Total No. of Questions : 5]

SEAT No. :

P4351

[Total No. of Pages : 2

[5453]-1002

M. Pharmacy (Semester - I) (Pharmacognosy)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

(2018 Pattern)

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

Instructions to the candidates:

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

Q1) Discuss in detail instrumentation and principle involved in NMR Spectroscopy. **[15]**

OR

Give an exhaustive account of UV visible spectroscopy, explain role of UV spectroscopy in phytochemical research.

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

a) Explain utility of HPTLC in natural product research.

b) Give an exhaustive account of differential thermal analysis.

c) Write a note on gel electrophoresis.

d) Describe in detail affinity chromatography.

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

a) Discuss in detail Fermi resonance with suitable example.

b) Explain principal involved in gas chromatography.

c) Give an exhaustive account of derivative differential thermal analysis.

d) Describe in detail Atmospheric pressure chemical ionization.

e) Discuss in detail instrumentation and principle involved in spectrofluorimetry.

P.T.O.

Q4) Discuss in detail instrumentation and principle involved in Mass spectroscopy. **[15]**

OR

Give an exhaustive account of X- ray crystallography, explain significance of X- ray crystallography in herbal research.

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

a) Capillary electrophoresis

b) Ion exchange chromatography

c) MALDI

d) Flame emission spectroscopy

e) UPLC

Total No. of Questions : 5]

SEAT No. :

P4186

[Total No. of Pages : 2

[5453] - 1005

M.Pharmacy

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA101)

(2018 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Compare proton NMR to C13 NMR. Write methods for simplification of complex NMR spectrum. **[15]**

OR

Explain the phenomenon of Fluorescence using energy level diagram. Comment on factors affecting efficiency of fluorescence.

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

a) Write different types of molecular vibrations. Why is IR spectrum called as a fingerprints of a molecule?

b) Discuss Electronic transitions in UV spectroscopy. Explain the terms Red Shift and Blue Shift.

c) Write factors affecting Rf value in TLC. What are different development methods in TLC?

d) Write methods of X-ray production.

P.T.O.

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

a) What are sample handling techniques for solid samples in IR?

b) Discuss working of Quadrupole and Time of Flight Mass analyzers.

c) Applications of Flame emission spectroscopy.

d) Write principle, advantages and limitations of Thermal conductivity detector.

e) What is isocratic and gradient elution in chromatography?

Q4) What are hard and soft ionization source in Mass spectrometry? Explian with suitable examples of each. **[15]**

OR

Write principle and applications of Ion exchange chromatography? Discuss various types of resins used.

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

a) Magnetic Anisotropy

b) Applications of Atomic absorption spectroscopy

c) Advantages of UHPLC

d) Difference spectroscopy

e) Applications of Gel electrophoresis.

Total No. of Questions : 5]

SEAT No. :

P4187

[Total No. of Pages : 2

[5453] - 1006

M.Pharmacy (Pharmaceutical Chemistry)

ADVANCED ORGANIC CHEMISTRY - I

(2018 Pattern) (Semester - I) (MPC 102T)

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

Instructions to the candidates:

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

Q1) What is retrosynthesis & synthon approach? Add a note on C-C disconnection. **[15]**

OR

Explain reaction mechanism and applications of Baeyer-Villiger reaction, Michael addition reaction & Suzuki reaction.

Q2) Explain the detailed mechanism of the following reactions with synthetic applications: Any Two. **[15]**

a) Brook rearrangement.

b) Dieckmann Reaction.

c) Mannich Reaction.

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

a) Explain Knorr Pyrazole synthesis and Pinner Pyrimidine Synthesis.

b) Strategies for synthesis of three membered ring systems through synthon approach.

c) Explain bimolecular elimination reaction with example.

d) Discuss any two methods of determining reaction mechanisms.

e) Explain the preparation, salient features of Aluminum isoprpoxide and mention its applications in organic synthesis.

P.T.O.

Q4) Write synthesis of Ketoconazole; Celecoxib & Alprazolam. **[15]**

OR

Explain protection for hydroxy & carboxyl groups with suitable example.

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

a) Discuss stability of carbocations considering Hyperconjugation.

b) Discuss stability of carbanions considering Inductive effect.

c) Explain Synthetic application of Diazomethane and Wittig reagent.

d) Discuss the Hoffmann and Zaitsev (Saytzeff) rules of elimination with suitable examples.

e) Discuss the sandmeyer reaction and its synthetic applications to obtain various substituted benzenes.

