

[Total No. of Pages : 2

[6570]-68

First Year M. Pharmacy

MPB-201T : PROTEIN & PROTEIN FORMULATION

(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.*
- 3) *Draw well labelled diagram wherever necessary.*

Q1) Attempt any one from the following :

[15]

- a) Enlists various methods for protein sequencing. Explain Edman degradation technique in detail.
- b) How proteins can be purified & Enlist? Explain the different methods used for the protein purification.

Q2) Attempt any two from the following :

[15]

- a) Describe CADD techniques in Peptidomimetics.
- b) Discuss forced degradation studies relevance to development of protein therapeutics.
- c) Explain types of mass spectrometry for protein structure.
- d) What are the different methods of gel electrophoresis?

Q3) Attempt any three from the following :

[15]

- a) Write a note on Neo Spears.
- b) Explain the phenomenon of development of non-peptide Peptidomimetics.
- c) Describe in brief Reproducibility and image analysis.
- d) A note on Rai-Farnesyl transferase inhibitors.
- e) Discuss Isolation of intracellular protein.

P.T.O.

Q4) Attempt any one from the following :

[15]

- a) Classify Peptidomimetics in detail with example.
- b) Explain in brief about 2D-Gel electrophoresis with its principle & applications.

Q5) Write short note on (Any 3) :

[15]

- a) Chromatographic techniques in protein purification.
- b) Liposomes in protein formulation.
- c) Properties & benefits of PEGylation in protein formulations?
- d) Stability problems in proteins? Explain in brief.
- e) How does Edman degradation help in protein sequencing?



Total No. of Questions : 5]

SEAT No. :

PE-4956

[Total No. of Pages : 2

[6570]-69

M. Pharmacy (Pharmaceutical Chemistry)
MPC-201T : ADVANCED SPECTRAL ANALYSIS
(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.*

Q1) a) Discuss principle, instrumentation and applications of Flash Chromatography. **[15]**

OR

b) Compile the principle, instrumentation and applications of LC-MS.

Q2) Attempt any Two. :

[15]

- a) How will you calculate the absorption maxima for cyclic dienes by using Woodward-Fieser rule?
- b) Predict and explain the signal positions (δ values) and spin-spin splitting in the NMR spectrum of:
 - i) *n*-butanol
 - ii) 2-chloropropane
 - iii) acetaldehyde
 - iv) *n*-propylamine
- c) Explain Mc-Lafferty Rearrangement with suitable example.
- d) Discuss principle and instrumentation of LC-NMR.

P.T.O.

Q3) Attempt any Three :

[15]

- a) Elaborate Woodward -Fieser rule for α and β Carbonyl Compounds.
- b) What is ortho effect in mass spectrometry? Explain with example
- c) How will you differentiate ethyl acetate and methyl acetate by NMR.
- d) Explain Principle and applications of GC-MS
- e) Discuss ELISA in detail.

Q4) a) Determine the probable structure of compound from the following Data

[15]

MF: $C_4H_{10}O$

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

^1H NMR (δ ppm) : i) δ : 1.03, doublet, 6H

ii) δ : 1.92, multiplet, 1H

iii) δ : 2.11, doublet, 2H

iv) δ : 5.11, singlet, 1H

Explain NOESY and COSY NMR techniques.

OR

- b) Elaborate the principle, instrumentation and applications of Super Critical Fluid Chromatography.

Q5) Write short note on (any Three) :

[15]

- a) ATR-IR
- b) Ring Rule in Mass Spectroscopy
- c) Bioassay
- d) Radioimmunoassay of Insulin
- e) 1-D NMR



Total No. of Questions : 5]

SEAT No. :

PE-4957

[Total No. of Pages : 2

[6570]-70

First Year M. Pharmacy

**MPG-201T : MEDICINAL PLANT BIOTECHNOLOGY
(2019 Pattern) (Semester - II)**

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) Attempt any one of the following :

[15]

- a) What is transgenic plant? Explain various methods used in gene identification, localization and sequencing of genes.
- b) What is genetic code? Give its salient features. Explain regulation of gene expression with suitable examples.

Q2) Answer the following (Any two) :

[15]

- a) Explain DNA recombinant technology with it's applications.
- b) Explain production of enzymes of pharmaceutical interest by fermentation technology.
- c) Explain mechanism of protoplast fusion with suitable examples.
- d) Define fermentation? Give it's application in pharmacy and allied fields.

Q3) Answer the following (Any three) :

[15]

- a) Give applications of immobilization techniques in secondary metabolite production.
- b) What is protoplasm? Explain the process of protoplast fusion with example.
- c) Write a short note on transgenic plants.
- d) What is biotransformation? Explain bioreactors for pilot and large scale culture of plant cell.

P.T.O.

Q4) Attempt any one question of the following :

[15]

- a) What is RNA? Explain RNA and protein replication in detail.
- b) Describe different steps involved in plant tissue culture techniques along with various sterilization methods. Give its application in pharmacy and allied fields.

Q5) Write short note on (Any 3) :

[15]

- a) Cloning of plant cell.
- b) Sterilization methods used in tissue culture.
- c) Organogenesis and embryogenesis.
- d) Precursors and elicitors on the production of secondary metabolites.
- e) Single cell protein.



Total No. of Questions : 5]

SEAT No. :

PE4958

[Total No. of Pages : 2

[6570]-71

First Year M.Pharmacy

MPH 201T: MOLECULAR PHARMACEUTICS

(Nano Tech & Targeted DDS)

(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 a neat diagram wherever necessary.*

Q1) Long answer question (Solve any 1 out of 2)

[15]

- a) Elaborate on the different methods of Liposomal preparations and highlight important evaluation parameters for liposomes.

