Total No. of Questions : 5]

SEAT No. :

P-8917

[Total No. Of Pages : 2

[6111]-531
F.Y. M. Pharmacy
MPAT101T: Modern Pharmaceutical Analytical Techniques
Common for all specializations
(2019 Pattern) (Semester - I)

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

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

Q1) a) Give factors affecting chemical shift in NMR spectroscopy. Add a note on spin-spin coupling. **[15]**

OR

b) Explain working and instrumentation of FTIR. Enlist factors affecting vibrational frequencies.

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

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

Molecular Formula: $C_5H_{10}O$

IR: 2950 cm^{-1}, 1720 cm^{-1}

PMR: δ 2.6 (septet, 1H), 2.1 (singlet, 3H), 1.0 (doublet, 6H)

C^{13}NMR: 195 (singlet), 42 (doublet), 18 (quartet), 11 (quartet)

b) Explain factors affecting separation in electrophoresis and discuss about Isoelectric focusing.

c) Elaborate principle, instrumentation and advantages of HPTLC.

d) Write principle, instrumentation and advantages of UPLC.

P.T.O.

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

a) Describe Instrumentation of Flame Emission Spectroscopy.

b) Discuss instrumentation of Differential Thermal Analysis.

c) Write a note on Capillary electrophoresis.

d) Describe instrumentation and working of FT-NMR.

e) Explain Detectors used in UV/Visible spectroscopy.

Q4) a) Discuss fragmentation patterns and rules in Mass Spectrometry. Give applications of Mass Spectrometry. **[15]**

OR

b) Give a detailed account on instrumentation of Gas Chromatography.

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

a) Factors affecting TGA results.

b) Different X-ray diffraction methods and Bragg's Law.

c) Heat flux and power compensation DSC.

d) MALDI

e) Gel Electrophoresis.

Total No. of Questions : 5]

SEAT No. :

P8918

[Total No. of Pages : 2

[6111]-532
First Year M.Pharmacy
MRA101T: GOOD REGULATORY PRACTICES
(2019 Credit Pattern) (Semester - I)

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

Instructions to the Candidate:

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

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

a) Give detail account of ICH Q1 A guideline.

b) Explain about Good Automated Laboratory Practices in details.

Q2) Medium length answers (Any 2) **[2×7.5=15]**

a) Give brief account Subpart C & D of 21 CFR part 211.

b) Write in detail about analytical method validation.

c) Give Challenges and benefits in implementing electronic documentation Systems under GDP.

d) Classification of Medical device and IVDs under GHTF Guidance docs.

Q3) Short Answer (Any 3) **[3×5=15]**

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

b) Give detail about laboratory management and personal details under GALP.

c) What do you mean by GDP? Give the principle od GDP for GLP.

d) Write a note on cleaning validation.

e) Write a note on software evaluation checklist.

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

a) Explain in detail EC principles of GMP Article 6 to Article 14.

b) Explain in detail 21 CFR part 11.

P.T.O.

Q5) Short notes (Any 3) **[3×5=15]**

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

b) Write a note on ISO 13485.

c) Validation of HAVC

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

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

Total No. of Questions : 5]

SEAT No. :

P8919

[Total No. of Pages : 2

[6111]-533

First Year M.Pharmacy

MPB 102T : MICROBIAL AND CELLULAR BIOLOGY

(2019 Credit Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) What is mutagenesis? Explain types and application of mutagenesis in strain improvement. **[15]**

OR

Explain different types of animal cell culture. Write the applications of cell cultures in pharmaceutical industry and research.

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

a) Write the mechanism of microbial pathogenicity of common microbial diseases.

b) Explain the morphology, cultural and physiological characteristics of actinomycetes.

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

d) Explain different methods used for isolation of important microbes.

Q3) Write a note on (any three). **[15]**

a) Structure and types of RNA.

b) Apoptosis and oncogenes.

c) Anti-viral assays.

d) Cell division and its regulation.

e) Stem cells and its applications.

P.T.O.

Q4) Explain in detail events of fertilization and applications of in vitrofertilization. **[15]**

OR

Write in short central dogma of molecular biology with reference to transcription and translation.

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

a) Therapy for common fungal infections

b) Cytoskeleton and cell movements

c) Phage mutation and lysogeny

d) Structure of DNA

e) Pathology of bacterial infections

Total No. of Questions : 5]

SEAT No. :

P8920

[Total No. of Pages : 2

[6111]-534

First Year M.Pharmacy (Pharmaceutical Chemistry)

MPC 102T : ADVANCED ORGANIC CHEMISTRY - I

(2019 Credit Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) What is Multi - Component synthesis? Discuss about mechanism and synthetic applications of Hantzsch reaction, passerini reaction and strecker synthesis. **[15]**

OR

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

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

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

b) Describe about method of formation, stability and synthetic applications of carbenes and nitrenes.

c) Write mechanism and synthetic applications of Michael addition reaction and vilsmeyer - Haack reaction.

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

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

a) Explain strategies for synthesis of five membered rings systems through synthon approach.

b) Write mechanism and synthetic applications of sandmeyer reaction and O_3 onolysis.

c) Discuss any two methods of determining reaction mechanism.

d) Write synthesis of Antipyrine and alprazolam.

e) Describe about synthetic applications of diazomethane and osmium teroxide in organic reactions.

P.T.O.

Q4) Explain protection for Amino group and aminoacids with suitable example. **[15]**

OR

Describe mechanism and application of combes quinoline synthesis and traube purine synthesis with suitable examples of drugs.

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

a) Write a note on free radicals.

b) Discuss stability of carbocations and carbanions.

c) Synthetic applications of Aluminium is opropoxide and titanium chloride.

d) E1 and E2 Elimination reactions.

e) Mechanism and synthetic applications of Ugi reaction and passerini reaction.

Total No. of Questions : 5]

SEAT No. :

P8921

[Total No. of Pages : 2

[6111]-535

First Year M.Pharmacy

MPG - 102 T : ADVANCED PHARMACOGNOSY - I

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

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

Instructions to the candidates:

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

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

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

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

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

a) Write a note on current trends and future scope of Nutraceuticals.

b) Objectives and functions of Indian Council of Agricultural Research.

c) Write a note on Ex - situ conservation of medicinal plants.

d) Explain in detail about importance of pharmacognosy in herbal drug industry.

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

a) FSSAI guidelines.

b) Formulation and standardization of Nutraceuticals.

c) Dietary fibres.

d) Herbs as functional food.

e) Health benefits of Ginseng.

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) Explain in detail about Current good agricultural practices.

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

a) Isolation of Rutin

b) Characteristic features of Withanolides.

c) Medicinal uses and health benefits Flax seeds.

d) Bio drug - drug interaction with suitable examples.

e) Occurrence and isolation of α and β - carotene.

Total No. of Questions : 5]

SEAT No. :

P8922

[Total No. of Pages : 2

[6111]-536

First Year M.Pharmacy

MPH 102 T : DRUG DELIVERY SYSTEMS

(2019 Credit Pattern) (Semester - I)

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

Instructions to the candidates:

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

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

a) How do transdermal drug delivery systems (patches) work, and what are their advantages over other routes of drug administration?

b) Explain in brief about rate controlled drug delivery system. Discuss in detail about Osmotic activated drug delivery system.

Q2) Answer any two out of four each question carries (7.5 marks). **[2×7.5=15]**

a) Describe 3D printing technology for manufacture of tablets.

b) How does the gastrointestinal (GI) tract pose obstacles to oral protein delivery, and what strategies are used to overcome them?

c) Compare natural polymers with synthetic polymers Give five examples of semisynthetic polymers.

d) What is the principle of mucoadhesion, and how does it play a role in buccal drug delivery?

Q3) Answer any 3 out of 5 each carries 5 marks. **[3×5=15]**

a) How are vaccines traditionally administered, and describe the limitations of conventional vaccine delivery methods?

b) How does the reticuloendothelial system (RES) and renal clearance impact the systemic delivery of proteins and peptides?

c) Enlist the types of penetration enhancers commonly used in transdermal formulations, and how do they differ in their effects?

d) Give importance and applications of personalized medicines.

e) Elaborate upon role of Ion exchange resins as controlled drug delivery carriers.

P.T.O.

