Total No. of Questions : 5]

SEAT No. : ____

P2792

[Total No. of Pages : 2

[5855]-101

First Year M. Pharmacy

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(2019 Pattern) (Semester-I) (MPAT101T)

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

Instructions to the candidates:

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

Q1) Explain Van-Deemter equation. Give a comparative account on High performance liquid chromatography and Ultra performance liquid chromatography. **[15]**

OR

Describe various sample introduction techniques and detectors used in Gas chromatography.

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

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

Molecular formula: $C_9H_{10}O$

IR : 3015 cm^{-1} , 1720 cm^{-1}

PMR : δ 7.9 (m,10mm), δ3.65 (s,4 mm),

δ 2.2 (S, 6 mm)

b) Describe TOF, single and double fousing mass analyzers.

c) Elaborate the principle and instrumentation of Differential scanning calorimetry.

d) Describe the ideal properties and types of solvents used in UV, IR and NMR.

P.T.O.

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

a) Write a note on deviations from Beers-Lamberts law.

b) Describe factors affecting TGA results.

c) Discuss factors affecting guenching of fluorescence.

d) Give relaxation processes in NMR.

e) Describe group frequency region in IR spectroscopy.

Q4) Explain EI, APCI, FAB and ESI. Add a note on metastable ion and isotopic peaks. **[15]**

OR

Describe Spin-Spin splitting and coupling constant in detail. Compose ^{1}H NMR with $^{13}CNMR$.

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

a) Derivative differential thermal Analysis.

b) Rotating crystal and powder technique used in XRD.

c) Interferences in Atomic Absorption Spectroscopy.

d) Bragg's Law

e) Principle and Instrumentation of Gel Electrophorell's.

Total No. of Questions : 5]

SEAT No. :

P2793

[Total No. of Pages : 2

[5855]-102
First Year M. Pharmacy
DRUG DELIVERY SYSTEM
(2019 Pattern) (Semester-I) (MPH 102T)

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

Instructions to the candidates:

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

Q1) Answer any 1 out of 2 **[15]**

a) Explain in brief controlled drug delivery system and discuss in details osmotic Drug delivery system.

b) Discuss in details formulation and evaluation of Buccal formulations.

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

a) Give classification, properties and applications of polymers.

b) Discuss the mechanism of drug release from SR/CR formulations.

c) Explain working and applications of Franz Diffusion cell apparatus.

d) Compare natural polymers with synthetic polymers Give 5 exmaples of semisynthetic polymers.

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

a) What are matrix tablets and their applications.

b) Give importance of personalized medicines.

c) Explain with example P^H activated DDS.

d) What are invitro and invivo challenges for protein drug delivery systems.

e) Explain microneedle array based transdermal drug delivery system.

P.T.O.

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

a) Explain various approaches/principles of gastro retertive DDS.

b) Give eleborate account of evaluation of SRDFs.

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

a) Telepharmacy and its applications.

b) IVIVC and its significance.

c) Nasal vaccines.

d) Vapour pressure activated DDs.

e) Permeation enhancers in trans dermal drug delivery systems.

Total No. of Questions : 5]

SEAT No. :

P2794

[Total No. of Pages : 2

[5855]-103
First Year M. Pharmacy
MPH 103T : MODERN PHARMACEUTICS
(2019 Pattern) (Semester-I)

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

Instructions to the candidates:

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

Q1) Define preformulation. Explain drug-excipient interaction with suitable examples. Aslo add about the techniques to indentify them. **[15]**

OR

What is process validation? Elaborate the process validation of tablet dosage form.

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

a) Explain small volume parenteral.

b) Elaborate on qualifications of equipments.

c) Discuss Budget & cost control.

d) Explain concept of Total quality management.

Q3) Attempt any 3. **15]**

a) Discuss DLVO theory.

b) Give application of optimization in pharmaceuticals.

c) Give significance of (F_2) & (F_1) similarity & dissimilanty factors.

d) Explain compaction profile.

e) Elaborate the process of production & planning control.

P.T.O.

Q4) Explain in detail current good manufacturing practices. **[15]**

OR

Explain in detail physics of tablet compression.

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

a) Settling in suspension.

b) Stability testing.

c) Simplex method of optimization.

d) Elaborate on sales forecusting

e) Heckel plot & its significance.

Total No. of Questions : 5]

SEAT No. : ____

P2795

[Total No. of Pages : 2

[5855]-104

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

REGULATORY AFFAIRS

(2019 Pattern) (Semester-I) (MPH104T)

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

Instructions to the candidates:

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

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

Describe objective and organization of ICH. Elaborate on ICH Q guidelines.

OR

Write a note on development of clinical trial protocol and describe institutional review board.

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

a) Give detailed account of Hatch Waxmam Act and its amendments.

b) Write a note on 21CFR.

c) Describe CMC.

d) What is inform consent? Write its procedure.

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

a) Explain NDA regulatory approval process.

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

c) Describe post marketing surveillance.

d) Write a note on post marketing surveillance.

e) Write a note on institutional review board.

P.T.O.

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

a) Explain scaleup process approval changes.

b) Explain in detail Drug Master File.

Q5) Attempt any Five **[15]**

a) Write a short note on HIPAA.

b) Write a note on ECTD.

c) Explain Investigational Medical Product Dossies (IMPD).

d) Enlist ICH-S guidelines.

e) Write a short note on informed consent process.

Total No. of Questions : 5]

SEAT No. :

P2796

[Total No. of Pages : 2

[5855]-105
First Year M. Pharmacy
ADVANCED ORGANIC CHEMISTRY-I
(2019 Pattern) (Semester-I) (MPC 102T)

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

Instructions to the candidates:

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

Q1) What is nucleophilic substitution reaction. Explain about stereochemistry and factors affecting nucleophilic uni-and bimolecular substitution reactions (SN1 and SN2). **[15]**

OR

Outline the mechanism and discuss the synthetic importance of the following.

a) Mannich reaction

b) Sandmeyer reaction

c) Doebner Miller reaction

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

a) Write synthesis of Hydroxychloroquine and Mercaptopurine.

b) Explain the preparation, salient features of dicyclohexylcarbodimide and Osmium tetroxide and explain their applications in organic synthesis.

c) What are elimination reactions? Write about their mechanism, stereochemistry and factors affecting E1 reactions.

d) Explain the strategies for synthesis of four and five membered ring system through synthon approach.