♦ ♦ ♦

Total No. of Questions : 5]

SEAT No. :

P4188

[Total No. of Pages : 2

[5453] - 1008

M.Pharmacy (Pharmaceutics)

DRUG DELIVERY SYSTEMS

(2018 Pattern) (Semester - I) (MPH 102T)

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

Instructions to the candidates:

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

Q1) Discuss in detail the physicochemical and biological approaches for sustained/ controlled release formulations. **[15]**

OR

Discuss in detail various techniques for formulation of transdermal drug delivery system.

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

a) Explain chemical and physical approaches for permeation enhancement of drug through skin.

b) Discuss about transdermal delivery of vaccines.

c) Discuss in brief, barriers for protein delivery.

d) Discuss in detail the mechanisms and theory of mucoadhesion.

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

a) Discuss osmotic activated drug delivery systems.

b) Enumerate and explain evaluation tests for mucoadhesive systems.

c) Explain any two approaches to extend GI transit time.

d) Discuss drug delivery through Intravitreal Implants.

e) Elaborate upon importance of personalised medicine.

P.T.O.

Q4) Explain challenges associated with formulation of buccal drug delivery system and explain evaluation tests for buccal formulations. **[15]**

OR

Discuss mechanism of drug release from SR/CR formulations.

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

a) Pharmacogenetics.

b) Telepharmacy.

c) Iontophoresis.

d) Biodegradable polymers used is SR/CR form.

e) Monolithic drug delivery system.

Total No. of Questions : 5]

SEAT No. :

P4189

[Total No. of Pages : 2

[5453] - 1009

M.Pharmacy (Pharmacology)

MPL 102T : ADVANCED PHARMACOLOGY

(2018 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Describe in detail the pharamacology of adrenaline. **[15]**

OR

Classify antiarrhythmic drugs. Describe in detail the pharmacology of Class I antiarrhythmic agents. **[15]**

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

a) Describe the pharmacology of morphine.

b) Write in detail pharmacology of atropine.

c) Classify diuretics. Give an account on loop diuretics.

d) Classify antiepileptic drugs. Explain the pharmacology of phenytoin.

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

a) Write about management of myocardial infarction.

b) Give a detailed account on Prostaglandins.

c) Write a note on local anaesthetics.

d) Describe the mechanism of action and adverse effects of cardiac glycosides.

e) Explain the therapeutic utility of nitrates in angina pectoris.

P.T.O.

Q4) Classify sedatives and hypnotics. Give a detail account on the pharmacology of Benzodiazepines. **[15]**

OR

Classify hypolipidemic drugs. Explain the pharmacology of statins. **[15]**

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

a) Drug excretion

b) Heparin

c) G protein coupled receptors

d) Fibrinolytics and antiplatelet drugs.

e) ACE inhibitors

♦ ♦ ♦

Total No. of Questions : 5]

SEAT No. :

P4190

[Total No. of Pages : 2

[5453] - 1010

M.Pharmacy (Pharmaceutical Quality Aussurance)

QUALITY MANAGEMENT SYSTEMS

(2018 Pattern) (Semester - I) (MQA 102T)

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

Instructions to the candidates:

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

Q1) Discuss in length the concept of "Strategic Quality Management" in pharmaceutical Industry. **[15]**

OR

Discuss the meaning of customer & customer focus with special reference to customer satisfaction & delight.

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

a) What is the importance of 'Quality Culture' in Pharmaceutical Industry?

b) Discuss 'Bench-Marcking' process.

c) Discuss importance of 'Quality-Metrics Indices'.

d) What is Six-System inspection model? Briefly disucss each of the system.

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

a) What do you understand by Cost of Quality?

b) Discuss the importance of ISO-9001 - 2015 standards.

c) Comment on Statistical Process Control.

d) What is the meaning of 'Scrap & Trash'? and discuss importance of it's management.

e) Discuss the process of Root Cause Analysis.

P.T.O.

Q4) Define and discuss the term "Quality of a Pharmaceutical Product"? **[15]**

OR

Discuss the importance and process of 'Knowledge Management' with reference to ICH Q10.

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

a) Risk assessment & control.

b) Quality by Design.

c) NABL - Certification Process.

d) Risk ranking according to ICH - Q9.

e) Mission and vision statements.