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

a) Explain in details evaluation of delivery systems of proteins and other macromolecules.

b) Explain in details novel ophthalmic formulations used to overcome occular barriers.

Q5) Write note on any 3 out of 5, each question carries 5 marks. **[3×5=15]**

a) Pharmacogenetics and Categories of Patients for Personalized Medicines.

b) Drug delivery systems with zero order drug release.

c) Importance of % CDR vs Time study in oral sustained release formulations.

d) Feedback regulated drug delivery systems.

e) Single shot vaccine.

Total No. of Questions : 5]

SEAT No. :

P-8923

[Total No. Of Pages : 2

[6111] - 537
F.Y. M.Pharm.
MPL 102T: Advanced Pharmacology - I
(2019 Pattern) (Semester - I)

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

Instructions to the candidates:

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

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

a) Classify alpha adrenergic agonist. Discuss the pharmacology of reversible non selective alpha-adrenergic blockers.

b) Define hypertension, classify antihypertensives. Explain the pharmacology of Salbutamol.

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

a) Write a pharmacology of Antimanic drugs

b) Write the pharmacology of aldosterone receptor antagonist.

c) Explain significance of Biotransformation in drug action.

d) Write a note on Local anesthetics

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

a) Enzyme linked receptors

b) Bio synthesis and storage of histamine

c) Morphine and its derivatives

d) Mechanism of action and therapeutic uses of Furosemide

e) SNRIs as antidepressants

P.T.O.

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

a) What is Parkinson's Disease? Explain pharmacotherapy of Anti parkinson's Disease.

b) What are types of Autocoids? Explain mechanism of action and pathophysiological actions of prostaglandins.

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

a) Pre and post anesthetic medications

b) Glutamate as neurotransmitter.

c) Kinins

d) Explain the steps involved in neurotransmission.

e) Nitrates in cyanide poisoning.

Total No. of Questions : 5]

SEAT No. : ____

P-8924

[Total No. Of Pages : 2

[6111] - 538

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

MQA102T: QUALITY MANAGEMENT SYSTEMS

(2019 Pattern) (Semester - I)

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

Instructions to the candidates:

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

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

a) Describe in detail types, reasons, process, advantages and limitations of benchmarking

b) Explain pharmaceutical quality management as per ICH Q10

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

a) Give importance of statistical control charts in pharmaceuticals

b) Explain the different dimensions of quality.

c) Elaborate on NABL certification and accreditation

d) Explain ISO 9001 guidelines for quality management

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

a) Comment on concept of self inspection in pharmaceutical industry

b) Explain process capability

c) Principles of six sigma

d) Operational excellence

e) Basic principles of TQM

P.T.O.

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

a) Explain six system inspection model

b) Explain ICH Q8 guidelines

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

a) Explain McKinsey 7s model

b) Handling Out of specification results

c) Area clearance or Line clearance in Pharma Industry

d) HACCP

e) Photostability testing of drug and drug products

Total No. of Questions : 5]

SEAT No. :

P-8925

[Total No. of Pages : 2

[6111]-539

F.Y. M. Pharm.

MRA-102 T: DOCUMENTATION AND REGULATORY WRITING

(2019 Pattern) (Semester - I)

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

Instructions to the candidates:

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

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

a) What are audits? Explain the process of preparation and conduct of audits.

b) Explain in detail modules of CTD.

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

a) Explain in detail site master file

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

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

d) Explain in detail Internal and External Audits.

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

a) Write a note on post approval labeling changes.

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

c) Write a note on ISO risk management standard.

d) Establishment Inspection Report (EIR).

P.T.O.

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

a) Describe the types of audits and its GMP compliance

b) Explain Sugam system of CDSCO.

Q5) Answer any Three **[15]**

a) Corrective and Preventive action (CAPA).

b) Write a note on ACDT Format.

c) Write a note on seizure and injunctions.

d) Write a note on post approval changes (SUPAC).

e) Explain Root cause analysis.

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Total No. of Questions : 5]

SEAT No. : [ ]

P8926

[Total No. of Pages : 2

[6111]-540

First Year M.Pharm. (Pharmaceutical Biotechnology)

MPB 103 T : BIOPROCESS ENGINEERING AND 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.***

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

a) Explain in detail about the effects of aeration and agitation on mass transfer during fermentation.

b) Discuss various Bioreactors used for immobilized Bioprocess.

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

a) Discuss various techniques used for preservation of stock culture.

b) Discuss various cultivation system in fermentation scale up process.

c) Briefly discuss various media for fermentation.

d) Discuss in detail about working and application of Fluidised Bed Reactor.

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

a) Write principle of Bioautography technique.

b) Explain Contineous culture.

c) Discuss significant of rheological properties in Bioprocess.

d) Enlists various methods to preserve stock culture.

e) Write advantages and drawbacks of Batch fermentation process.

P.T.O.

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

a) Discuss in detail about various chromatographic techniques used in down streaming process.

b) Explain various sterilization methods for fermentation media.

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

a) Preservation of stock culture of microbes.

b) HTST sterilization.

c) Immobilization of whole cell.

d) Fed Batch Cultivation.

e) Bioproduction of Vitamin C.

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Total No. of Questions : 5]

SEAT No. :

P8927

[Total No. of Pages : 2

[6111]-541

First Year M.Pharmacy

MPC 103T : ADVANCED MEDICINAL CHEMISTRY

(2019 Credit Pattern) (Semester - I)

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

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Figures to the right indicate full marks.***
3) ***Do not write anything on question paper except seat number.***

Q1) Explain Target identification and validation in drug development. What are the challenges encountered in developing a clinically useful drug? **[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.

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

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

b) Discuss stereo - chemical aspects in drug absorption, distribution, and metabolism.

c) Describe in detail about COX_1 and COX_2 inhibitors.

d) Give focus on antineoplastic antibiotics.

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

a) Comment on neuraminidase inhibitors as antivirals.

b) Explain Rationale of prodrug design and practical consideration of prodrug design.

c) Classify antivirals with suitable example. Write chemistry and mode of action of amantadine.

d) Explain lead identification and optimization.

e) How aspirin is selective COX_1 antagonist? Write mode of action of salicylates.

P.T.O.

Q4) Classify peptidomimetics? Explain designing of peptidomimetics by manipulation of the amino acids. **[15]**

OR

Explain stereoselectivity with examples. Give the significance and role of chirality in specific examples of therapeutic agents.

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

a) Methods for lead search.

b) Histamine receptors.

c) ACE inhibitors as antihypertensive agents.

d) Explain Enzyme inhibitors in medicine.

e) Strategies to combat drug resistance in antibiotics.

Total No. of Questions : 5]

SEAT No. : ____

P-9705

[Total No. of Pages : 2

[6111]-542
F.Y. M.Pharmacy
(MPG-103T) : PHYTOCHEMISTRY
(2019 Pattern) (Semester - I)

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

Instructions to the candidates :

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

Q1) Describe in detail principle, working, application, of SCFE Techniques along with their advantages and disadvantages. **[15]**

OR

Discuss different chromatographic techniques use in structural elucidation of plant drugs.

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

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

b) Explain isolation, purification, characterization and industrial importance of Digitoxin.

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

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

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

a) Discuss in detail stationary and mobile phases used in liquid and gas chromatography.

b) Explain successive and exhaustive extraction.

c) Explain in detail clinical studies emphasizing on phases of clinical trials.

d) Explain in detail the lead structure selection process and structure development in drug discovery and development.

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

P.T.O.

Q4) Discuss in detail about preparative HPLC and flash chromatography techniques of separation of plant drugs. **[15]**

OR

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

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

a) Methods of fractionation.

b) Structural elucidation of menthol.

c) GCMS Fingerprinting.

d) Structural elucidation of Kaempferol.

e) Structure development and product discovery process in natural products.

▽▽▽▽

Total No. of Questions : 5]

SEAT No. :

P8928

[Total No. of Pages : 2

[6111]-543

First Year M.Pharmacy

MPH 103T : MODERN PHARMACEUTICS

(2019 Credit Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) What are optimization parameters? Explain factorial design using suitable example. **[15]**

OR

Explain in detail physics of tablet compression.

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

a) Explain stability of emulsion in detail.

b) Validation of rotary mixer granulator.

c) Discuss various dissolution models.

d) What is Heckel plot? Give its significance.