P.T.O.

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

a) Discuss Vilsmeyer-Haack reaction with respect to its mechanism and synthetic applications.

b) What is rearrangement reaction? Discuss Smiles rearrangement.

c) Write mechanism and synthetic applications of Strecker synthesis.

d) Define retrosynthesis. Elaborate on C-X and C-C disconnections with respect to carbonyl groups.

e) Explain the protection of amino groups with suitable examples.

Q4) Write synthesis of Metronidazole, Triamterene and Theophyline. **[15]**

OR

Explain the methods of formation, stability and synthetic applications of carbocations and carbanions.

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

a) Free radicals.

b) Sharpless asymmetric epoxidation.

c) Biginelli reaction and its synthetic applications.

d) Combes Quinoline synthesis and Traube Purine synthesis.

e) Synthetic applications of Wilkinson reagent and Witting reagent.

Total No. of Questions : 5]

SEAT No. : ____

P2797

[Total No. of Pages : 2

[5855]-106

First Year M. Pharmacy

MPC 103T : ADVANCED MEDICINAL CHEMISTRY

(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) ***Do not write anything on questions paper except seat number.***

Q1) Discuss stereo-chemical aspects in drug absorption, metabolism, distribution and elimination with case studies. **[15]**

OR

Discuss about various stages of drug discovery and Explain lead discovery, identification, validation and diversity of drug targets with suitable examples.

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

a) Describe anticonvulsants interacting with GABAA receptor.

b) Give focus on antineoplastic antibiotics.

c) Give the classification and detail account of H_1 and H_2 receptor antagonists.

d) Discuss chemistry of prostaglandins, Leukotrienes.

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

a) Classify antivirals. with suitable examples. write chemistry and mode of action of Amantadine.

b) How Aspirin is selective Cox-I antagonist? Write mode of action of Salicylates.

c) Explain various theories of drug-receptor interactions.

d) What is drug resistance? Explain its causes in light of antibiotics.

e) Prodrugs are useful for stabilizing metabolically unstable drugs; justify with examples.

P.T.O.

Q4) Classify antihypertensive agents with examples and their mechanism of action. Give an account of calcium channel blockers. **[15]**

OR

Classify peptidomimetics. Explain designing of peptidomimetics by manipulation of the amino acids.

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

a) Rationale and practical consideration of prodrug design.

b) Rational design of covalently and non -covalently binding enzyme inhibitors.

c) Strategies to combat drug resistance in antibiotics.

d) ACE inhibitors as antihypertensive agents.

e) Significance of High Throughput screening in drug development.

Total No. of Questions : 5]

SEAT No. : ____

P2798

[Total No. of Pages : 2

[5855]-107

First Year M. Pharmacy

MPC 104T : CHEMISTRY OF NATURAL PRODUCTS

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

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

Instructions to the candidates:

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

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

Explain the development of cardiovascular agents from plant products.

OR

What are steroids? Discuss stereochemistry and nomenclature of steroids. Add a note on chemistry of contraceptive agents.

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

a) What are characterization details of penicillin?

b) Explain development of epidophyllotoxins as anticancer agents

c) Discuss classification, isolation and biological activity of alkaloids.

d) Explain chemistry of macrolide antibiotics.

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

a) Write structure elucidation methods for Flavonoids

b) Highlight on the spectroscopic details of camphor.

c) What are macrolide antibiotics? Explain with examples.

d) Write a note on oligonucleotide therapy.

e) Explain principles of DNA and RNA estimation.

P.T.O.

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

Comment on the development of morphine derivatives in therapy.

OR

What are vitamins? Discuss chemistry and Physiological significance of Vitamin B1, B2 and B12.

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

a) Physiological significance of folic acid and Niacin.

b) Classification and applications of Terpenoids.

c) Explain structural characterization of Penicillin.

d) Write a note on Gene Therapy

e) Write the active constituents present in following crude drugs.

Petrocarpus marsupium and Trigonella foenum graccum in diabetic therapy.

Total No. of Questions : 5]

SEAT No. : [ ]

P2799

[Total No. of Pages : 2

[5855]-108

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

QUALITY MANAGEMENT SYSTEMS

(2019 Pattern) (Semester-I) (MQA102T)

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

Instructions to the candidates:

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

Q1) Describe the process of returns and recalls of pharmaceutical products. **[15]**

OR

Explain ICH Q9 in detail. **[15]**

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

a) Explain benchmarking.

b) Explain CAPA in pharma industry.

c) Elaborate on MABL certification and accreditation.

d) Explain elements of PQS as per ICH Q10.

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

a) Give dimensions of quality.

b) Give definition and importance of statistical process control.

c) Explain principles of Six sigma.

d) Explain operational excellence.

e) Give basic principles of TQM.

P.T.O.

Q4) Discuss in detail process of handling customer complaints of pharmaceutical products. **[15]**

OR

Explain WHO-GMP requirements for pharmaceuticals. **[15]**

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

a) ICH guidlines for stability testing.

b) Out of Trend.

c) Concept of Self inspection.

d) HACCP.

e) Quality by design.

Total No. of Questions : 5]

SEAT No. : [ ]

P2800

[Total No. of Pages : 2

[5855]-109

First Year M. Pharmacy (Pharmaceutical quality assurance)

QUALITY CONTROL AND QUALITY ASSURANCE

(2019 Pattern) (Semester-I) (MQA103T)

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

Instructions to the candidates:

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

Q1) Discuss importance and control parameters during manufacturing operations in pharmaceutical indsutry. **[15]**

OR

Elaborate in process and finished product quality control test for solid dosage forms. **[15]**

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

a) Explain in brief about CGMP guidelines as per schedule M.

b) Elaborate about maintenance of distribution records.

c) Discuss about material management including raw material analysis and finished products.

d) Explain importance and scope of Good Labrotory practices.