♦ ♦ ♦

Total No. of Questions : 5]

SEAT No. :

P4191

[Total No. of Pages : 2

[5453] - 1011

M.Pharmacy (Pharmaceutical Chemistry)

ADVANCED MEDICINAL CHEMISTRY

(2018 Pattern) (Semester - I) (Theory) (MPC 103 T)

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

Instructions to the candidates:

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

Q1) Classify antihypertensive agents with suitable example. Explain in detail ACE inhibitors. **[15]**

OR

What are the causes for drug resistance? Explain the strategies used to combat drug resistance. Add a note on resistance in anticancer therapy. **[15]**

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

a) Describe in detail about COX_1 and COX_2 inhibitors.

b) Write about antimetabolites as antineoplastic agents.

c) Give focus on mechanisms of action of anticonvulsants with suitable example.

d) Discuss the aspects of ethics and in vivo study in drug development process.

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

a) Write about theories of drug receptor interaction.

b) Explain the chemistry and mechanism of action of anticholinesterases.

c) Explain prodrugs to improve patient acceptability.

d) Highlight enzyme inhibitors in medicine.

e) Describe chemistry of prostaglandins.

P.T.O.

Q4) Explain stereoselectivity with examples. Give the significance and role of chirality in specific examples of therapeutic agents. **[15]**

OR

Discuss the cholinergic receptors. Classify cholinergic agents with examples and give an account of cholinergic receptor antagonists. **[15]**

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

a) Methods for lead search.

b) Prodrugs to sustain drug action.

c) Bioisosterism.

d) Histamine receptors.

e) Challenges in Drug development.

Total No. of Questions : 5]

SEAT No. :

P4192

[Total No. of Pages : 2

[5453] - 1012
F.Y. M. Pharmacy
PHYTOCHEMISTRY
(2018 Pattern) (Semester - I) (MPG 103T)

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

Instructions to the candidates:

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

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

OR

Elaborate a detail account of phytochemical fingerprinting in the characterization of herbal extracts using HPTLC with a brief account of its application in structure elucidation of phytoconstituents.

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

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

b) Explain history of herbs as source of drugs and drug discovery.

c) Explain various parameters involved in selection of method and choice of solvent for extraction.

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

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

a) Explain in detail isolation, purification and industrial importance of with anolides.

b) Explain in detail application of LCMS in the characterization of herbal extracts.

P.T.O.

c) Explain in detail spectroscopic characterizations for structural elucidation of carvone.

d) Explain in detail clinical studies emphasising on phases of clinical trials.

e) Explain successive and exhaustive extraction.

Q4) Elaborate a detail account of spectroscopic characterizations for structural elucidation of caffeine. **[15]**

OR

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

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

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

b) Radiotracing Techniques.

c) Microwave assisted extraction.

d) Structural elucidation of menthol using spectroscopy.

e) GCMS Fingerprinting.

♦ ♦ ♦

Total No. of Questions : 5]

SEAT No. :

P4193

[Total No. of Pages : 2

[5453] - 1013

M. Pharmacy

MODERN PHARMACEUTICS

(2018 Pattern) (Semester - I) (MPH 103T)

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

Instructions to the candidates:

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

Q1) Explain the hazard and risk analysis in pharmaceutical products and risk analysis in pharmaceutical products. **[15]**

OR

How are excipients standardized? Write a note on drug- excipient, excipient - excipient and excipient - package interaction.

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

a) What is the importance of material managements in pharmaceutical industry? Explain in detail aspect of material managements.

b) Explain concept and importance of preformulation. Discuss in brief preformulation studies of Dispersions.

c) Explain need for optimization. Give an account in detail optimization by factorial design.

d) Define validation. Explain in detail Equipment Validation.

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

a) Concept and objectives of stability of pharamaceuticals.

b) Standard operating procedure.

c) IPQC

d) ANOVA

e) Statistical design

P.T.O.

Q4) Explain in detail similarity factors -f2 and f1, Higuchi and Peppas plot and Linearity with concept of significance. **[15]**

OR

Define validation. Discuss validation of a unit operation with one case study.

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

a) IQ, OQ & PQ of facilities.

b) Sales forecasting.

c) Distribution of forces.

d) Diffusion and Dissolution parameters.

e) Evaluation of parenterals.

Total No. of Questions : 5]

SEAT No. :

P4194

[Total No. of Pages : 2

[5453] - 1014

M. Pharmacy (Pharmacology)

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(2018 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Discuss in detail the various methods employed in the screening of anti-asthmatic and anti-allergic drugs. **[15]**

OR

Describe in detail the different methods employed in the screening of anti-arrhythmic drugs. **[15]**

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

a) Describe the screening methods for anti-parkinsonian agents.

b) Discuss the various methods employed in the screening of sedative, hypnotic and anxiolytic agents.

c) Explain in detail various methods used in screening of immunomodulators.