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

a) Explain scope and importance of validation.

b) Explain concept of inventory management and control.

c) Discuss study of consolidation parameters.

d) Give significance of similarity (f2) and dissimilarity (f1) factor.

e) Elaborate concept of industrial and personal relationship.

P.T.O.

Q4) What is diffusion? Explain factors affecting diffusion. Add a note on Higuchi model. **[15]**

OR

Explain in detail formulation of small volume parenteral along with its evaluation tests.

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

a) Explain pharmacokinetic parameters.

b) Analytical techniques used in drug - excipients interactions.

c) Simplex method as an optimization tool.

d) Sale forecasting.

e) Concept of total quality management.

Total No. of Questions : 5]

SEAT No. :

P8929

[Total No. of Pages : 2

[6111]-544

First Year M.Pharmacy

MPL 103T : PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(2019 Credit Pattern) (Semester - I)

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

Instructions to the candidates:

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

Q1) Discuss the various methods employed in the screening of anti-diabetic agents. **[15]**

OR

Discuss the various methods employed in the screening of hepatoprotective agents.

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

a) Describe in detail the different in vivo models employed in the screening of antiepileptic.

b) Discuss the various methods employed in the screening of anti - hypertensive agents.

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

d) Describe the screening methods for anxiolytic agents.

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

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

b) Describe the advantages of alternative experimental models.

c) Write the screening methods for antipsychotic agents.

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

e) Explain various methods used in screening of immunomodulators.

P.T.O.

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

OR

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

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

a) Immunoassay for insulin.

b) Principles of optimization of immunoassay

c) CPCSEA Guidelines for animals

d) Limitation of animal experimentation

e) Good laboratory practice of experimental animals.

Total No. of Questions : 5]

SEAT No. :

P-8930

[Total No. of Pages : 2

[6111]-545

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

QUALITY CONTROL AND QUALITY ASSURANCE

(2019 Pattern) (Semester - I) (MQA 103T)

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

Instructions to the candidates :

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

Q1) Discuss in detail the IPQC and FPQC tests for tablet dosage form **[15]**

OR

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

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

a) Discuss in detail the structure of ICH and steps in ICH process.

b) Discuss in detail the concept and evolution of quality contol and quality assurance. Give the responsibilities of quality control department.

c) Write in detail about CTD & eCTD.

d) Discuss about Good Warehousing Practices.

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

a) Write about mix-ups and cross contamination.

b) Discuss the IPQC & FPQC for the creams.

c) What is change control? Explain the design of documents for change control.

d) Elaborate about retention and retrieval of documents in Pharmaceutical Industry

e) Write about controlled and uncontrolled documents.

P.T.O.

Q4) Discuss in detail about IPQC and FPQC tests of parenteral dosage form. **[15]**

OR

Discuss in detail about CPCSEA guidelines with protocol for conduct of nonclinical testing.

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

a) Three tier documentation

b) Drug product reprocessing and salvaging

c) Batch manufacturing record

d) Sanitation of manufacturing premises in pharmaceutical industry.

e) CDER and CBER.

Total No. of Questions : 5]

SEAT No. :

P-9884

[Total No. of Pages : 2

[6111]-546A

M. Pharmacy

MRA-103 T: CLINICAL RESEARCH REGULATIONS

(2019 Pattern) (Semester - I)

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

Instructions to the candidates:

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

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

a) Define clinical research. Explain in brief about various phases of clinical research. Write a note on dose escalation method.

b) Explain in brief about ICMR ethical guidelines for biomedical research.

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

a) Write the responsibilities of sponsor, CRO and investigator in ethical conduct of clinical research.

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

c) Explain about E7 guidelines on Studies in support of General Geriatrics Population.

d) Describe briefly biostatistics applied in clinical research,

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

a) Write a note on Ethics of clinical research in special population.

b) ANDA regulations, governing clinical trials.

c) Write the informed consent process and documentation in clinical trials.

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

e) Explain the different types of clinical Studies.

P.T.O.

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

a) Discuss in brief about important features of Good Clinical Practice Guidelines (ICH GCP E6).

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

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

a) Nuremberg Code.

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

c) Purpose, scope and recordkeeping in context of CFR 21 part 54.

d) Clinical research regulations in European Union.

e) FDA Med Watch.

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Total No. of Questions : 5]

SEAT No. :

P8932

[Total No. of Pages : 2

[6111]-547

First Year M.Pharm. (Pharmaceutical Biotechnology)

MPB - 104T : ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

(2019 Credit Pattern) (Semester - I)

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

Instructions to the candidates:

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

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

a) Discuss various drug delivery approaches for therapeutic proteins.

b) Discuss detail classification and general properties of enzymes.

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

a) Explain microbial biodegradation of chemical and industrial wastes.

b) Briefly discuss various cell signaling pathways.

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

d) Explain Biotransformation process for chiral drugs.

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

a) Write flow chart for production of Insulin by r-DNA technology.

b) What are Restriction Endonuclease Enzymes? Write their various classes.

c) Briefly explain various oncogenes.

d) Write the significant of Human Genome Project.

e) Write the applications of microbes in environment monitoring.

P.T.O.

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

a) Discuss the production of therapeutic protein from transgenic animals.

b) Discuss various cell signaling defects and disease.

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

a) Production of Trypsin.

b) Xenobiotics.

c) Production of single cell protein.

d) r-DNA production of Hepatitis-B vaccine.

e) Biosensors.

Total No. of Questions : 5]

SEAT No. : ____

P8933

[Total No. of Pages : 2

[6111]-548
First Year M.Pharmacy
PHARMACY 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.***
3) ***Draw well labelled diagrams wherever necessary.***

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

Explain how antimalarial drug therapy has developed from certain plants.

OR

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

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

a) What are characterization details for Vit-C.

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

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

d) Discuss in detail structural elucidation of ephedrine.

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

a) Explain male sex hormones giving chemistry and structures.

b) Explain chemistry of macrolid antibiotics.

c) Write importance of cardiac glycosides. Giving their structure.

d) Discuss structural elucidation of Reserpine.

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

P.T.O.

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

Explain the significance of anticancer drugs developed from plant sources.

OR

Discuss structural characterization using IR, ^{1}H-NMR, ^{13}C-NMR and Mass spectroscopy for following natural compounds : Camphor and any 1 Digitalis glycosides.

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

a) Physiological significance of Vitamin C and Folic acid supplements.

b) Development of agents derived from plant sources for Liver dysfunction.

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

d) Write the active constituents present in following crude drugs: *Gymnema sylvestre and Salacia reticulate* in diabetic therapy.

e) Discuss clinical applications of rDNA technology.

Total No. of Questions : 5]

SEAT No. : ____

P8934

[Total No. of Pages : 2

[6111]-549

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

Q1) What are regulatory requirements to assure the quality in herbal/natural products? **[15]**

OR

Elaborate current challenges in upgrading and modernization of herbal formulations.

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

a) Write note on Foreign Trade Policy of India.

b) What is novelty and non-obviousness?

c) Describe protocols for stability testing of natural products.

d) Explain global regulatory status of herbal drugs.

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

a) What is Total Quality Management (TQM) explain its principle.

b) Write note on “ISO-9000”.

c) Describe process of project selection.

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

e) What do pilot scale and scale up mean?

P.T.O.

Q4) What are WHO guidelines for assessing quality of herbal medicines with reference to Pesticide residues? **[15]**

OR

Explain comparative monograph parameters for herbal drug in Indian Pharmacopoeia, Siddha Unani Pharmacopoeia and Ayurvedic Pharmacopoeia.

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

a) Copyright.

b) Capital management.

c) Plant Design Steps.

d) TRIPS.

e) Patent opposition, revocation.

Total No. of Questions : 5]

SEAT No. : ____

P8935

[Total No. of Pages : 2

[6111]-550

First Year M.Pharmacy

MPH 104T : 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) Long answer questions (Any 1) **[1 × 15 = 15]**

a) Explain in details about Hutch Waxman act.

b) Explain the regulatory requirement of combination products for market authorization.