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

a) What are various guidelines for handling of waste and scrap disposal in manufacturing unit.

b) Comment on regulated and non regulated markets concept in pharmaceuticals.

c) Explain about CTD and eCTD.

d) Discuss in detail about ICH guidelines with emphasis on Q series guidelines.

e) Discuss about control of contamination and Good warehousing practices.

P.T.O.

Q4) Elaborate the concept of quality assurance department and quality control department with suitable example. **[15]**

OR

Discuss in detail about Quality control of parenteral dosage form. **[15]**

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

a) Intermediates and bulk products.

b) Three Tier documentation.

c) PIC.

d) CPCSEA guidelines.

e) SOP

Total No. of Questions : 5]

SEAT No. : [ ]

P2801

[Total No. of Pages : 2

[5855]-110

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

MQA 104T : PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

(2019 Pattern) (Semester-I)

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

Instructions to the candidates:

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

Q1) Discuss in detail various quality control tests for glass & plastic containers. **[15]**

OR

Explain in detail stages of drug discovery & development.

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

a) What is stability testing of pharmaceutical products? Discuss about accelerated stability testing.

b) Explain the concept of Preformulation studies and discuss preformulation parameters for drug substance.

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

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

P.T.O.

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

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

b) Write about format & contents of abbreviated new drug application (ANDA)

c) Explain the various issues facing modern durg Packaging.

d) Explain the techniques for the study of crystal properties of drug substances.

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

Q4) Discuss in detail manufacturing, manufacturing flowcharts & in process quality control tests for tablet dosage forms. **[15]**

OR

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

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

a) Documentation in Technology transfer

b) Types of glass used for pharmaceutical packaging

c) Significance need of preformulation studies.

d) Post marketing surveillance

e) Supplemental new drug application (SNDA)

Total No. of Questions : 5]

SEAT No. : ____

P2802

[Total No. of Pages : 2

[5855]-111
First Year M. Pharmacy
GOOD REGULATORY PRACTICES
(2019 Pattern) (Semester-I) (MRA101T)

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

Instructions to the candidates:

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

Q1) Answer any one (15 marks each)

a) Explain in detail 21 CFR part 211.

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

Q2) Answer any two (7-5 marks each)

a) Explain future of GLP regulations.

b) Explain principles of GALP regulations and GALP requirments.

c) Write down general checklist of 21 CFR Part 11.

d) Write in detail about analytical method validation.

Q3) Answer any Three (5 marks each)

a) What are the legal GDP requirments?

b) Write a note on cleaning validation.

c) What are the principles of GDP.

d) Write a note on software evaluation checklist.

e) What are the GALP requirments?

P.T.O.

Q4) Answer any one (15 marks each)

a) Explain in detail ICH Q1 A guideline.

b) Explain in detail controlling the GLP inspection process.

Q5) Answer any Three (5 Marks each)

a) Write a note on ISO 13485.

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

c) Write a note on GDP documentation.

d) Explain in detail types of qualification.

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

Total No. of Questions : 5]

SEAT No. : ____

P2803

[Total No. of Pages : 2

[5855]-112

First Year M. Pharmacy

DOCUMENTATIONS AND REGULATORY WRITING

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

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

Instructions to the candidates:

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

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

a) Explain CTD overview and module 3.

b) Explain in detail ACTD.

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

a) Explain inspection of manufacturing facilities by regulatory agencies.

b) Explain in detail DMF.

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

d) Write a note on post marketing reporting requirements.

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

a) Explain product development report.

b) Explain CTD module 1.

c) Give the difference between CTD and ACTD.

d) What are internal and external audit, timeline for audit and audit follow up.

e) Explain in brief product litecycle managment.

P.T.O.

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

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

b) Explain in detail quality system requirements for national good manufacturing practice inspectorate.

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

a) Write a note on post approval labeling changes.

b) Write a note on EIR and warning letter.

c) Write a note on seizure and injunctions.

d) Write a note on inspection and drug distribution channel.

e) Write a note on corrective and preventive action.

Total No. of Questions : 5]

SEAT No. : [ ]

P2804

[Total No. of Pages : 2

[5855]-113
First Year M. Pharmacy
CLINICAL RESEARCH REGULATIONS
(2019 Pattern) (Semester-I) (MRA 103T)

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 is clinical trial? Explain indetail about various phases of clinical trials.

b) What is Nuremberg's code? Explain indetail about Ethical principles governing informed consent process.

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

a) Explain in short about ethics inclinical research Add a note on medical device.

b) What is CFR 21 part 314? Explain in detail with importance.

c) E-7 studies in support of general populations. Geriatrics.

d) EU Annaul Safety Report (ASR)

Q3) Solve any three **15]**

a) What is IND Application?

b) Explain in short about ANDA.

c) Significance of clinical trials

d) Differentiate between Bioavaliability and Bioequivalence studies.

e) Phase III studies in clinical trial.

P.T.O.

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

a) Explain in detail about FDA. Safety reporting requirements for IND & BA/BE.

b) What is institutional review board? Give the details of Ethics Committee composition, roles, responsibilities, review and approval process.

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

a) Clinical research regulations in EU

b) C R O

c) Data safety maintaing Board

d) India ECP.

e) Phase I studies in clinical trial

Total No. of Questions : 5]

SEAT No. :

P2805

[Total No. of Pages : 2

[5855]-114

F.Y. M. Pharmacy

MRA104T : REGULATIONS & LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD AND NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

(2019 Credit Pattern) (Semester-I)

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

Instructions to the candidates:

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

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

a) Give regulatory requirement & approval procedure for drug & cosmetics and medical devices.

b) Explain guidelines & regulatory requirements for Bioequivalence study.