OR

- b) Explain in detail the formulation aspects and key evaluation parameters for Aerosol drug delivery system.

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 addressed?
- b) Explain the various preparation techniques for Nanoparticles.
- c) Highlight about method of preparation for phytosomes.
- d) Outline the major events & biological process involved in drug targeting.

Q3) Short answer questions (Solve any 3 out of 5)

[15]

- a) Write about Antisense molecules.
- b) What are the formulation strategies of intranasal drug delivery systems?
- c) Discuss the potential target diseases for gene therapy and application of gene therapy in treating cancer.
- d) Write a note on electrosomes.
- e) What are the different types of containers used in the delivery of pulmonary drugs and how do they impact drug stability?

P.T.O.

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

a) Describe the formulation and evaluation aspects of microspheres.

OR

b) Elaborate in detail ex-vivo and in-vivo gene therapy. Highlights their potential advantages and limitations.

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

a) Define biodistribution and highlight its importance in designing effective drug delivery systems.

b) Preparation and potential applications of niosomes.

c) Explain phagocytosis and pinocytosis.

d) Role of aptamers in drug delivery and diagnostics.

e) Therapeutic uses and advantages of Aquasomes.



Total No. of Questions : 5]

SEAT No. :

PE4959

[Total No. of Pages : 2

[6570]-72

First Year M.Pharm

MPL-201T : ADVANCED PHARMACOLOGY-II

(2019 Credit Pattern) (Semester-II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

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

- a) Categorize the antidiabetics used in the management and treatment of Type-II Diabetes Mellitus. Outline the pharmacology of sulphonylureas.
- b) Classify Antibiotics and explain Beta Lactam Antibiotics in detail.

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

- a) Compile mechanism of Cisapride, Domperidone and metoclopramide.
- b) Write pharmacology of anyone Nucleoside/Nucleotide Reverse Transcriptase inhibitors.
- c) Write the significance of immunosuppressants.
- d) Classify anti-asthmatics, write the mechanism of action and therapeutic uses of Salbutamol.

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

- a) Write Pharmacological action of anyone proton pump inhibitors.
- b) Explain biochemical mechanisms of antimicrobial resistance.
- c) Describe the role of free radicals in the etiopathology of diabetes.
- d) Evaluate the impact of circadian rhythms on disease development and provide specific examples.
- e) Outlines the mechanism of action, antimicrobial spectrum and resistance of Ciprofloxacin.

P.T.O.

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

- a) Classify antimalarials. Explain the pharmacology of Chloroquine.
- b) Classify anticancer agents with examples. Discuss pharmacology of anyone anticancer agents.

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

- a) Pharmacology of drugs used in Worm infestation.
- b) Curcumin as an antioxidant
- c) Pharmacotherapy of constipation
- d) Metronidazole.
- e) Monoclonal antibodies.



Total No. of Questions : 5]

SEAT No. :

PE4960

[Total No. of Pages : 2

[6570]-73

**F.Y.M. Pharmacy (Pharmaceutical Quality Assurance)
MQA-201T : HAZARDS AND SAFETY MANAGEMENT
(2019 Credit Pattern) (Semester-II)**

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) a) What is air-based hazards. Explain in detail air circulation maintenance in pharmaceutical industry for sterile area. **[15]**

OR

b) What are sources of chemical hazards? Classify types of chemical hazards and it's influence on environment. Add a note on MSDS. **[15]**

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

- a) Discuss the hazards associated with organic solvents and safety measures while handling organic solvents.
- b) Explain effluent treatment procedure.
- c) Explain types of fires and fire extinguishers.
- d) Discuss in detail about renewable and non-renewable resources.

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

- a) Write in brief about BOD and COD.
- b) Discuss fundamentals of accident prevention
- c) Write a note on industrial processes and hazards potential.
- d) Write a note on disposal of hazardous waste
- e) Explain environmental hazards based on soil and their management.

P.T.O.

Q4) a) What are explosion hazards? Write in short about mechanical and chemical explosion. Discuss the preventive and protective management from fire and explosion. [15]

OR

b) Explain in detail various risk management methods and tools as per ICH guidelines. [15]

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

- a) Explain the concept of ecosystem with its structure and function.
- b) What is TLV concept? Discuss significance and various threshold limits.
- c) Write a note on role of emergency services.
- d) Write a note on labelling guidelines for chemicals.
- e) Write a note on critical training for risk management.



Total No. of Questions : 5]

SEAT No. :

PE4961

[Total No. of Pages : 2

[6570]-74

First Year M.Pharmacy

**MRA201T : REGULATORY ASPECTS OF DRUGS AND
COSMETICS**

(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 the approval process for drugs according to NDA and ANDA. **[15]**

OR

Explain in detail about legislation and regulations for import manufacture, distribution and sale of cosmetics in Brazil. **[15]**

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

- a) Describe Marketing Authorization procedures in EU (Decentralized procedure).
- b) Explain distribution and sale of cosmetics in European Union & Australia.
- c) Discuss regulatory requirements for registration of drugs in WHO through prequalification program.
- d) Enlist the regulatory requirements for registration of drugs and post approval requirements in ASEAN.

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

- a) Describe regulatory Approval Process for Investigational New Drug (IND).
- b) Drug regulatory approval process in Japan.
- c) Describe changes to an approved NDA/ANDA.
- d) Explain the concept of emerging market. What are the countries covered under emerging market?
- e) Discuss the import of cosmetics in ASEAN countries.

P.T.O.