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

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

a) Write a note on anesthesia and euthanasia.

b) Write various methods employed in the screening of CNS stimulants.

c) Describe the various methods used in screening of aphrodisiac agents.

d) Describe the various methods used in screening of anticancer agents.

e) Write the screening methods for hepatoprotective agents.

P.T.O.

Q4) Describe the various methods used in screening of antifertility agents. **[15]**

OR

Discuss the various methods employed in the screening of antiepileptic agents. **[15]**

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

a) Screening methods for anti-inflammatory agents.

b) Screening methods for anti-ulcer agents.

c) Screening methods for antidiabetic agents.

d) Limitations of animal experimentation and advantages of alternative experimental models.

e) Transgenic animals.

♦ ♦ ♦

Total No. of Questions : 5]

SEAT No. :

P4195

[Total No. of Pages : 2

[5453] - 1015

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA 103T : QUALITY CONTROL AND QUALITY ASSURANCE

(2018 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Define and elaborate the concept of "Quality Assurance" and summarize the job responsibilities of head of "Quality Control" department and head of "Quality Assurance" department. **[15]**

OR

Discuss the concept of Batch Manufacturing Record (BMR) with suitable formats for the manufacturing of Tablet Dosage Form.

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

a) Elaborate the content of CPCSEA guidelines.

b) Explain the procedure for Quality Audit Plan and reports in Pharmaceutical Manufacturing Unit.

c) Provide guidelines for Design, Construction and Plant Layout for a Pharamaceutical Industry.

d) How and why are distribution records maintained?

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

a) Differentiate between Quality Assurance and Quality Control.

b) What is change Control? Explain and design documents for change control.

P.T.O.

c) State the significance of personnel training.

d) Provide guidelines for Warehousing as per schedule M.

e) What should firm do if its drug products or components have been subjected to improper storage conditions such as those caused by Natural disaster?

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

OR

What are IPRs? Discuss the scope and importance of intellectual property rights for a Pharma Researchers.

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

a) Printed packaging material.

b) Calibration record.

c) Drug Master File.

d) Significance of IPQC.

e) Quality Control of Packaging Material.

♦ ♦ ♦

Total No. of Questions : 5]

SEAT No. :

P4353

[Total No. of Pages : 2

[5453]-1016

M. Pharmacy (Pharmaceutical Chemistry) (Semester - I)

MPC-104T : CHEMISTRY OF NATURAL PRODUCTS

(2018 Pattern)

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

Instructions to the candidates:

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

Q1) What are minor flavonoids? Give general structure and examples of minor flavonoid. Mention a general scheme for isolation of flavonoids. **[15]**

OR

Explain d-tubocurarine as a prototype/lead compound for evolution of modern day neuromuscular blockers.

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

a) Give detail classification of cardiac glycosides. Draw structure of chemical constituents of digitals.

b) Give significance of 1H NMR, 13C NMR and Mass spectroscopy in structural of elucidation.

c) Elucidate the structure of Morphine.

d) Explain chemistry of Macrolide antibiotics.

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

a) Give significance of IR in structural elucidation.

b) Elucidate the structure of citral.

c) Add a note on gene therapy.

d) Add a note on structural elucidation of beta carotine.

e) Elaborate about natural drugs affecting CNS.

P.T.O.

Q4) What are terpenes? Give their complete classification. Mention their significance and medicinal applications. **[15]**

OR

What are alkaloids? Give their general classification including one medicinal example from each class. Write the general scheme for isolation of alkaloids from plants. Draw structures of stereoisomers of medicinal value isolated from *Ephedra*.

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

a) Write the physiological significance of Vitamin A, Vitamin B_1, Vitamin C and Vitamin B_{12}.

b) Name the chemical constituents isolated from Trigonella foenum graecum and *Swertia chirata*

c) What is steroidal nucleus? Give structures of estradiol, Testosterone and progesterone.

d) What are Nucleotides? Draw the structure of a Nucleotide.

e) Give biological source, chemical constituents and uses of turmeric.

Total No. of Questions : 5]

SEAT No. :

P4196

[Total No. of Pages : 2

[5453] - 1017

M. Pharmacy (Pharmacognosy)

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

(2018 Pattern) (Semester - I) (MPG 104T)

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

Instructions to the candidates:

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

Q1) Explain infrastructural requirements of herbal industry involved in production of standardized extracts and various dosage forms. **[15]**

OR

What is monograph of herbal drug? Explain general parameters of monograph of herbal drugs. **[15]**

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

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

b) Write note on Export and import (EXIM) policy of India.

c) Describe protocols for stability testing of natural products.

d) Explain global regulatory status of herbal drugs.