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

a) Give brief guidelines for drug testing in animals/ preclinical study.

b) Give ICH and WHO guidelines for stability study.

c) Write ethical guidelines for human participants.

d) Give rationale for animal testing study.

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

a) What are the responsibilities of CDSCO & State licensing authority?

b) Give format & content of Regulatory Dosier filing.

c) Write in brief on BCS classification of drug.

d) Define industrial design & discuss need of IPR to protect it.

e) Briefly explain the process of obtaining copyright. Differentiate between copyright infringement & Trademark infringement.

P.T.O.

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

a) Write in brief about Indian pharmacopoeial standards, BIS standards and ISO standards.

b) Explain rules & guidelines for approval of Drugs & Cosmetics, Medical Devices, Biological & Herbals & Food and nutraceuticals in India

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

a) Explain the powers of drug Inspecter.

b) What are the conditions for grant of license for manufacture of Ayurvedic and Unani Drugs.

c) What are geographical indications? Write its function.

d) Discuss Schedule X.

e) Define

i) Spurious drug

ii) Misbranded drug

iii) Drug

iv) Cosmetics

v) Registered Medical Practitioner

Total No. of Questions : 5]

SEAT No. :

P2806

[Total No. of Pages : 2

[5855]-115

First Year M. Pharmacy (Pharmaceutical Biotechnology)

MICROBIAL AND CELLULAR BIOLOGY

(2019 Pattern) (Semester-I) (MPB102T)

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) Attempt any one. **[1×15=15]**

a) Write a note on structural, morphological, physiological features of bacteria, Fungi, actinomycetes.

b) Write in detail about fertilization and events, invitro fertilization, embryonic germ cells and stem cells and applications.

Q2) Attempt any two. **[2×7.5=15]**

a) What is a cytoskeleton? How does it help in cellular movement?

b) Explain in detail the nutrient composition and transformed cell culture.

c) Write the mechanism of action of antimicrobial agents.

d) Write a note on structure of cell. Enlist types of cell organelles with function.

Q3) Attempt any three. **[3×5=15]**

a) Write a note on industrially important micro organism with examples.

b) What are various aerobic and anaerobic fuelling mechanisms.

c) Explain cellular movements in detail.

d) Write a note on mutagenesis.

e) What is Chemotherapy?

P.T.O.

Q4) Attempt any one. **[1×15=15]**

a) What are nucleic acids? Write a note different types of DNA & RNA and central dogma of molecular biology.

b) Write in detail about RNA processing modification maturation, splicing editing and amplification.

Q5) Attempt any three. **[3×5=15]**

a) What are bacteriophages. Explain the genetic organization of bacteriophages?

b) What are embryonic germ cells and stem cells & their applications.

c) Differentiate between prokaryotes and eukaryotes.

d) Explain cell division and how it is regulated.

e) Write in brief therapies for common fungal infections.

Total No. of Questions : 5]

SEAT No. : ____

P2807

[Total No. of Pages : 2

[5855]-116

First Year M. Pharmacy (Pharmaceutical Biotechnology)

MPB202T: BIOPROCESS ENGINEERING AND TECHNOLOGY

(2019 Pattern) (Semester-I) (MPB103T)

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

Instructions to the candidates:

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

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

a) Explain basic principle of fermentation.Draw explanatory diagram with necessary parts and their functions.

b) Discuss various Bioreactors used for immobilized Bioprocess.

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

a) Discuss various principles for process scale up of fermentation process.

b) Explain microbial transformation of alkaloids.

c) Discuss theory of mass transfer during Bioprocess.

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

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

a) Describe flow chart for Bioproduction of Citric acid.

b) Write principle of Bioautographic Technique.

c) Discuss synchronous culture.

d) Describe various techniques used for cell disruption.

e) Write advantages and drawbacks of Batch fermentation process.

P.T.O.

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

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

b) Explain in detail about Biotransformation of steroids.

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

a) Airlift Bioreactor.

b) Preservation of stock culture of microbes.

c) Computer control in Bioprocess.

d) Determination of KLa value.

e) Bioproduction of Vitamin-C.

Total No. of Questions : 5]

SEAT No. : ____

P2808

[Total No. of Pages : 2

[5855]-117

First Year M. Pharmacy

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

(2019 Pattern) (Semester-I) (MPB104T)

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

Instructions to the candidates:

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

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

a) Discuss detail classification and general properties of enzymes.

b) Explain various drug delivery approaches for therapeutic proteins.

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

a) Discuss Biotransformation of any one steroidal drug.

b) Explain techniques of gene cloning.

c) Briefly discuss various cell signaling pathways

d) Discuss in detail about gene therapy.

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

a) What are Biosensors? Write ideal characteristics of Biosensors.

b) Write applications of microbes in environmental monitoring.

c) Discuss principle and applications of PCR

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

P.T.O.

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

a) Discuss the production of therapeutics protein from trunsgenic animals.

b) Explain detail procedure about extruction and pyrification of enzymes.

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

a) Microbial production of amylase

b) Gene Librury

c) Oncogenes

d) Human genome project

e) Production of Single cell protein.

Total No. of Questions : 5]

SEAT No. : ____

P2809

[Total No. of Pages : 2

[5855]-118

First Year M. Pharmacy

ADVANCED PHARMACOLOGY-I

(2019 Pattern) (Semester-I) (MPL102T) (Theory)

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

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Draw neat labelled diagrams wherever necessary.***
3) ***Figures to the right indicate full marks.***
4) ***Do not write anything on question paper except you seat no.***

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

a) Classify Sympatholytics. Describe pharmacology of beta blockers.

b) Define Atherosclerosis. write the pharmacology of HMG -CoA reductase inhibitors.

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

a) Describe pharmacology of Gabapentin.

b) Describe the Pharmacology of Thiazide diuretics.

c) Classify General Anestheics. Write about stages of Anesthesia.

d) Explain the role of Phosphodiesterase inhibitors in CHF.