Q4) Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. **[15]**

OR

Explain in detail the marketing authorization requirements for drug in GCC countries. **[15]**

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

- a) Marketing Authorization (MA) transfers
- b) Compliance of European Pharmacopoeia (CEP)
- c) Abbreviated New Drug Application (ANDA)
- d) SADC
- e) Certificate of pharmaceutical Product



Total No. of Questions : 5]

SEAT No. :

PE-4962

[Total No. of Pages : 2

[6570]-75

M.Pharmacy

MPB202T : IMMUNOTECHNOLOGY

(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) Long answer question (Solve 1 out of 2)

[15]

- a) Write structure and general functions of antibody.
- b) Explain adaptive immunity. Differentiate between humoral and cell-mediated immunity.

Q2) Attempt Any Two (Solve 2 out of 4)

[15]

- a) Discuss classical pathway of complement system.
- b) Explain structure and properties of immunoglobulin classes
- c) Describe list of activators for alternative pathway.
- d) Explain production and purification of monoclonal antibodies.

Q3) Attempt Any Three (Solve 3 out of 5)

[15]

- a) Explain Functions of cytokines.
- b) Differentiate between primary and secondary lymphoid organs.
- c) Enlist subunit vaccine with suitable example.
- d) Write a note on western blot analysis.
- e) Explain Stem cell technology

P.T.O.

Q4) Long answer question (Solve 1 out of 2)

[15]

- a) Explain Hybridoma Technique? Discuss in detail methodology of Hybridoma Technique.
- b) Explain in detail about recombinant vaccine with suitable example.

Q5) Write short notes on (Solve 3 out of 5)

[15]

- a) RIA
- b) Myasthenia Gravis
- c) Conjugate vaccine.
- d) Chemiluminescence assay.
- e) ELISA



Total No. of Questions : 5]

SEAT No. :

PE-4963

[Total No. of Pages : 2

[6570]-76

F.Y. M. Pharmacy

MPC-202 T : ADVANCED ORGANIC CHEMISTRY - II

(2019 Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

- 1) All questions are compulsory.
- 2) Figures to the right indicate full marks.
- 3) 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 and its 12 principles with suitable examples. Explain the working, principle of continuous flow reactors. Discuss their advantages and applications in organic synthesis. [15]

OR

What are racemates and resolution? Explain in detail about various methods used for resolution of racemic mixture. [15]

Q2) Attempt Any Two : [15]

- a) What is the basic principle behind ultrasound-assisted reactions? Give one example each of a homogeneous and a heterogeneous sonochemical reaction.
- b) What are pericyclic reactions? Comment on cycloaddition reaction and sigmatropic rearrangement.
- c) Explain about different types of catalysis. Give a detail account on Wilkinson catalyst.
- d) Explain the concept of geometrical isomerism. Differentiate between cis—trans and E-Z isomerism with suitable examples.

P.T.O.

Q3) Attempt Any Three :

[15]

- a) Explain CIP sequence rule for stereoisomers with suitable examples.
- b) Comment on Transition metal and organo-catalysis with suitable examples?
- c) Explain the stereoselective synthesis with examples.
- d) Comment on uses of enzymes in organic synthesis.
- e) Describe about Ionic liquids and solvent free reactions

Q4) Explain the mechanism of microwave-assisted organic synthesis. Discuss its merits, demerits and applications in heterocyclic synthesis. **[15]**

OR

Describe the principles of solid-phase peptide synthesis. Describe in detail various solid supports and linkers used. Comment on t-BOC and Fmoc strategies. **[15]**

Q5) Write short notes on (Any Three) :

[15]

- a) Describe methods of asymmetric synthesis using chiral auxiliaries with suitable examples.
- b) Describe principle and applications of Phase transfer catalysis.
- c) Write note on electrocyclic reactions.
- d) Comment on side reaction in peptide synthesis.
- e) Add a note on principle and applications of Photochemical reactions.



Total No. of Questions : 5]

SEAT No. :

PE-4964

[Total No. of Pages : 2

[6570]-77

F.Y. M. Pharmacy

**MPG - 202 T : ADVANCED PHARMACOGNOSY - II
(2019 Pattern) (Credit System) (Semester - II)**

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) Elaborate with suitable examples various Pharmacokinetic and Pharmacodynamic issues produced in herbal remedies.
- b) Elaborate detail account of Ethnopharmacology in drug evaluation and drug discovery process with suitable examples.

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

- a) Comment on Efficacy of Herbal Drugs.
- b) Explain in detail different Types of Adulteration and substitutions of herbal drugs.
- c) Comment on analytical profile of *Andrographis paniculata* and state its pharmacological significance.
- d) Discuss *in vivo* screening methods for hepatoprotective drugs of natural origin.

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

- a) Significance of determination of Microbial Load in Natural Products
- b) Explain OECD guidelines for Oral Toxicity studies.
- c) Elaborate Impact of Ethnobotany on traditional medicine.
- d) *In-vivo* screening techniques for Wound healing drugs.
- e) Analytical profile of *Embelica officinalis*.

P.T.O.

Q4) Answer the Questions (Solve any one) :

[15]

- a) Elaborate detail account of determination of Pesticide Residues and Heavy Metals in herbs and their formulations along with its significance.
- b) Comment on the need of Phyto-pharmacological screening in new drug development. Discuss various assays used for *In-vitro* evaluation of anticancer drugs.

Q5) Short Notes (Solve any three) :

[15]

- a) Validation of Herbal Therapies.
- b) Reverse Pharmacology.
- c) Analytical profile of *Psoralea corylifolia*.
- d) *In-vitro* screening techniques for Antioxidant Potential.
- e) Analytical profile of *Coleus forskholii*.