Q2) Medium length answers (Any 2) **[2 × 7.5 = 15]**

a) Explain the concept of BA and BE with special emphasis on its outsourcing in CRO.

b) Describe general requirements of filling ANDA approval process.

c) Explain SUPAC concept in pharmaceutical industry.

d) What is MFR. Give various parts of MFR.

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

a) Give the organization and benefits of CTD.

b) TGA and its objectives.

c) Give the significance of post-market surveillance required by FDA.

d) What are ICH guidelines? Explain their significance with examples.

e) What is significance of coordination between Industry & FDA?

P.T.O.

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

a) Explain in details about NDA & ANDA regulatory process.

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

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

a) Differentiate between CTD & e-CTD.

b) CFR Title-21

c) HIPAA

d) MAHR

e) DMF

Total No. of Questions : 5]

SEAT No. :

P-8936

[Total No. of Pages : 2

[6111]-551

M. Pharmacy

MPL-104 T: CELLULAR AND MOLECULAR PHARMACOLOGY

(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 neat labelled diagrams wherever necessary.***

Q1) Discuss the principles and applications of DNA recombinant technology. **[15]**

OR

Discuss Pharmacogenomics. Explain role of gene variation in health. **[15]**

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

a) How cell signaling and communication takes place between cells?

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

c) Discuss the role of caspases in apoptosis.

d) Explain in detail, principles and applications of flow cytometry.

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

a) What is DNA electrophoresis? Give its applications.

b) Describe the types of immunotherapeutics.

c) Explain principle and applications of flow cytometry.

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

e) Describe basic equipments used in cell culture laboratory.

P.T.O.

Q4) Describe structure and functions of cells in detail. **[15]**

OR

Explain the types of ELISA. Give its advantages, disadvantages and applications. **[15]**

Q5) Write short note on (ANY THREE) **[15]**

a) Gene sequencing.

b) SDS PAGE

c) JAK / STAT signaling pathway.

d) General procedure for cell culture.

e) Cryopreservation.

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Total No. of Questions : 5]

SEAT No. :

P-8937

[Total No. of Pages : 2

[6111]-552

M. Pharmacy

MQA104 T : PRODUCT DEVELOPMENT AND TECHNOLOGY TRANFER

(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 neat labelled diagrams wherever necessary.***

Q1) Explain solubility, Enlist methods to improve solubility and discuss in detail any one method to improve solubility of drug. **[15]**

OR

Explain the concept of pre-formulation studies and discuss pre-formulation parameters for drug substance.

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

a) Explain concept and significance of pilot plant scale up and give details of large scale manufacturing technique with respect to equipment, process and quality control of parenteral dosage form.

b) Explain in detail stages of drug discovery and development.

c) Explain steps in technology transfer from R & D to production and give constitution of technology transfer team and their responsibilities.

d) Describe types of plastics used in pharmaceutical packaging and explain Aseptic packaging systems.

P.T.O.

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

a) Explain the stability testing process while product development.

b) What is polymorphism and explain technique to study polymorphism of drug substance.

c) Explain the various issues facing modern drug packaging.

d) Explain technique for the study of crystal properties of drug.

e) Explain the quality control test for container and closures.

Q4) Discuss in detail manufacturing, manufacturing flow chart and in - process quality control test of emulsion. **[15]**

OR

Explain in detail documentation in technology transfer with regards to development report, technology transfer plan and exhibit plan.

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

a) Write a note on IND

b) Write a note on Scale Up Post Approval Change (SUPAC)

c) Write a note on ANDA

d) Write a note on post marketing surveillance

e) Write a note on Supplemental New Drug Application (SNDA).

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Total No. of Questions : 5]

SEAT No. :

P-8938

[Total No. of Pages : 2

[6111]-553

M. Pharmacy

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

(2019 Pattern) (Semester - I)

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

Instructions to the candidates:

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

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

a) Explain in detail regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals and Food & Nutraceuticals in India.

b) Discuss guidelines for drug testing in animals along with CPCSEA guidelines. Give rationale for conducting studies.

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

a) Discuss ICMR-DBT guidelines for stem cell research.

b) Explain formats and contents of regulatory dossier filing for clinical trials or investigations.

c) Ethical guidelines for human participants.

d) Explain the responsibilities of CDSCO & State licensing authority.

P.T.O.

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

a) Give ICH and WHO guidelines for stability study.

b) Explain regulatory requirements for Bioequivalence study.

c) Offences & penalties in narcotic drugs & psychotropic substances.

d) Describe copyright & work protected under copyright act.

e) Define industrial design & explain role of IPR to protect it.

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

a) Explain bioavailability and bioequivalence study in detail along with BCS classification of drugs and regulatory requirements.

b) Explain rules schedules and guidelines of Narcotics Drugs and Psychotropic Substances Act.

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

a) Patent Act 1970 & its amendments.

b) Schedule M framed under D & C act rules there under.

c) Drugs and Magic Remedies act 1955.

d) Guidelines for Drugs and Cosmetics act 1940 and rules 1945.

e) Define and give role

i) Copyright

ii) Trademark

iii) Drugs and Cosmetics

iv) Industrial Design

v) BIS

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Total No. of Questions : 5]

SEAT No. :

P-9880

[Total No. of Pages : 2

[6111]-554A

F.Y. M. Pharmacy

MPB201T : PROTEINS & PROTEIN FORMULATION

(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

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

a) Write in brief on Biophysical characterization of proteins.

b) Define and classify Peptidomimetics with example.

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

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

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

c) Write a note on Edman sequencing.

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

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

a) Explain various chromatographic techniques in protein purification.

b) Describe in brief liposomes in protein formulation.

c) What kind of inhibitors are transition state analogs?

d) Enlist the stability problems in proteins? Explain in brief.

e) How does Edman degradation help in protein sequencing?

P.T.O.

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

a) What is protein engineering? Explain the approaches & applications of protein Engineering.

b) What is Proteomics? Explain in brief techniques of proteomics.

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

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

b) Tryptic Peptide Mapping.

c) A note on ACEI inhibitors.

d) Explain different types of proteomics.

e) Forced degradation studies of protein.

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Total No. of Questions : 5]

SEAT No. : ____

P8939

[Total No. of Pages : 2

[6111] - 555

M.Pharmacy

MPC 201T : ADVANCED SPECTRAL ANALYSIS

(2019 Credit Pattern) (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) ***Black figures to the right indicate full marks.***

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

OR

Write elaborative note on 2D NMR. How 2D NMR techniques are different from 1D NMR techniques?

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

a) Explain instrumentation and application of Supercritical fluid Chromatography.

b) How will you differentiate the following pair of compounds from their IR spectra?

i) Formaldehyde and Acetone

ii) Methyl amine and Dimethyl amine

iii) Methanol and Formic acid

c) Predict and explain the chemical shift (δ) values and spin-spin splitting in the NMR spectrum of

i) *n*-butanol

ii) 2-chloropropane

iii) acetaldehyde

iv) *n*-propylamine.

d) Explain general fragmentation rules for interpretation of organic compounds in mas spectrometry.

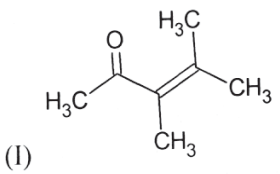
P.T.O.

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

a) Explain Mc-Lafferty rearrangement with suitable example.

b) Write a note on CE-MS.

c) Predict the UV maxima for each of the following subtances.



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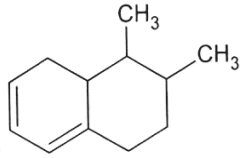

(II)

d) Discuss Metastable ion peaks and isotopic peaks in mass spectrometry.

e) Explain ATR highlighting its principle.

Q4) a) Find out the probable structure of compound from the following data; **[15]**

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

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

^1H NMR (δ ppm) :

i) δ: 0.88, singlet, 6H

ii) δ: 1.86, multiplet, 1H

iii) δ: 2.45, doublet, 2H

iv) δ: 7.15, singlet, 5H

b) Write a note on LC-FTIR.