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

a) What are the advantages of ARB's over ACEI.

b) Give an account of G protein coupled receptors.

c) Explain in detail biosynthesis of Prostaglandins.

d) Explain actions of Ach on its receptors.

e) Write in brief pharmacological actions of Dopamine.

P.T.O.

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

a) What are Coronary artery diseases? Explain pharmacology of nitrates.

b) Classify Opioid analgesics. Explain in detail pharmacology of Morphine.

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

a) Organophosphorous poisoning

b) Ganglionic blockers

c) Local anesthetics.

Total No. of Questions : 5]

SEAT No. : [ ]

P2810

[Total No. of Pages : 2

[5855]-119

First Year M. Pharmacy

MPL 103T : PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I

(2019 Pattern) (Semester-I)

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

Instructions to the candidates:

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

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

OR

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

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

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

b) Discuss the various methods employed in the screening of Anti-asthmatic 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 screening methods for anti-diarrheal agents.

c) Describe the screening methods for diuretics agents.

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

e) Explain various methods used in screening of immunomodulators.

P.T.O.

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

OR

Maintenance and breeding of laboratory animals as per CPCSEA Guidelines.

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

a) Immunoassay for digoxin.

b) Euthanasia of experimental animals.

c) Applications of Transgenic animals.

d) Alternate to animal experiments.

e) Good laboratory practice of experimental animals.

Total No. of Questions : 5]

SEAT No. :

P2811

[Total No. of Pages : 2

[5855]-120

First Year M. Pharmacy

MPL 104T : 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 side indicate full marks.***
3) ***Draw well labelled diagrams wherever necessary.***

Q1) Describe various types of vectors and applications of DNA recombinant technology. **[15]**

OR

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

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

a) How polymorphism affects drug metabolism?

b) Describe JAK/STAT pathway as a infracellular signaling pathway.

c) Discuss Nitric oxide and Diacylglycerol as second messengers.

d) Describe cyclic AMP signaling pathway in cells.

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

a) Discuss various types of gene transfer techniques.

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

c) Describe glucose uptake assay.

d) Write the applications of proteomic science.

e) Comment on western blotting technique.

P.T.O.

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

OR

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

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

a) Ligand gated ion channels receptions.

b) Inositol triphosphate (IP_3)

c) Importance of si RNA and Micro RNA

d) Calcium influx assays

e) Micro array techniques

Total No. of Questions : 5]

SEAT No. :

P2812

[Total No. of Pages : 2

[5855]-121

First Year M. Pharmacy

ADVANCED PHARMACOGNOSY-I

(2019 Pattern) (Semester-I) (Credit System) (MPG102T)

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

Instructions to the candidates:

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

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

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

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

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

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

b) Write a note on Marine toxins.

c) Write short note on Formulation and standardisation of Nutraceuticals.

d) Write a note on digestive enzymes.

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

a) Current Good Collection practices.

b) Regulatory aspects of Nutraceuticals.

c) Medicinal and Health benefits of Taxol.

d) Current trends and future scope on Nutraceuticals.

e) Classification of Functional food with suitable examples.

P.T.O.

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

a) Write in detail about the occurrence, isolation and characteristic feature of Shatavarins and Hesperidin.

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

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

a) Bio drug-food interaction with suitable examples.

b) Occurrence and isolation of Vascine.

c) Medicinal uses and health benefits herbal tea.

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

e) Isolation of Ellagic acid.

Total No. of Questions : 5]

SEAT No. : ____

P2813

[Total No. of Pages : 2

[5855]-122
First Year M. Pharmacy
PHYTOCHEMISTRY
(2019 Credit Pattern) (Semester-I) (MPG103T)

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

Instructions to the candidates:

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

Q1) What are clinical trials? Elaborate phases of clinical trials and protocol for clinical studies use for drug discovery and development. **[15]**

OR

Elaborate a detail account of spectroscopic characterization for structural elucidation of Glycyrrhizin. **[15]**

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

a) Discuss in detail advances in thin Layer chromatography for plant drug analysis.

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

c) Explain isolation, purification, characterisation and industrial importance of Digitoxin.

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

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

a) Discuss in detail stationary and mobile phase used in liquid and Gas chromotography.

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

c) Explain in detail drug registration.

d) Provide principle and working of CCCET technique.

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

P.T.O.

Q4) Describe in detail Biosynthesis, isolation, purification, characterisation and industrial application of sennosides. **[15]**

OR

Describe principle, working, applications of SCFE techniques along with their advantages and disadvantages. **[15]**

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

a) Structural elucidation of Menthol.

b) Artemisin in drug discovery and development.

c) Elaborate recent advances in extraction method for plant drug with merits over conventional methods.

d) GCMS fingure printing.

e) Structural elucidation of Kaempferol.

Total No. of Questions : 5]

SEAT No. : ____

P2814

[Total No. of Pages : 2

[5855]-123

First Year M. Pharmacy (Pharmacognosy)

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

(2019 Pattern) (Semester-I) (MPG104T)

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

Instructions to the candidates:

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

Q1) What are infrastructural requirements of herbal industry involved in production of standerdized extracts and various dosage forms? **[15]**

OR

Explain comparative study regarding monographs in IP, Ayurvedic Pharmacopoeia, siddha and Unani Pharmacopoeia.

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

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

b) Write note on EXIM Policy of India.

c) Describe protocols for stability testing of natural products.

d) Explain global regulatory status of herbal drugs.

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

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

b) What do pilot scale and scale up mean?

c) What is clinical laboratory testing of natural products?

d) Write note on “Geographical indications”.

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

P.T.O.

Q4) Explain Indian and international patent laws applicable to herbal and natural products and their process. **[15]**

OR

What are WHO guidelines on Good manufacturing practices for the production of herbal medicines.