Total No. of Questions : 5]

SEAT No. :

PE4965

[Total No. of Pages : 2

[6570]-78

First Year M. Pharmacy

**MPH 202T- ADVANCED BIOPHARMACEUTICS AND
PHARMACOKINETICS**

(2019 Credit Pattern) (Semester - II)

Time : 3Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) Explain in detail why plasma concentration remains steady as long as constant rate i.v. infusion is continued, when an i.v. bolus injection is given as a loading dose before starting i.v. infusion. **[15]**

OR

Describe various transport models for drug absorption. Describe the absorption of basic and acidic drug across gastro intestinal tract with justification and examples.

Q2) Answer the following (Any 2) **[15]**

- a) Describe the methods used to calculate K_E from urinary excretion data. What are the advantages of urinary data over plasma data?
- b) Describe the mechanism of drug transport by comparing passive diffusion with active transport of drug.
- c) Explain various physico chemical properties of drug that limit the distribution. Add a note on significance of drug distribution in body.
- d) Write a note on non-compartmental analysis along with its advantages and limitations.

P.T.O.

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

- a) Discuss Wagner - Nelson method along with its importance, advantages and limitations.
- b) Elaborate on how enterohepatic cycling of drug affects its bioavailability.
- c) The half life of propranolol in 70 kg patient is 6 hours and v_d is 8.5 L/kg. Assuming one compartmental kinetics calculate Elimination rate constant K_E and Total clearance Cl_T
- d) What are the advantages and limitations of randomized, balanced, cross-over design in BE studies.
- e) Describe importance of IVIVC and types of IVIVC.

Q4) What is the purpose of BA/BE studies? Comment on Bioequivalence study designs and regulatory guidelines for BA/BE studies. [15]

OR

Explain in detail various methods used to estimate absorption rate constant (K_a) when the drug is given by oral administration and follows one compartment model.

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

- a) Applications of Pharmacokinetics.
- b) Biosimilar drug products.
- c) Two compartmental model.
- d) Compare single dose studies Vs multiple dose BA/BE studies.
- e) BCS and BDDCS



Total No. of Questions : 5]

SEAT No. :

PE4966

[Total No. of Pages : 2

[6570]-79

First Year M. Pharm.

**MPL 202T : PHARMACOLOGICAL AND TOXICOLOGICAL
SCREENING METHODS-II
(2019 Credit Pattern) (Semester - II)**

Time : 3Hours]

[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 the in vivo methods of assessing female reproductive toxicity studies.
- b) Define safety pharmacology? Explain the scope, importance and principles of safety pharmacology.

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

- a) Write a note on *in vitro* and *in vivo* studies for genotoxicity.
- b) Explain the three R's for more ethical use of animals in laboratories. Explain *in vitro* methods as an alternative methods for animal toxicity studies.
- c) Discuss the concept of GLP and its importance in New Drug Development Process.
- d) Explain acute inhalation toxicity studies as per OECD guidelines.

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

- a) Describe the significance of ethical and regulatory requirements for toxicity studies.
- b) Write a note on HERG assay and its importance.
- c) Discuss the study design, conduct and evaluation of ocular toxicity study.
- d) Explain the regulatory requirements of ICH for the new drug safety assessment.
- e) Discuss in detail about *in vivo* carcinogenicity studies.

P.T.O.

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

- a) Discuss the determination of LD_{50} in acute toxicity testing of drugs as per OECD.
- b) Define IND. Explain the importance and the list of studies needed for IND submission.

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

- a) Ames Test
- b) Teratogenicity studies
- c) Importance and applications of Toxicokinetic studies
- d) Schedule Y
- e) Chromosomal aberration studies



Total No. of Questions : 5]

SEAT No. :

PE4967

[Total No. of Pages : 2

[6570]-80

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

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.*
- 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) What are the types of steam used in pharmaceutical industry? How is steam system validated?
- b) Describe the key parameters considered during analytical method validation as per ICH requirements.

Q2) Medium Length answers (Solve 2 out of 4)

[2×7.5=15]

- a) What are the exclusive benefits conferred to a patentee after patent approval?
- b) What are the instrument qualification parameters for a UV-Visible spectrophotometer as per Indian Pharmacopoeia?
- c) Write a brief conclusion on the importance of accuracy and precision in analytical method validation.
- d) What is the role and significance of Intellectual Property Rights in pharmaceutical research and development?

P.T.O.

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

- a) Assess the importance of Thermal Distribution and Thermal Penetration for Autoclave.
- b) What is the significance of process validation in the coating process of tablets?
- c) Explain of validation of utility systems.
- d) Discuss merits and demerits of validation.
- e) Describe the lifecycle approach of Computerized System Validation in pharmaceutical quality systems.

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

- a) What is the importance of a well-documented Technology Transfer process in pharmaceutical production?
- b) Explain the concept and importance of instrument qualification. How is FTIR qualified as per regulatory guidelines?

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

- a) What is the significance of GAMP in maintaining validation and operational control of automated pharmaceutical systems?
- b) What is cleaning validation? State its importance and discuss sampling techniques and MACO calculation.
- c) Why is validation essential in the pharmaceutical industry? Explain its impact on product quality and compliance.
- d) Differentiate between Calibration, Validation and Qualification.
- e) Explain the working of HVAC with its validation steps.



Total No. of Questions : 5]

SEAT No. :

PE4968

[6570]-81

[Total No. of Pages : 2

First Year M. Pharmacy

**MRA 202T : REGULATORY ASPECTS OF HERBALS &
BIOLOGICALS**

(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) Describe in detail how the European Union's biosimilarity or comparability examination is done. **[15]**

OR

Describe the safety, quality, and legal framework for herbal goods in India.