OR

What are Radioimmunoassays? Explain Radioimmunoassay for

i) Inuslin

ii) Digitalis

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

a) Flash Chromatography

b) Applications of GC-AAS

c) COSY in NMR

d) Ring rule in MS

e) ELISA

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Total No. of Questions : 5]

SEAT No. :

P8940

[Total No. of Pages : 2

[6111]-556
First Year M.Pharmacy
MPG201T : MEDICINAL PLANT BIOTECHNOLOGY
(2019 Credit Pattern) (Semester - II)

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

Instructions to the Candidate:

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 genetic code? Give its silent features. Explain regulation of gene expression with suitable example.

OR

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

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

a) Explain different immobilization technique of plant cell. Give its applications.

b) Write about DNA recombinant technology with its applications.

c) Define fermentation? Give its application in pharmacy and allied fields.

d) Explain mechanism of protoplast fusion with suitable example.

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

a) What is biotransformation? Explain bioreactors for pilot and large scale cultures of plant cell.

b) Explain DNA replication with its applications.

c) Write a note on 'synthetic seed and monoclonal variation'.

d) Explain the regulation of gene expression with suitable example.

Q4) What is PCR? Explain various applications of PCR in plant genome analysis. **[15]**

OR

What is RNA? Give its types. Explain RNA replication with its significance.

P.T.O.

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

a) Gene transfer in plants and its applications

b) Organogenesis and Embryogenesis

c) Single cell Protein

d) Precursors and elicitors on the production of Secondary metabolites.

Total No. of Questions : 5]

SEAT No. :

P8941

[Total No. of Pages : 2

[6111]-557
First Year M.Pharmacy
MOLECULAR PHARMACEUTICS
MPH 201T : 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 right indicate full marks.***
3) ***Draw neat diagrams wherever necessary.***

Q1) Solve any one out of two. **[15]**

a) What are the concepts, events and biological process involved in drug targeting?

OR

b) Describe in detail methods of preparation of liposomes

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

a) What are critical aspects in evaluation of nanoparticle?

b) Explain liposomal gene therapy.

c) Explain method for preparation of niosomes.

d) Write in detail on application of monoclonal antibodies.

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

a) What is ex-vivo therapy?

b) Differentiate between aquasomes and phytosomes.

c) Discuss evaluation of aerosol.

d) Discuss aptamer as drug of future.

e) Explain dry powder inhaler.

P.T.O.

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

a) Write in detail on preparation and evaluation of microspheres.

b) Discuss different types of intra nasal route delivery system and explain factors affecting nasal drug absorption.

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

a) Liposomal gene therapy

b) Brain targeting

c) Electrosomes

d) Propellant

e) Non-viral gene transfer

Total No. of Questions : 5]

SEAT No. :

P8942

[Total No. of Pages : 2

[6111]-558
First Year M.Pharm.
MPL201T: Advanced Pharmacology-II
(2019 Credit Pattern) (Semester - II)

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

Instructions to the Candidate:

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) Classify Oral Hypoglycemic agents. Write the pharmacology of sulphonylureas.

b) Write the mechanism of action, antimicrobial spectrum, antimicrobial resistance and therapeutic uses of penicillin.

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

a) Explain pharmacology of antiulcer drugs

b) Classify immunosuppressant drugs based on mechanism of action.

c) Discuss the biochemical mechanism of antibiotic resistance.

d) Explain Patho-physiological role of thyroid hormones.

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

a) Explain the Pharmacotherapy of Diarrhoea

b) Discuss the mechanism of actions of first generation anti- TB drugs.

c) Write the applications of chronopharmacology in treatment of peptic of ulcer

d) Write the pharmacotherapy of irritable bowel syndrome

e) What are antioxidants? Write various types of radicals. Write the role of free radicals in the etiopathology of diabetes.

P.T.O.

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

a) Classify antiasthamatics. Explain in detail pharmacology of bronchodilators.

b) Write classification, mechanism of action, antimicrobial spectrum, antimicrobial resistance and therapeutic uses of aminoglycosides.

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

a) Toxicity of anticancer drugs.
b) Insulin
c) Curcumin as an antioxidant.
d) Antithyroid drugs
e) Prokinetics

Total No. of Questions : 5]

SEAT No. : ____

P-8943

[Total No. Of Pages : 2

[6111] - 559
F.Y.M. Pharm
PHARMACEUTICAL QUALITY ASSURANCE
Hazards and Safety Management
(2019 Pattern) (Semester - II) (MQA - 201T)

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

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

Q1) Explain air circulation in pharmaceutical industry for non-sterile area. Add a note on the HVAC system. **[15]**

OR

Explain ICH Guidelines on risk assessment and risk management methods and tools. **[15]**

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

a) Discuss in detail on control strategies for handling of toxic gases and oxygen displacing gases.

b) Discuss the Hazards related to Radioisotopes.

c) Describe various physicochemical parameters for measurement of effluents.

d) Explain strategies for accident prevention.

P.T.O.

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

a) Explain in brief the various hazards which can occur due to air and water and suitable measures to prevent them.

b) Discuss the strategies for fire prevention.

c) Write in short about critical training for risk management.

d) Elaborate on Management of over exposure to chemicals and significance of various Threshold limits.

e) Add a note on Preliminary Hazard analysis.

Q4) a) What are Industrial hazards? Classify types of chemical hazards and its influence on environment. Add a note on MSDS. **[15]**

OR

b) Explain Fire triangle and discuss the strategies for fire extinguishment.

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

a) Protective and preventive management from fires and explosions

b) Write in brief about disposal of hazardous material.

c) Explain the role of emergency services in hazard management

d) Give in detail about natural resources and methods of conservation.

e) Discuss physicochemical measurement of effluents.

Total No. of Questions : 5]

SEAT No. :

P-8944

[Total No. Of Pages : 2

[6111] - 560
F.Y. M. Pharmacy
MRA201T: Regulatory Aspects of Drugs and Cosmetics
(2019 Pattern) (Semester - II)

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

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

Q1) Explain Hatch Waxman Act? Discuss the impact of this Act on drug approval and Highlight the key aspects of SNDA **[15]**

OR

Explain the regulatory requirements for registrations of drugs and post approval requirements in China. **[15]**

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

a) Write briefly about packaging and labelling requirements in EU

b) Explain DMF system in Japan

c) Describe regulatory pre-requisites related to marketing authorization requirements for drugs in Russia.

d) Describe regulatory pre-requisites related to marketing authorization requirements for drugs in Brazil.

P.T.O.

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

a) Discuss about post-marketing surveillance in Japan

b) Explain New Drug Application(NDA)

c) Describe history and evolution of United States Federal, Food, Drug and Cosmetic

d) Describe the regulations of sale of cosmetics in CIS countries.

e) Discuss the import of cosmetic in ASEAN countries.

Q4) a) Describe Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA **[15]**

b) Explain the regulatory requirements for registrations of drugs and post approval requirement in South Korea.

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

a) Certificate of suitability (CoS) in EU

b) Active Substance Master Files (ASMF) system in EU

c) Content and approval process of IMPD

d) Prerequisites for marketing authorization of drugs in CIS countries

e) Certificate of Pharmaceutical Product

Total No. of Questions : 5]

SEAT No. :

P8945

[Total No. of Pages : 2

[6111]-561

F.Y. M.Pharm. (Pharmaceutical Biotechnology)

MPB 202T : IMMUNOTECHNOLOGY

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

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

Instructions to the candidates:

1) ***Answer all questions.***
2) ***Figures to the right indicate full marks.***

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

Discuss in detail about Hypersensitivity types - I to IV reactions.

OR

Discuss in detail about primary and secondary lymphoid organs.

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

a) What are cytokines? Discuss their biological role.

b) Discuss classical pathway of complement system.

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

d) Write examples of organoleptic Autoimmune Diseases.

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

a) Differentiate between primary and secondary lymphoid organs.

b) Write basic characteristics of complement system.

c) Discuss about primary lymphoid organs.

d) Enlist cytokines that regulate adaptive immune response.

e) List out activators for alternative pathway.

P.T.O.

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

What is Hybridoma Technique? Discuss in detail methodology of Hybridoma Technique.

OR

Discuss on attenuated and inactivated viral vaccines.