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

a) Ayurvedic Pharmacopoeia.

b) Current challenges of herbal formulations.

c) Copyright.

d) TRIPS.

e) Plant Design.

Total No. of Questions : 5]

SEAT No. : ____

P2815

[Total No. of Pages : 2

[5855]-201

First Year M. Pharmacy

MOLECULAR PHARMACEUTICS (Nano Tech and Targeted DDS)

(2019 Pattern) (Semester-II) (Theory) (MPH 201T)

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

Instructions to the candidates:

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

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

a) Write in detail on concept, preparation and evaluation of pulmonary drug delivery system.

OR

b) Write in detail on potential target diseases for gene therapy.

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

a) What is the challenge before formulation scientist in tumor targeting and brain specific delivery.

b) What are the critical aspects in the evaluation of nano particles.

c) Write in details on applications of monoclonal antibodies.

d) Comment on advantages of antisense molecules.

Q3) Solve any three out of five. **[15]**

a) Write a note on types of containers for pulmonary drug delivery systems.

b) Can gene therapy give relief to cancer patients?

c) Write a note on evaluation of intra nasal route delivery systems.

d) Explain the term biodistribution.

e) What are limitations of nanoparticles?

P.T.O.

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

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

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

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

a) Electrosomes

b) Aptamers

c) Propellants

d) Aquasomes

e) Niosomes

Total No. of Questions : 5]

SEAT No. :

P2816

[Total No. of Pages : 2

[5855]-202

First Year M. Pharmacy

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS

(2019 Pattern) (Semester-II) (MPH202T)

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

Instructions to the candidates:

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

Q1) What is pharmacokinetics? Elaborate on the pharmacokinetic models along with its applications and discuss one compartment open model I.V. bolus administration. **[15]**

OR

Define IVIVC. Discuss different levels of IVIVC along with its applications in pharmaceutical Industry.

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

a) What is non linear pharmacokinetics? What are the causes and how will you determine the nonlinearity?

b) Describe the mechanism of drug transport by comparing passive and facilitated diffusion.

c) What is the purpose of BA/BE studies? Describe methods for assessment of bioavailability.

d) Discuss in detail various transport models.

P.T.O.

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

a) Explain why drugs are better absorbed from small intestine?

b) What is difference between absolute and effective surface area. How it can be improved for hydrophobic drug.

c) The half life of propranolol in 60 kg patient is 4 hours and v_d is 5.5 L/kg. Assuming one compartmental kinetics calculate Elimination rate constant K_E and Total Clearance Cl_T

d) Compare single dose with multiple dose bioavailability studies.

e) Explain which parameters decide time to reach steady state plasma concentration of drug after I.V. infusion.

Q4) List various factors affecting absorption and explain in detail pharmaceutical factors affecting absorption of drug from GI tract. **[15]**

OR

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

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

a) BCS and BDDCS.

b) Bio similar drug products.

c) Two compartmental model

d) pH-partition hypothesis.

e) Pharmacokinetic drug interactions.

Total No. of Questions : 5]

SEAT No. : ____

P2817

[Total No. of Pages : 2

[5855]-203
First Year M. Pharmacy
COMPUTER AIDED DRUG DEVELOPMENT
(2019 Pattern) (Semester-II) (MPH203T)

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

Instructions to the candidates:

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

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

a) Explain in detail clinical data collection and management add a short note on Regulation of Computer System.

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

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

a) Explain in detail nucleoside transporter OCT and OATP.

b) Explain in detail IVIVC and add a note on in-vitro dissolection.

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

d) Explain drug absorption with their parameters.

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

a) Define quality, Quality by Design (QbD) and Quality Target Product Profile (QTPP)

b) Explain in detail artificial intelligence.

c) Explain BCRP and HPEPTL

d) Write a note on comparison between Descriptive and mechanistic models .

e) Explain in detail computer simulation in isolated tissue & organ.

P.T.O.

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

a) Write in detail on In-Vitro in vivo correlation Significance in biopharmaceutical characterization.

b) Write in detail about the In-Lilico modelling techniques used to study intestinal permeation of drugs.

Q5) Answer the following (Solve 3 of 5) **[3×5=15]**

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

b) Write short note on use of computers in marketting analysis.

c) What are Robotics, Give its applications

d) Define modelling and enlist various modelling techniques.

e) Compare population and non-population PK/PD.

Total No. of Questions : 5]

SEAT No. : ____

P2818

[Total No. of Pages : 2

[5855]-204

First Year M. Pharmacy (Pharmaceutics)

COSMETIC AND COSMECEUTICALS

(2019 Pattern) (Semester-II) (MPH 204T)

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

Instructions to the candidates:

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

Q1) Explain mechanism of sunscreens. Classify them and write regulatory aspects for sunscreen product development. **[15]**

OR

What do you mean by herbal skin care cosmetics? Write in detail about the Indian regulatory requirements for labeling of topical cosmetics.

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

a) Write in detail about the thickeners used in cosmetic industry.

b) Discuss in detail about COSMOS guidelines with respects to preservatives and foaming agents.

c) Discuss in detail about the formulation development of shampoo.

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

a) Various types of creams

b) Formulation designing of deodorants

c) Lipsticks-preparation and evaluation

d) Hair growth cycle

e) Surfactants: classification and applications.

P.T.O.

Q4) Write in detail about the physiological consideration of skin in relation to cosmetic applications, Write in detail about anti acne formulations. **[15]**

OR

Discuss regulatory provisions relating to the import of cosmetics and manufacturing of cosmetics. Add a note on misbranded and spurious cosmetics.

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

a) Depilatories

b) Preservatives used in cosmetic products.

c) Nail lacquer

d) Skin sensitivity test

e) Anti acne formulation.

Total No. of Questions : 8]

SEAT No. :

P2819

[Total No. of Pages : 2

[5855]-205
First Year M. Pharmacy
ADVANCED SPECTRAL ANALYSIS
(2019 Pattern) (Semester-II) (MPC 201T)

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

Instructions to the candidates:

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

Q1) Discuss radioimmunoassay and bioassay. **[15]**
Elaborate radioimmunoassay for Digitalis

OR

Compile principle instrumentation and applications of GC-AAS.