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

- a) What are the EU's criteria for the quality of herbal products?
- b) Explain the term pharmacovigilance.
- c) Give a word on the laws, safety, and quality of herbal goods in India.
- d) Compose a note about EU advertising regulations.

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

- a) What guidelines govern the determination of biosimilarity?
- b) According to Indian laws, what data are required for preclinical studies?
- c) List the distinctions between biosimilars and generic medications.
- d) What are the EU's stability requirements for vaccinations?
- e) Write about the TSE/BSE assessment.

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

OR

Describe about pre-clinical and clinical development factors.

P.T.O.

Q5) Write short notes on (Any Three):

[15]

- a) What labeling specifications do US legislation stipulate for blood products?
- 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 advertising regulations as per EU.
- e) Explain about the US Blood and Blood Products Regulations additional requirements.



Total No. of Questions : 5]

SEAT No. :

PE-4969

[Total No. of Pages : 2

[6570]-82

F.Y. M. Pharmacy

PHARMACEUTICAL BIOTECHNOLOGY

MPB-203T : Bioinformatics & Computer Technology

(2019 Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

- 1) All questions are compulsory.
- 2) Figures to the right indicates full marks.

Q1) Attempt any one out of two :

[1 × 15 = 15]

- a) Discuss in detail protein structure prediction.
- b) Explain in detail “multiple sequence alignment”.

Q2) Attempt any two out of Four :

[2 × 7.5 = 15]

- a) Write a note on sequence Analysis.
- b) Discuss homology modelling.
- c) What is drug designing? Explain its principle.
- d) What is lead discovery? Explain application of bioinformatics in microarray analysis.

Q3) Attempt any three out of Five :

[3 × 5 = 15]

- a) Define bioinformatics. What are bioinformatics databases?
- b) What is Force field methods of protein informatics.
- c) What is FASTA?
- d) Write a note on “internet and bioinformatics”
- e) Write about high throughput screening and virtual screening.

P.T.O.

Q4) Attempt any one out of two :

[1 × 15 = 15]

- a) Write in detail about the evolutionary change in nucleotide sequence & add a note on nucleotide substitution.
- b) Discuss kind of docking methods of protein & ligand.

Q5) Attempt any three out of Five :

[3 × 5 = 15]

- a) What is CLUSTALX?
- b) Explain in detail genetic mapping.
- c) Explain laboratory based approaches method of gene prediction.
- d) Write a note on Nematode biology.
- e) Explain in detail protein informatics.



Total No. of Questions : 5]

SEAT No. :

PE-4970

[Total No. of Pages : 2

[6570]-83

First Year M. Pharmacy (Pharmaceutical Chemistry)
MPC-203T : COMPUTER AIDED DRUG DESIGN
(2019 Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) Attempt any ONE : [15]

- a) Explain the role of CADD in drug discovery with suitable examples.
- b) Give detail account on use of CADD for predicting ADMET properties of new molecules.

Q2) Attempt any TWO : [15]

- a) Explain HIV protease inhibitor and give applications of it.
- b) What is QSAR? Explain hydrophobic parameters in QSAR with suitable example.
- c) What is pharmacophore? Discuss about pharmacophore identification and Pharmacophore modelling.
- d) Explain process of energy minimization methods used in CADD.

Q3) Attempt any THREE : [15]

- a) Discuss the principle and applications of Hansch Analysis in the development of CADD.
- b) What is bioactive conformation? Give its significance in drug discovery.
- c) What is AchE? Giving examples of various AchE inhibitors.
- d) What is docking? Comment on protein preparation and target preparation aspect involved in docking.
- e) Elaborate in detail on free Wilson analysis.

P.T.O.

Q4) Attempt any one :

[15]

- a) Experimental and theoretical approaches for the determination of Physicochemical parameters used in QSAR.
- b) Describe the importance of molecular and quantum mechanics in drug design.

Q5) Write short note on (any THREE) :

[15]

- a) Fragment based drug design
- b) Drug receptor interaction
- c) Development of agents acting on HMG CoA reductase using CADD
- d) Contour map analysis
- e) Statistical methods used in QSAR



Total No. of Questions : 5]

SEAT No. :

PE-4971

[Total No. of Pages : 2

[6570]-84
F.Y. M.Pharmacy
PHARMACOGNOSY
MPG203T : Indian System of Medicine
(2019 Credit Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) Develop a novel protocol for stability testing of a semi-solid Unani formulation, combining traditional and modern guidelines. **[1 × 15 = 15]**

OR

Assess how effectively the current regulatory system and national pharmacopoeias ensure the quality of all ISM formulations in India.

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

- a) Create a Standard Operating Procedure (SOP) for health and hygiene in an ISM manufacturing setting.
- b) Differentiate the preparation methods of an Ayurvedic Arishta and a Homoeopathic tincture.
- c) Describe the documentation and record-keeping procedures required by Schedule T.
- d) Explain the various forms of Yoga and their philosophies.

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

- a) Discuss the roles of CCRU and CCRH in promoting Unani and Homoeopathy, respectively.
- b) Analyze how Naturopathy and Yoga principles can be incorporated into modern preventative healthcare for chronic lifestyle diseases.

P.T.O.

- c) Evaluate the impact of the Geographical Indication (GI) Bill on traditional medicine practitioners and small-scale manufacturers in India.
- d) Create the documentation needed for a New Drug Application (NDA) for a phytopharmaceutical derived from an Ayurvedic herb.
- e) Discuss the challenges in the Safety of Herbal Medicines.