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

a) Interferon - y

b) Principles and applications of ELISA.

c) Antigen Presenting Cells (APC)

d) Peptide vaccine

e) Tumor Necrosis Factor (TNF)

Total No. of Questions : 5]

SEAT No. : [ ]

P-8946

[Total No. of Pages : 2

[6111]-562

F.Y.M. Pharmacy (Pharmaceutical Chemistry)

MPC-202 T: ADVANCED ORGANIC CHEMISTRY - II

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

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

Instructions to the candidates:

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

Q1) Elaborate on Fmoc, Boc and Benzyl protection strategies in peptide synthesis with suitable examples. Add a note on the cleavage reagents used for deprotection. **[15]**

OR

Elaborate on various strategies of asymmetric synthesis with suitable examples. Comment on examples of chiral pool.

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

a) Explain mechanism of Diel's Alder Reaction.

b) Write Principle involved in Microwave assisted reactions. Add note on its applications in synthesis.

c) Explain Working principle, advantages and synthetic applications of continuous flow reactors.

d) Elaborate on the rules for nomenclature of stereoisomers.

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

a) Add a note on resolution of racemic mixture.

b) Discuss Various resins and linkers used in solid phase peptide synthesis.

c) Differentiate between homogenous and heterogenous catalysis.

d) Discuss various examples of reactions catalysed by Transition Metals.

e) Describe mechanism involved in photochemical reaction with suitable examples.

P.T.O.

Q4) Explain with suitable example [3,3] and [2,3] Sigmatropic rearrangement. Add a note on Woodward Hoffman Rule. **[15]**

OR

Discuss in detail each Principle of Green Chemistry with examples.

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

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

b) Write a note on electrocyclic reactions.

c) Elaborate on synthetic applications of Ultrasound assisted reactions.

d) Discuss examples and applications of ionic liquids.

e) Elaborate on principle involved in Phase transfer catalysis.

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Total No. of Questions : 5]

SEAT No. : ____

P-8947

[Total No. of Pages : 2

[6111]-563

F.Y. M. Pharmacy

MPG-202 T: ADVANCED PHARMACOGNOSY - II

(2019 Pattern) (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.***

Q1) Attempt Any One Question : **[15]**

a) Elaborate detail account of determination of Pesticide Residues and Heavy Metals in herbs and their formulations along with its significance.

b) Elaborate detail analytical profile of *Emblica officinalis* along with its Pharmacological significance.

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

a) Explain in detail different Types of Adulteration and substitutions of herbal drugs.

b) Comment on analytical profile of *Andrographis paniculata*.

c) Discuss in *vivo* evaluation techniques for Hepatoprotective drugs.

d) Elaborate a detail account of Efficacy of Herbal medicinal products.

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

a) Comment on impact of microbial contamination on quality of natural drugs.

b) Comment on Pharmacodynamic issues of herbal remedies with suitable examples.

c) Comment on analytical profile of *Coleus forskholii*.

d) Explain in detail regulations in herbal remedies.

e) Explain the concept of Ethnopharmacology and its significance in drug evaluation.

P.T.O.

Q4) Attempt Any One Question : **[15]**

a) Elaborate in detail Role of Ethnobotany in herbal drug evaluation and its Impact on traditional medicine.

b) Discuss in details Phyto-Pharmacological Screening of drugs with emphasis on New Strategies for evaluating of Natural Products

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

a) Analytical Profiles of *Psoralea corylifolia*

b) Validation in Herbal Therapies

c) Bioprospecting is a tools for drug discovery

d) Pharmacokinetic issues of Herbal remedies

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

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Total No. of Questions : 5]

SEAT No. :

P-8948

[Total No. Of Pages : 2

[6111] - 564
M. Pharmacy
MPH202T: Advanced Biopharmaceutics and Pharmacokinetics
(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) Discuss in detail how various pharmacokinetic parameters can be estimated when a drug is given as an i.v. bolus injection and follows one compartmental model? **[15]**

OR

What is non linear pharmacokinetics? What are the causes and how will you determine the nonlinearity? Comment on determination of Michaelis- Menten constant.

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

a) Explain the basis of BCS classification. Discuss different models for determination of permeability.

b) Explain about pH - partition Hypothesis.

c) Explain how, the 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.

d) What is the effect of presystemic metabolism on bioavailability of drug? How it can be addressed?

P.T.O.

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

a) Explain what dose - dependent kinetics is? Give methods of detection.

b) Write a note on value of distribution and its importance.

c) If the drug is given by i.v. bolus route and the elimination rate constant Ke of drug is $0.153hr^{-1}$ and total clearance is found to be 51.07 L/hr, calculate half-life and volume of distribution of drug V_d

d) Using Noyes-Whitney's equation, discuss the diffusion layer theory and the variables that influence drug dissolution.

e) Write a note on cytochrome P-450 based drug interactions. What is the effect of these interactions on bioavailability of drug?

Q4) Discuss in detail about various types of pharmacokinetic models explain their significance and limitations. **[15]**

OR

What are the problems associated with bioavailability of drug? How these issues can be addressed by various formulation approaches?

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

a) Pharmacokinetic applications to modified drug released products.

b) Compare Compartmental modeling with non-compartmental model.

c) Compare single dose studies Vs multiple dose BA/BE studies.

d) What are biowaivers? Discuss regulatory guidelines for biowaivers.

e) Method of residuals for estimation of Ka.

Total No. of Questions : 5]

SEAT No. :

P-8949

[Total No. of Pages : 2

[6111]-566

F.Y. M. Pharmacy

MPL 202T: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

(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 in brief the importance and applications of toxicokinetic studies. Write a note on toxicokinetic evaluation of preclinical studies.

b) Define acute, chronic and subacute study. Explain the process of determining LD50 in acute toxicity testing of drugs as per OECD guidelines.

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

a) Explain how will you test the compound for carcinogenicity?

b) Discuss the importance of male reproductive toxicity studies.

c) Explain the Inhalation studies as per OECD guidelines.

d) Define safety pharmacology. Write its concept and importance.

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

a) Describe in detail the Tier l and Tier 2 safety pharmacology studies.

b) Explain *in vivo* and *in vitro* genotoxicity studies.

c) Discuss acute eye irritation studies.

d) Write a note on assessment of renal toxicity studies.

e) Discuss the *in vivo* methods of assessing female reproductive toxicity studies.

P.T.O.

Q4) Attempt Any One **[15]**

a) Explain in brief about alternative methods for animal toxicity studies.

b) Discuss the key features of ICH guidelines for toxicity studies.

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

a) Chromosomal aberration studies.

b) HERG assay

c) Teratogenicity studies

d) Types of toxicology

e) Importance of IND

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Total No. of Questions : 5]

SEAT No. :

P-8950

[Total No. of Pages : 2

[6111]-567

F.Y. M. Pharm.

MQA 202T: PHARMACEUTICAL VALIDATION

(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

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

a) What is Qualification? Explain the Factory acceptance test and Site Acceptance test.

b) What is Computerised System Validation? Discuss GAMP 5V model

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

a) Qualification of pure steam system.

b) Explain the need of requalification after Preventive Maintenance.

c) Comment on cleaning of pharmaceutical facility and cleaning equipment used.

d) Rights of patentee

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

a) Explain qualification of autoclave

b) Discuss merits and demerits of validation.

c) Retrospective validation

d) Discuss the stage of "Process Design" during process validation

e) Benefits to patentee

P.T.O.

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

a) Differentiate between Calibration, Validation and Qualification.

b) Comment on Process validation of creams and ointments.

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

a) Explain working of HVAC system. How is it validated?

b) Give an account of different water treatment system validation.

c) "Qualification steps for HPTLC".

d) Cleaning in Place.

e) Method validation parameters for limit test.

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Total No. of Questions : 5]

SEAT No. :

P-9707

[Total No. of Pages : 2

[6111]-568

M. Pharmacy

MRA202T : REGULATORY ASPECTS OF HERBALS & BIOLOGICALS

(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

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

OR

Write the detailed information on how to package and label biological products as per USFDA.

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

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

b) Make a note in the master file of Pluma.

c) Give a word on the laws, safety, and quality of herbal goods in India.

d) Write a note on pharmacovigilance.

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

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

b) List the distinctions between biosimilars and generic medications.

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

d) Write about the TSE/BSE assessment.

e) What guidelines govern the determination of biosimilarity?

P.T.O.

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

OR

Describe in completely the USA BLA application procedure.