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

a) How will you calculate the absorption maxima for dienes by using woodward- fiser rule?

b) Predict and explain the signal positions (δ values) and spin-spin splitting in the HMR spectrum.

i) N-butanol ii) 2-Chloropropane

iii) Acetaldehyde iv) N-propylamine

c) Explain Mc-Lafferty Rearrangement with suitable example.

d) Discuss principle and instrumentation of supercritical fluid chromatography

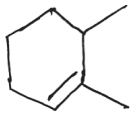
Q3) Attempt any three. **[15]**

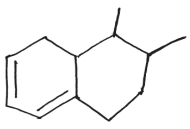
a) Comment on abundance and reason of formation of different isotopic peaks in mass spectrometry.

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

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

d) Predit the UV maxima for each of following compounds.

i) 

ii) 

e) Discuss two atmospheric pressure ionization Techniques of LC-Ms.

P.T.O.

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

MF: $C_9H_{10}O$

UV : 280nm (Ethanol)

IR ccm^{-1}) : 1715, 1590, 1550

1H NMR (δ PPM): i) δ : 2.09- singlet, 3H

ii) δ : 3.65, singlet, 2H

iii) δ : 7.29, singlet, 5 H

b) Elaborate LC-NMR Technique.

OR

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

a) Flash chromatography

b) Ring rule in Mass spectrometry.

c) ATR-IR

d) ELISA

e) Capillary electrophoresis - mass spectrometry (CE-Ms)

Total No. of Questions : 5]

SEAT No. : [ ]

P2820

[Total No. of Pages : 2

[5855]-206

First Year M. Pharmacy (Pharmaceutical Chemistry)

ADVANCED ORGANIC CHEMISTRY - II

(2019 Pattern) (Semester-II) (Theory) (MPC202T)

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 types of cataysis and illustrate each type with suitable example. Add a note on their applications. **[15]**

OR

Explain the concept of Green chemistry? Describe the principle and applications of Microwave assisted and ultrasound assisted reactions.

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

a) Explain FMOC and BOC protection strategies and their cleavage reagents in solid phase peptide synthesis?

b) Explain Diels Alder reaction with respect to its mechanism and stereochemistry.

c) Describe organo-catalysis with suitable examples?

d) Explain the methods of racemic resolution.

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

a) Describe working principle and advantages of continuous flow reactors.

b) Processes of photochemical reactions.

c) Discuss the applications of phase transfer catalysis.

d) Elaborate on use of enzymes in organic synthesis.

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

P.T.O.

Q4) Explain CIP sequence rule for stereoisomers with suitable examples. Add a note on criteria to decide symmetry of molecule. **[15]**

OR

Explain with example solid phase peptide synthesis with respect ot procedure, resins and linkers.

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

a) Applications of Ionic liquids and solvent free reactions.

b) Chiral Auxilliaries.

c) Solution phase peptide synthesis.

d) Application of Chiral synthesis.

e) Twelve principles of Green Chemistry.

Total No. of Questions : 5]

SEAT No. : ____

P2821

[Total No. of Pages : 2

[5855]-207

First Year M. Pharmacy (Pharmaceutical Chemistry)

COMPUTER AIDED DRUG DESIGN

(2019 Pattern) (Semester-II) (MPC203T)

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

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Answer 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) Describe the advancement of drug design in the field of HMG-CoA reductases focusing on the role of CADD. **[15]**

OR

Citing suitable examples explain the role of CADD in drug discovery.

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

a) What is a conformational analysis? Explain the process in detail citing a suitable example.

b) Explain the process of Free Wilson analysis.

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

d) Detail the principle and application of *Hansch* analysis in development of CADD.

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

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

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

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

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

a) Analysis of a receptor (or enzyme) interaction

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

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. : [ ]

P2822

[Total No. of Pages : 2

[5855]-208

First Year M. Pharmacy

PHARMACEUTICAL PROCESS CHEMISTRY

(2019 Pattern) (Semester-II) (MPC 204T) (Theory)

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

Instructions to the candidates:

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

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

a) Explain synthetic strategies. Give a detail account on Bench, Pilot & large scale process.

b) Describe concept of crystallization. Explain factors affecting crystallization.

Q2) Answer Any TWO **[15]**

a) Explain fire hazards along with types of fire extinguishers.

b) Write in brief about Personal Protection Equipment (PPE).

c) What are types of halogenation. Write about catalytic halogenation.

d) Explain production of Vit-B-12.

Q3) Answer Any THREE **[15]**

a) What is steam distillaction. Give its applications.

b) Explain working of vacuum crystallizer and its modification.

c) What are different ways of extraction. Explain counter current way of extraction.

d) Explain working, principle of multiple effect evaporater.

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

P.T.O.

Q4) Answer any ONE **[15]**

a) Discuss Nitration- unit process with respect to the kinetics and mechanism and equipments used in nitration.

b) Classify commercially operated filters. Explain in detail plate and frame type of filters.

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

a) Classification and applications of evaporators.

b) Streamlining synthetic reaction steps and route selection.

c) Occupational Health & Safety Assessment Series (OHSAS).

d) Theories of filtration.

e) Material Safety Data Sheet (MSDS).

Total No. of Questions : 8]

SEAT No. : [ ]

P2823

[Total No. of Pages : 2

[5855]-209
First Year M. Pharmacy
HAZARDS AND SAFETY MANAGEMENT
(Pharmaceutical Quality Assurance)
(2019 Pattern) (Semester-II) (MQA 201T)

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

Instructions to the candidates:

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

Q1) Explain components of five triangle and classification of five. Add a note on the preventive and portective management from fire and explosions. **[15]**

OR

What is air based hazards. Discuss in detail air circulation maintainence in pharmaceutical industry for sterile area. **[15]**

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

a) Define Industrial hazard and risk. Discuss sources of five hazards and explosion.

b) Discuss the ICH guideline on risk assessment.

c) Discuss the control measures while handling flammable material, dust explosions and pyrophoric material.

d) What is MSDS? Write in detail the sections of MSDS.