Q4) Answer any ONE :

[1 × 15 = 15]

- a) Evaluate the statement: ‘Schedule T fully addresses all quality challenges specific to complex polyherbal formulations.’ Justify your answer using examples.
- b) Propose a comprehensive stability study protocol for an Ayurvedic semi-solid formulation (*avaleha*), outlining specific parameters and testing intervals based on regulatory guidelines.

Q5) Write a note on any THREE :

[3 × 5 = 15]

- a) Objectives and components of GMP.
- b) *Panchamahabhuta* and *Tridosha*.
- c) Role of aroma oils and carrier oils for stress and anxiety management.
- d) Authentication process for bio crude drugs.
- e) Applications of *Gunapadam* in modern pharmacology.



Total No. of Questions : 5]

SEAT No. :

PE4972

[Total No. of Pages : 2

[6570]-85

F.Y. M. Pharmacy

MPH203T : COMPUTER AIDED DRUG DEVELOPMENT

(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 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.

[3×5=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.



Total No. of Questions : 5]

SEAT No. :

PE4973

[Total No. of Pages : 2

[6570]-86

First Year M. Pharmacy

MPL 203 T : PRINCIPLES OF DRUG DISCOVERY

(Revised 2019 Credit Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) Long answer question :

- a) What are the applications of NMR & X-ray crystallography in protein structure predictions? **[15]**

OR

- b) i) What is 3D - QSAR. Discuss in detail the relation SAR versus QSAR. **[8]**
- ii) Define rational drug design & explain types of drug design. **[7]**

Q2) Medium length answers solve any two.

[2×7½=15]

- a) Explain G-protein coupled receptor (GPCRs).
- b) Explain in details about molecular docking.
- c) Describe in details about microarray techniques.
- d) Discuss process of assessment of drug targets for safety during drug discovery.

P.T.O.

Q3) Short answer questions solve any three

[3×5=15]

- a) Write a note on ELISA.
- b) Give a short note on lead optimization in drug discovery.
- c) Explain enzymes & enzymes inhibition process in drug discovery.
- d) Write about characteristics & impact of biomarkers.
- e) Explain Hantzsch analysis & Free Wilson analysis.

Q4) Long Answer Questions

- a) i) Explain in details the detection methods used in HTS. **[8]**
ii) Write about electrophysiological patch clamp process. **[7]**

OR

- b) Write in detail about physio chemical parameter used in QSAR studies. **[15]**

Q5) Short notes on any three :

[3×5=15]

- a) What is parallel synthesis? Explain in detail.
- b) Write a principle involved in design of pro-drugs.
- c) Enlist the types of regression.
- d) Note on proteomics.
- e) Add note on Scaffold hopping.

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Total No. of Questions : 5]

SEAT No. :

PE4974

[Total No. of Pages : 2

[6570]-87

First Year M. Pharmacy

MQA 203T : AUDITS AND REGULATORY COMPLIANCE

(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 diagram wherever necessary.*

Q1) Attempt any one from the following. [15]

- a) Describe importance of audit in pharmaceutical industry. Explain audit planning in detail.
- b) What is the importance of HVAC system in parenteral manufacturing plant? Describe the significance of HVAC audits in a sterile manufacturing facility. Describe the auditing of these systems in detail.

Q2) Attempt any two from the following. [15]

- a) Comment on bulk pharmaceutical Chemical (drug substance) vendor audit.
- b) Give detail account on deficiencies found during regulatory audits.
- c) Describe the auditing criteria for the water and raw materials in the microbiological laboratory.
- d) Explain the auditing parameters in general areas of interest in the water and raw materials in microbiological laboratory.

P.T.O.

Q3) Attempt any three from the following. [15]

- a) Describe the transitioning to quality system approach in pharmaceutical manufacturing environment.
- b) Outline classification of deficiencies.
- c) Differentiate between process audit & product audit.
- d) Give detail account on responsibilities of auditors and auditees during regulatory audit.
- e) Discuss about facilities need to be focused at auditing of sterile production.

Q4) Attempt any one from the following. [15]

- a) Discuss elements of quality system model described in the FDA's pharmaceutical quality system guidelines.
- b) Explain in detail about quality systems approach with respect to pharmaceutical cGMP regulations.

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

- a) Audit of packaging material vendors
- b) Process audit and product audit
- c) Audit report
- d) Parameters for an auditing of packaging materials.
- e) Auditing ETP by pollution control authorities.



Total No. of Questions : 5]

SEAT No. :

PE4975

[Total No. of Pages : 2

[6570]-88

First Year M. Pharmacy

**MRA 203 T : REGULATORY ASPECTS OF MEDICAL DEVICES
(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.*

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

- a) Give a thorough explanation of the global medical devices nomenclature.
- b) Explain in detail quality system requirements and clinical evaluation for ASEAN.

Q2) Answer Any Two out of Four. [15]

- a) Explain about labeling requirements 21CFR part 801.
- b) Write a note on adverse event reporting of medical devices.
- c) Write a note on validation and verification of medical devices.
- d) Explain about clinical investigation plan for medical devices.

Q3) Answer Any Three out of Five [15]

- a) Describe about Global Harmonization Task Force (GHTF).
- b) Explain Medical devices working group.
- c) Write a note on good clinical practice for medical devices.
- d) Give in details about ISO13485.
- e) Write about medical devices registration procedures in Japan.

P.T.O.

Q4) Answer Any One out of Two.

[15]

- a) Describe in details about ISO14971's quality risk management for Medical devices.
- b) Explain in details about CE certification process.