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

a) What labeling specifications do US legislation stipulate for blood products?

b) Market Authorization Application Data Requirements as per EU.

c) What are the European Union's vaccination safety regulations?

d) Compose a note about EU advertising regulations.

e) Explain about the US Blood and Blood Products Regulations additional requirements.

Total No. of Questions : 5]

SEAT No. :

P8951

[Total No. of Pages : 2

[6111]-569

First Year M.Pharmacy (Pharmaceutical Biotechnology)

MPB203T : BIOINFORMATICS AND COMPUTER TECHNOLOGY

(Credit 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. **[15]**

Discuss in detail protein structure prediction.

OR

Explain in detail "multiple sequence alignment".

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

a) What is drug designing? Explain the principle of drug design.

b) Discuss homology modelling?

c) What is lead discovery? Explain application of bioinformatics in microarray analysis?

d) What is FASTA and BLAST?

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

a) Define bioinformatic. What are bioinformatic databases?

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

c) What are the components of Bioinformatics?

d) Write application of Bioinformatics.

e) Write about high throughput screening and virtual screening.

P.T.O.

Q4) Long answer question. **[15]**

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

OR

Write in detail about the evolutionary change in nucleotide sequence and add a note on nucleotide substitution.

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

a) Discuss methods of protein ligand docking.

b) What is importance of nucleotide sequence and write about pattern of nucleotide?

c) What is CLUSTALX?

d) Classify methods of protein ligand docking?

e) Write a note on Nematode biology.

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Total No. of Questions : 5]

SEAT No. :

P8952

[Total No. of Pages : 2

[6111]-570

First Year M.Pharmacy (Pharmaceutical Chemistry)

MPC 203T : COMPUTER AIDED DRUG DESIGN

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

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

Instructions to the candidates:

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

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

OR

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

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

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

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

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

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

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

a) Free Wilson analysis.

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

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

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

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

P.T.O.

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

OR

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

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

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

b) Conformational analysis

c) Contour map analysis

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

e) *Hansch* analysis

Total No. of Questions : 5]

SEAT No. :

P8953

[Total No. of Pages : 2

[6111]-571

First Year M.Pharmacy (Pharmacognosy)

MPG 203T : 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) Describe stability studies and shelf life of ISM formulation. **[15]**

OR

Explain Good manufacturing practice of Indian system of medicine.

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

a) Explain Aromatherapy in detail.

b) Explain Geographical indication bill

c) Explain various meditation and meditation techniques.

d) What is Gunapadam. Explain in detail?

Q3) Solve any - three. **[15]**

a) Explain CCRAS in detail.

b) Elaborate Ayurveda system of medicine.

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

d) Elaborate raw drugs in Siddha system of medicine.

P.T.O.

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

a) Describe principles of treatment in Homeopathy system of medicines.

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

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

a) GAP

b) ISM

c) Explain Yoga system in detail.

d) CCRS

e) Explain Preparation technique as per Unani Pharmacopeias.

Total No. of Questions : 5]

SEAT No. :

P8954

[Total No. of Pages : 2

[6111]-572

First Year M.Pharmacy

MPH 203T : COMPUTER AIDED DRUG DEVELOPMENT

(2019 Credit Pattern) (Semester - II)

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

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Answer of the two sections should be written in 2 separate answer books.***
3) ***Digits written at right side indicate full marks of that question.***

Q1) Answer in details (Any 1 out of 2). **[1×15=15]**

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

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

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

a) Explain in brief computational modelling for drug disposition.

b) Write a detail account on AI and robotics.

c) Explain IVIVC in detail and give a note on in vitro dissolution.

d) Explain in detail nucleoside transporter OCT and OATP.

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

a) Compare Population and non - Population PK/PD.

b) Write the benefits of pharmaceutical automation in packaging.

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

d) Describe Design Space, Lifecycle and risk assessment.

e) Explain BCRP and hPEPTI.

P.T.O.

Q4) Answer in details (Any 1 out of 2). **[1×15=15]**

a) Explain in detail fed vs fasted state and biowaiver consideration.

b) Write the significance of In - vitro - In vivo correlation in biopharmaceutical characterization.

Q5) Answer in details (Any 3 out of 5). **[3×5=15]**

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

b) Explain in detail computer simulation in whole organism.

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

d) Write a short note on BBB choline transporter.

e) Explain in detail artificial intelligence.

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Total No. of Questions : 5]

SEAT No. :

P-8955

[Total No. Of Pages : 2

[6111]-573
F.Y. M.Pharm.
MPL 203T: PRINCIPLES OF DRUG DISCOVERY
(2019 Pattern) (Semester - II)

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

Instruction to the candidates:

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

Q1) Long answer questions

a) Explain methods and importance of Genomics, Proteonomics and Bioinformatics **[15]**

OR

b) How will you explain role of transgenic animals in target validation **[8]**

c) Explain in brief the role of protein microarrays **[7]**

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

a) Application of NMR and X-ray crystallography in protein structure prediction.

b) Describe molecular docking

c) Characteristics and importance of G-Protein-Coupled Receptors (GPCRs),

d) Describe types of protein structure

P.T.O.

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

a) Note on ELISA

b) Write electrophysiological patch clamp process

c) Write down Importance of Radio Ligand assay system

d) Write note on QSAR statistical method

e) Explain Enzymes and Enzymes Inhibition process in drug discovery

Q4) Long answer Questions **[15]**

a) Write on Biomarkers versus Surrogate End Points. **[8]**

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

OR

c) Explain Ion Channels, Membrane Transport Proteins (Transporters)**[15]**

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

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

b) Biomarkers for diabetes,

c) Definition of Biomarkers and their Classification

d) Note on Radioligand Assay Systems (RIA)

e) Explain Electrophysiological Patch Clamp

Total No. of Questions : 5]

SEAT No. :

P-8956

[Total No. Of Pages : 2

[6111] - 574
F.Y. M.Pharmacy
MQA 203T: AUDIT AND REGULATORY COMPLIANCE
(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) a) Explain significance of audit in pharmaceutical industry. Elaborate planning of audit in detail. **[15]**

OR

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: **[15]**

a) Give detailed discussion on external audit and internal audit along with its advantages.

b) Discuss various types of water system applied in pharmaceutical industry. Differentiate between WFI and SWFI. Explain in detail the manufacturing process, storage conditions and quality control of water for injection system.

c) Describe the auditing criteria for the water and raw materials in the microbiological laboratory.

d) Comment on auditing the solid dosage form department, specifically in tablet and capsule manufacturing processes.

P.T.O.

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

a) Explain about importance and various duties of auditor and auditee

b) Differentiate between process audit & product audit

c) Explain various deficiencies with its detail classification

d) Comment on various responsibilities of Quality Control unit as per cGMP.

e) Explain about audit system for warehouse

Q4) a) Explain the significance of audit for microbiology laboratory. Discuss detailed personnel and sample handling audit of microbiology laboratory. **[15]**

OR

b) Explain in detail about quality systems approach with respect to pharmaceutical cGMP regulations.

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

a) Corrective and preventive action

b) Auditing ETP by pollution control authorities

c) Audit of packaging material vendors

d) Audit checklist for API industries

e) FEFO and FIFO

Total No. of Questions : 5]

SEAT No. :

P-9883

[Total No. of Pages : 2

[6111]-575

F.Y. M. Pharmacy

MRA 203T : REGULATORY ASPECTS OF MEDICAL DEVICES

(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 except Seat number.***

Q1) Explain in details about the investigational device exemption and in vitro diagnostics. **[15]**

OR

Write in detail about quality risk management of medical devices.

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

a) Explain various types of clinical investigation of medical devices

b) Explain role global medical device nomenclature with examples

c) Write classification of medical devices as per Indian Regulations.

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

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

b) Investigational device exemption and in vitro diagnostics

c) Write a note on CE certification process.

d) Explain indetail ISO 13485.

P.T.O.

Q4) Write a note on regulatory approval process for medical devices as per premancet notification. **[15]**

OR

Explain in detail quality system requirements as per 21CFR part 820.

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

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

b) Write a note on product life cycle of madical devices..

c) quality system requirements for medical devices as per ASEAN.

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

e) Write a note on pre-market approval.