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

a) What are methods for Quality assurance in herbal drugs?

b) What do pilot scale and scale up mean?

c) What is clinical laboratory testing of natural products?

d) Write note on "Geographical indications"

e) What is management approach to long-term success through custormer satisfaction?

P.T.O.

Q4) Write an essay on Indian and international patent laws applicable to herbal and natural products and their process. **[15]**

OR

What are WHO guidelines on Good Manufacturing Practices (GMP) for the production of phytomedicines. **[15]**

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

a) Ayurvedic Pharmacopeia.

b) Current challenges of herbal formulations.

c) Copyright.

d) TRIPS

e) Plant Design

♦ ♦ ♦

Total No. of Questions : 3]

SEAT No. :

P4197

[Total No. of Pages : 2

[5453] - 1018

M. Pharmacy

REGULATORY AFFAIRS

(2018 Pattern) (Semester - I) (MPH 104T)

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

Instructions to the candidates:

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

Q1) Answer the following. **[20]**

a) What is Regulatory Affairs?

b) Give the Roles of Regulatory Affairs professionals?

c) What is an Investigational New Drug (IND) application?

d) What is a New Drug Application?

e) What is an Abbrevited New Drug Application (ANDA)?

f) What is a DMF.

g) Explain about a Generic Drug Product?

h) What are the types of DMF's?

i) What is a 505 (b)(2) application?

j) Focus on the goals of Regulatory Affairs Professionals?

Q2) Solve any two. **[20]**

a) Give Regulatory requirements of EU, MHRA, TGA and Row countries.

b) Focus on Investigation of medicinal product dossier (IMPD).

c) Write a note on Code of Federal Regulation.

P.T.O.

Q3) Answer the following (any five). **[35]**

a) Enlist the ICH Q guidelines.

b) Outsourcing of Bioavailability and Bioequivalence.

c) Post marketing Drug surveillance.

d) Note on - investigator brochure

e) What is HIPPA?

f) Highlight on Institutional review board.

g) Focus on ANDA for generic drugs.

Total No. of Questions : 5]

SEAT No. :

P4198

[Total No. of Pages : 2

[5453] - 1019

M. Pharmacy

CELLULAR AND MOLECULAR PHARMACOLOGY

Pharmacology

(2018 Pattern) (Semester - I) (MPL 104T)

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

Instructions to the candidates:

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

Q1) Define and classify receptors. Discuss in detail molecular structure and signal transduction via GPCRs. **[15]**

OR

Write detailed account on gene therapy and its clinical applications.

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

a) Write in detail mechanisms of apoptosis.

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

c) Discuss about recombinant DNA technology and its applications.

d) Explain in brief the effect of polymorphism in drug metabolism.

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

a) Explain in detail the basis and types of immunotherapeutic.

b) Discuss the role of genetic variation in drug transporters.

c) Explain the SiRNA and its importance.

d) Explain the principles and applications of Cell viability assays.

e) Discuss in detail intercellular signaling.

P.T.O.

Q4) Discuss in details molecular physiology of cell cycle and comment on its regulation. **[15]**

OR

Discuss in brief various types of ELISA techniques with advantages and disadvantages. Write note on its applications.

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

a) Downstream signaling for TK receptors.

b) Organization of genome.

c) Humanization of antibody therapy.

d) Cryopreservation.

e) RT - PCR.

Total No. of Questions : 5]

SEAT No. :

P4199

[Total No. of Pages : 2

[5453] - 1020

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA 104T : PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

(2018 Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) What are SUPAC and BACPAC? Discuss in detail SUPAC guidelines for change in site, batch size, manufacturing equipment and process along with suitable example. **[15]**

OR

Describe large scale manufacturing techniques including formula, equipment, process, stability and quality control for solid dosage forms in detail.

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

a) Describe Clinical Research Process step by step.

b) Discuss role of surfactants and co-solvents in solubility enhancement along with suitable examples.

c) Write about significance and design of Pilot plant scale up. How does it differ from large scale manufacturing.

d) Describe criteria for selection and evaluation of Pharmaceutical packaging material.

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

a) Give the quality control tests for glass as a packaging meterial.

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

P.T.O.

c) Define Polymorphism and discuss methods for its detection.

d) Discuss the development and information content for ANDA.

e) Write a note on aseptic packaging systems.

Q4) What is technology transfer? Discuss various documents involved in technology transfer of a dosage form. **[15]**

OR

Discuss in detail stability testing during product development as per ICH guidelines.

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

a) Medical device packaging.

b) Technology Transfer Plan

c) Significance and need of preformulation studies.

d) Post marketing surveillance.

e) SNDA

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