Q5) Answer Any Three out of Five.

[15]

- a) Write note on Clinical investigation of Medical devices.
- b) Investigational device exemption and in-vitro diagnostics.
- c) Write a note on product life cycle of medical devices.
- d) Give risk based classification with essential principles of medical devices and IVD's.
- e) Write about medical devices registration procedures in China.

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Total No. of Questions : 5]

SEAT No. :

PE-4976

[Total No. of Pages : 2

[6570]-89

M. Pharmacy

**MPB - 204T : BIOLOGICAL EVALUATION OF DRUG
THERAPY**

(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) Write elaboratively on cell line studies of anticancer drugs. **[15]**

OR

Discuss various methods for determination of rate of absorption.

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

- a) Discuss various pharmacokinetic equations in designing of dosage forms.
- b) Describe pre-clinical toxicity tests.
- c) What are various pharmacokinetic models?
- d) Discuss 'Gene therapy'?

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

- a) Discuss 'Growth factors' as biologic medicine.
- b) Write on pyrogens and pyrogen test.
- c) Write on antisense therapeutics.
- d) What is the scope and limitations of bioassay?
- e) What are the measures of bioavailability?

Q4) Write an exhaustive note on monoclonal antibodies emphasizing on their method of preparation. **[15]**

OR

Discuss organ transplantation with pros and cons.

P.T.O.

Q5) Write notes on any three :

[15]

- a) Assay of antibiotics.
- b) Non compartment modeling.
- c) Biologic medicines in NIDDM.
- d) Recombinant hormones.
- e) Clinical research.



Total No. of Questions : 5]

SEAT No. :

PE-4977

[Total No. of Pages : 2

[6570]-90

M. Pharmacy(Pharmaceutical Chemistry)

MPC - 204T : PHARMACEUTICAL PROCESS CHEMISTRY

(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 the question paper.*

Q1) Write briefly about principle, construction, working operation of plate and frame filter press.

OR

Elaborate the process of crystallization. What are the Polymorphs? Discuss factor affecting crystallization. **[15]**

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

- a) Explain fermentation process of production of antibiotics.
- b) Explain one case study on industrial reduction process.
- c) Write in brief about fire hazards, types of fire and fire extinguishers.
- d) Discuss the production of Lovastatin Using submerged fermentation technology.

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

- a) Write a note on Personal Protection Equipment.
- b) Describe about nitrating agents. Explain aromatic nitration with suitable example.
- c) What is halogenation? Discuss a case study industrial halogenations process.
- d) Write a note on Material Safety Data Sheet.
- e) Write the types of oxidative reactions.

P.T.O.

Q4) Give an account of scale up techniques and flow charts in API manufacturing with suitable examples.

OR

Explain in detail about the impurities in APIs, types and their sources including genotoxic impurities. **[15]**

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

- a) Production of Vitamin B12 by fermentation.
- b) Streamlining reaction steps.
- c) Catalytic hydrogenation.
- d) Factors affecting evaporation.
- e) Azeotropic distillation.



Total No. of Questions : 5]

SEAT No. :

PE-4978

[Total No. of Pages : 2

[6570]-91

F.Y. M. Pharmacy (Pharmacognosy)
MPG - 204 T : HERBAL COSMETICS (Theory)
(2019 Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates :

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

Q1) Explain in details the regulatory requirements with reference to manufacturing of cosmetics. **[15]**

OR

Elaborate import and export of herbal cosmetics.

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

- a) What is moisturizing cream? Discuss method of preparation of moisturizing cream.
- b) Explain formulation and standardization of Tooth pastes.
- c) Write in detail about chemistry of hairs.
- d) Explain formulation and evaluation of face powder.

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

- a) Discuss method of preparation of hair oils.
- b) Explain lipsticks as herbal cosmetics.
- c) How vanishing creams are prepared.
- d) Enlist quality control methods for herbal shampoo.
- e) Enlist various herbs used in cosmetics as an active ingredient.

P.T.O.

Q4) Attempt any one question of following :

[15]

- a) Explain raw material, preservatives and surfactants used in herbal cosmetics.
- b) Discuss in details formulation and optimization of herbal cosmetic.

Q5) Write a short note on any Three :

[15]

- a) Herbal Lipstick.
- b) Herbal deodorants.
- c) Toxicity screening in Animals.
- d) Plants used as hair growth.
- e) Economic aspects of Natural cosmetic.



Total No. of Questions : 5]

SEAT No. :

PE4979

[Total No. of Pages : 2

[6570]-92

First Year M. Pharmacy (Pharmaceutics)

MPH 204T : COSMETIC AND COSMECEUTICALS

(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 a neat diagram wherever necessary.*

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

- a) Define cosmetics? Give the detail classification of cosmetics. Explain regulatory provisions related to the manufacture, Import and labelling of cosmetics.

OR

- b) Highlight about common skin problems like dry skin, acne, pigmentation, prickly heat, wrinkles and explain about cosmetic formulations used for the treatment or management of these issues.

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

- a) Write in detail about formulation and evaluation of lipsticks.
- b) Explain the protocol for skin sensitivity tests.
- c) Discuss in detail about herbal agents used to prepare herbal hair care products.
- d) Write in detail about the thickeners used in cosmetic industry.

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

- a) Merits and Demerits of parabens in cosmetic formulation.
- b) Discuss the anti-dandruff formulations.
- c) What are the aspects of formulation designing of deodorants?
- d) What is misbranded and spurious drug? Explain penalties for the same as per D & C act.
- e) What do you mean loan licence? Elaborate the concept of loan licence.

P.T.O.