Total No. of Questions : 5]

SEAT No. :

P8957

[Total No. of Pages : 2

[6111]-576

First Year M.Pharmacy

MPB 204T : BIOLOGICAL EVALUATION OF DRUG THERAPY

(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) Discuss the general principles of bioassay with an example of any one official drug. Add a note on scope and limitations of bioassay. **[15]**

OR

Discuss biologic medicines in development to treat type II diabetes (NIDDM).

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

a) Explain 'hybridoma technique'.

b) Write on pyrogen test I.P.

c) Describe various pre - clinical toxicity tests.

d) Explain the principles and applications of cell line study.

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

a) Method of residuals.

b) Documents necessary for approval of biologics.

c) Interferon's.

d) Biologic medicines in blood disorder.

e) Preclinical evaluation of biological activity.

P.T.O.

Q4) What are the different pharmacokinetic models? Write in detail on 'compartment modeling'. **[15]**

OR

Write on regulations and documentation for approval of medical devices.

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

a) Discuss objectives of BA/BE studies.

b) Explain 'Wagner - Nelson' method.

c) Describe pharmacokinetic applications in dosage form designing.

d) How safety of packaging material is assessed?

e) What are measures of bioavailability?

Total No. of Questions : 5]

SEAT No. : [ ]

P8958

[Total No. of Pages : 2

[6111]-577

First Year M.Pharm. (Pharmaceutical Chemistry)

MPC204T : PHARMACEUTICAL PROCESS CHEMISTRY

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

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

Instructions to the candidates:

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

Q1) Explain in detail about the impurities in Active Pharmaceutical Ingredients, types and their sources including genotoxic impurities. **[15]**

OR

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

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

a) Define and enlist various unit operations. Comment in detail on crystallization.

b) Define Nitrating agents with examples. Explain kinetics and mechanism of nitration.

c) Define distillation. Comment on azeotropic and steam distillation.

d) Give general method for production of streptomycin.

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

a) Define extraction. Comment in detail on various methods of extraction.

b) Comment on types of fire and fire extinguishers

c) Define oxidation. Explain in detail types of oxidative reactions.

d) What is halogenation? Mention case study on Industrial halogenations process.

e) Comment on bench and pilot scale process.

P.T.O.

Q4) Define fermentation. Give its types. Explain the procedure for production of Lovastatin. **[15]**

OR

What do you mean by industrial safety. Write a detailed note on OHSAS - 1800 and ISO - 1400.

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

a) Enlist and explain factors affecting evaporation.

b) Differentiate between pressure and vacuum filtration.

c) Reaction progress kinetic analysis.

d) Effluents and its management.

e) Production of Vitamin B12.

Total No. of Questions : 5]

SEAT No. : ____

P8959

[Total No. of Pages : 2

[6111]-578

First Year M.Pharmacy (Pharmacognosy)

MPG 204T : HERBAL COSMETICS

(2019 Credit Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) What is preformulation and compatibility studies? Explain in detail. **[15]**

OR

Discuss in detail about regulatory requirement for herbal drug industry. **[15]**

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

a) Write the application of face powder.

b) Discuss different herbs used in polyherbal ointment.

c) Explain method of preparation of hair oil.

d) Describe sunscreen product.

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

a) Explain formulation and evaluation of Conditioners.

b) Explain toxicity of herbal cosmetics.

c) Discuss method of preparation of Herbal lotion.

d) How vanishing creams are prepared.

e) Write about physiology of face powder.

P.T.O.

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

a) Discuss in detail formulation and optimization of herbal cosmetics.

b) Explain in detail manufacturing and evaluation of cleansing cream.

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

a) Physiology of Skin.

b) Vanishing cream.

c) Toxicity screening in animal.

d) Evaluation method of face powder.

e) Herbal Hair growth formulation.

x x x

Total No. of Questions : 5]

SEAT No. :

P8960

[Total No. of Pages : 2

[6111]-579

First Year M.Pharmacy (Pharmaceutics)

MPH204T : COSMETIC AND COSMECEUTICALS

(2019 Credit Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) What are mouthwashes? Explain different types of mouthwashes. Add a note on formulation of mouthwash. **[15]**

OR

Give classification and applications of emollients in cosmetic products. Add a note on rheological additives.

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

a) Explain the common problems associated with teeth and gums.

b) Explain the structure of hair and hair growth cycle.

c) Discuss the factors that affect preservative efficacy in cosmetic formulations.

d) Describe classification of Perfumes and potential allergies listed in EU regulation.

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

a) Building blocks for moisturizing cream and cold cream.

b) Surfactants and its classification.

c) Merits and Demerits of parabens in cosmetic formulation.

d) Antiperspirants.

e) Manufacture related problems of lipsticks.

P.T.O.

Q4) Define sunscreens and give its classification with regulatory aspect. Add a note on evaluation of SPF. **[15]**

OR

What are nail lacquers? Give its ideal properties and explain formulation of nail lacquers.

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

a) Antidandruff formulation.

b) Misbranded and Spurious cosmetics.

c) Evaluation of lipstick formulation.

d) Biological aspects of body odor and effective cosmeceuticals to address the issue.

e) Challenges faced in formulating herbal cosmetics.

x x x

Total No. of Questions : 5]

SEAT No. : ____

P-8961

[Total No. of Pages : 2

[6111]-580

M. Pharmacy

MPL-204T : CLINICAL RESEARCH AND PHARMACOVIGILANCE

(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) Long answer question : **[15]**

Write regulatory guidelines for clinical trials. Note on details of informed consent in clinical trial with example.

OR

Classify Adverse drug reactions. Explain in Detail Adverse drug reaction with examples.

Q2) Medium length answers : solve any two : **[2 × 7.5 = 15]**

a) Phase I, II and III clinical trial.

b) Importance of clinical Research.

c) Clinical trial investigator.

d) "Schedule Y".

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

a) ICH-GCP

b) ADR Reporting system

c) Placebo study in clinical trials

d) Suspected adverse drug reactions with examples.

e) Roles of ICMR

P.T.O.

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

Describe in detail pharmacovigilance.

OR

Write on clinical trial documentation. Add note on phase - IV clinical trial.

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

a) Clinical trial monitoring

b) Methods of ADRs Reactions for detection adverse events.

c) Case report forms

d) IRB in clinical trial

e) Significance of safety monitoring

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Total No. of Questions : 5]

SEAT No. :

P-8962

[Total No. of Pages : 2

[6111]-581

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA - 204 T : PHARMACEUTICAL MANUFACTURING TECHNOLOGY

(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

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

OR

Describe process automation in tablet manufacturing. Add on pelletization and other techniques as improved tablet production methods. **[15]**

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

a) Problems in coating technology and remedies there of

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

c) Area planning in sterile product manufacturing

d) Manufacturing flowchart and IPQC test for capsules.

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

a) What factors should be considered while selecting closure lining

b) CIP

c) Lyophilization technique

d) IPQC test for sterile emulsion and suspensions

e) Analytical QbD

P.T.O.

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

OR

Discuss in detail containers and closures for pharmaceuticals with their advantages and disadvantages. **[15]**

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

a) Stability aspects of packaging material

b) Form Fill Seal Technology

c) PAT

d) Production planning

e) Drug - plastic interaction

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Total No. of Questions : 5]

SEAT No. :

P-9708

[Total No. Of Pages : 2

[6111] - 582

F.Y. M. Pharmacy

MRA 204T : REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

(2019 Pattern) (Semester - II)

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

Instruction to the candidates:

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

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

a) Explain in detail Good Manufacturing Practices for Nutraceuticals.

b) Describe about the regulations aspects for import & manufacture of nutraceuticals products in India.

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

a) What is Nutraceuticals? Give various categories of Nutraceuticals with example.

b) Give details about Recommended Dietary Allowances (RDA) in India.

c) Explain European Regulation on novel food ingredient.

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

P.T.O.

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

a) Give details about responsibilities of USFDA.

b) What is nutraceuticals? Classify them explain any two.

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

d) Recommended dietary allowance in US.

e) European Nutrition labeling requirements.

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

a) Explain role of NSF international in dietary supplements and Nutraceuticals Industries.

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

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

a) Role of Probiotics in management of disease.

b) Scope and Opportunities in Nutraceuticals Market.

c) WHO guidelines on nutrition.

d) Describe about Recommended Dietary Allowance in Europe.

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