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

- a) Write classification of perfume, give manufacturing procedure of perfume and highlight about potential allergens listed in EU regulation.

OR

- b) Explain in detail about the formulation ingredients of various dental Products. Add a note on evaluation of dentifrices.

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

- a) Sun protection factor
- b) Surfactants : Classification and applications.
- c) Various types of creams
- d) COSMOS Guidelines for foaming agents
- e) Nail care products



Total No. of Questions : 5]

SEAT No. :

PE4980

[Total No. of Pages : 2

[6570]-93

F.Y. M.Pharm.

**MPL 204T : CLINICAL RESEARCH AND
PHARMACOVIGILANCE**

(2019 Credit Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

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

Q1) Long Answer questions.

[15]

- a) Define good clinical practice. Explain in detail clinical trial phases with importance.

OR

Explain ethics of GCP study add a note on IRB and informed consent for clinical trial.

Q2) Solve any two.

[2×7½=15]

- a) Principles of biomedical research in clinical trial.
- b) Clinical trial case control and cohort study
- c) Detection of methods of ADRs.
- d) Importance of ICMR.

Q3) Solve any three.

[3×5=15]

- a) Clinical research organisation.
- b) Pharmacoepidemiology.
- c) Vaccine safety surveillance.
- d) ADR Reporting.
- e) Placebo study.

P.T.O.

Q4) Long Answer questions.

[15]

- a) Classify PVs. Explain in detail pharmacovigilance PVs methods.

OR

Explain basic steps in set up of PV center note on ICH - GCP.

Q5) Short note any three.

[3×5=15]

- a) Pharmacoeconomics
- b) Periodic safety update reports
- c) Clinical research associate
- d) IND & NDA for study of clinical trials
- e) Functions of PV study.



Total No. of Questions : 5]

SEAT No. :

PE4981

[Total No. of Pages : 2

[6570]-94

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

**MQA 204T : PHARMACEUTICAL MANUFACTURING
TECHNOLOGY**

(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) Discuss in detail about PAT as a driver for improving quality and reducing costs along with FDA initiative on process analytical technology. **[15]**

OR

What IPQC test are carried out for SVP and LVP with suitable example?

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

- a) Give manufacturing flowchart for Sterile and nonsterile products.
- b) Describe various packaging types such as blister packs, bubble packs, shrink packaging, and plastic pouches.
- c) Elaborate about principle, process and equipment with application in lyophilisation.
- d) Discuss about automation in pharmaceutical industry in manufacturing of coated products.

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

- a) Illustrate manufacturing of sterile ointments and emulsion.
- b) Discuss manufacturing flowcharts for soft and hard gelatin capsules.
- c) Describe closures and closure liners for sterile and non sterile pharmaceuticals.
- d) Describe the environmental control measures and wall and floor treatments with machineries in a parenteral manufacturing plant.
- e) Write in brief about scheduling and production planning.

P.T.O.

Q4) Discuss the legal requirements and licenses for the active pharmaceutical ingredients and formulation industries. Discuss the plant layout and factors influencing it. **[15]**

OR

Describe in detail various granulators, spheronizers and marumerisers in improved tablet production.

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

- a) Prefilled syringe
- b) Dry powder parenteral dosage form
- c) Stability aspects of packaging
- d) Needle free injection
- e) Fluidized bed coating.



Total No. of Questions : 5]

SEAT No. :

PE4982

[Total No. of Pages : 2

[6570]-95

F.Y. M.Pharm

**MRA 204T : REGULATORY ASPECTS OF FOOD AND
NUTRACEUTICALS**

(2019 Credit Pattern) (Semester - II)

Time : 3 Hours]

[Max. Marks : 75

Instructions to the candidates:

- 1) *Answer the questions as per the given options.*
- 2) *Marks are indicated for each question.*
- 3) *Write clear and structured answers.*

Q1) Long Answer (Answer Any 1) [1×15=15]

- a) Explain the role of NSF International in regulating dietary supplements and the nutraceutical industry.
- b) Discuss the history and regulatory evolution of food and nutraceuticals, emphasizing the significance of dietary supplements and functional foods in public health.

Q2) Medium - Length Answers (Answer Any 2). [2×7½=15]

- a) Describe the Food Safety Modernization Act (FSMA) and the Dietary Supplement Health and Education Act (DSHEA) of the USA, highlighting their impact on the nutraceutical industry.
- b) Outline the Recommended Dietary Allowances (RDA) guidelines applicable in the United States.
- c) Summarize the European standards for dietary supplement regulation.
- 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).

Q3) Short Answer Questions (Answer Any 3). [3×5=15]

- a) Overview of Recommended Dietary Allowances in Europe.
- b) Describe the core responsibilities of the U.S. FDA.
- c) Discuss the significance of nutrition labelling requirements
- d) Explain Good Manufacturing Practices (GMP) for nutraceuticals.
- e) Name two marketed nutraceutical products produced in India.

P.T.O.

Q4) Long Answer Questions (Answer Any 1).

[1×15=15]

- a) Compare and contrast the Recommended Dietary Allowances (RDA) across India, the USA, and the European Union.
- b) Explain the organizational structure and roles of the European food safety Authority (EFSA).

Q5) Short Notes (Answer Any 3).

[3×5=15]

- a) Explain the European regulations regarding Novel Foods and Novel Food Ingredients.
- b) Discuss the role of probiotics in health and disease management.
- c) Summarize the permitted labelling claims for dietary supplements.
- d) Describe EU directives and regulations governing the manufacture and sale of nutraceuticals.
- e) Describe the role of the food safety and standards Act in regulating food safety in India.