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

a) Write a note on fire extinguishment.

b) Discuss the control strategies while handling combustible gases and sulphonating reagents.

c) Explain the self -protective measures against workplace hazards.

d) Explain the effluent treatment procedure in an industry.

e) What is TLV concept? Discuss its significance and various threshold limits.

P.T.O.

Q4) Explain in detail various risk management tools used in industry. **[15]**

Discuss the hazards associated with organic solvents. Add a note on safety measures while handling organic solvents.

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

a) Explain the elements of safety management programme.

b) Write a note on factory Act and Rules.

c) Write in brief about BOD and COD.

d) Enlist and explain various renewable and non-renewable natural resources.

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

Total No. of Questions : 5]

SEAT No. : ____

P2824

[Total No. of Pages : 2

[5855]-210
First Year M. Pharmacy
PHARMACEUTICAL VALIDATION
(2019 Pattern) (Semester-II) (MQA202T)

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

Instructions to the candidates:

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

Q1) Attempt Any one question. **[15]**

a) Elaborate life cycle of Process validation as per USFDA guidelines.

b) What is "Validation Master Plan?" How is it executed?

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

a) Explain "Accuracy" of assay method with example.

b) Define process validation explain its types.

c) Explain the term "User Requirement specification" and its relation to DQ with suitable example.

d) Discuss "Qualification of Tablet Compression Mechine".

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

a) Discuss Autoclave validation.

b) What is International patenting procedure?

c) Describe copyright & Trademark.

d) How is membrane filtration process qualified?

e) State & compare types of steam.

P.T.O.

Q4) Attempt Any one of the following. **[1×15=15]**

a) Discuss validation of computerised systems.

b) Explain OQ-PQ for UV -visible spectrophotometer.

Q5) Write Short Notes on Any three **[3×5=15]**

a) Cleaning in place.

b) Intellectual property protection.

c) Calibration of weights & measures.

d) Organization for Validation.

e) Qualification for Fluidized Bed Dryer.

Total No. of Questions : 5]

SEAT No. :

P2825

[Total No. of Pages : 2

[5855]-211

First Year M. Pharmacy

AUDITS AND REGULATORY COMPLIANCE

(2019 Pattern) (Semester-II) (Theory) (MQA203T)

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 questions paper exicept seat number.***

Q1) Classify different types of pharmaceutical audit. Explain the management, objective and information gathering during audit. **[15]**

OR

Discuss elements of quality system model described in the FDA's pharmaceutical quality system guidelines.

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

a) Why are vendor audits conducted? Describe the auditing of a bulk pharmaceutical chemicals.

b) Explain parts and subparts of cGMP.

c) Discuss the auditing parameters in general areas of interest in the building and water in microbiology laboratory.

d) Classify and discuss the deficiencies found during audit.

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

a) Write a note on ETP audit.

b) Discuss pre-requisite attributes and qualification of a quality auditor.

c) Describe the transitioning to quality system approach in pharmaceutical manufacturing environment.

d) Discuss how granulation process and coating of a pharmaceutical product is audited.

e) Give a detail accounts on audit report.

P.T.O.

Q4) Give a detailed account of quality assurance audit of HVAC, water and water for injections. **[15]**

OR

Describe the step by step method of performing audit of microbiology laboratory.

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

a) Functions of quality assurance

b) HVAC system and its components.

c) Audit checklist for drug industry.

d) Auditing of ware house.

e) Product and process audit.

Total No. of Questions : 5]

SEAT No. : [ ]

P2826

[Total No. of Pages : 2

[5855]-212

First Year M. Pharmacy (Pharmaceutical Quality Assurance)

PHARMACEUTICAL MANUFACTURING TECHNOLOGY

(2019 Pattern) (Semester-II) (MQA 204T) (Theory)

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

Instructions to the candidates:

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

Q1) Explain PAT in detail alongwith its advantages. **[15]**

OR

What are in process quality control test for tablets and capsules?

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

a) Discuss key elements of QbD. What are advantages of QbD?

b) Explain IPQC test for dry powders.

c) Describe sterile product manufacturing area.

d) Comment on closure lining.

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

a) QbD for excipients.

b) Comment on 'Production Planning'.

c) FFS.

d) Rapid mixing and rota granulators.

e) CIP

P.T.O.

Q4) Describe in detail containers and closures for pharma ceuticals. **[15]**

OR

Describe the process of film coating. Describe in detail problems encountered in tablet coating and remedies.

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

a) Plastic pouching.

b) Quality control test for glass containers.

c) Spheronizers.

d) Factors affecting plant location.

e) Stability of packaging material.

Total No. of Questions : 5]

SEAT No. :

P2827

[Total No. of Pages : 2

[5855]-213

First Year M. Pharmacy

REGULATORY ASPECTS OF DRUGS OF COSMETICS

(2019 Pattern) (Semester-II) (MRA201T)

Time : 3 Hours] ***[Max. Marks : 70***

Instructions to the candidates:

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

Q1) Answer any one (15 marks each) **[15]**

a) Explain the organisation, structure and functions of FDA.

b) Enlist the regulatory requirements for registrations of drugs and post approval requirement in china and south korea.

Q2) Answer any two (7-5 marks each) **[15]**

a) Enlist the regulatory requirements for registration of drugs and post approval requirements in ASEAN.

b) Explain regulatory pre requisites related to marketing authorization in gulf countries.

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

d) Describe Drug and cosmetic get of united states.

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

a) Write a note on orange book

b) Write a note on DMF system in Japan

c) Write a note on ASEAN and EAC.

d) Describe organization and structure of EMA.

e) Describe Eudralex directives for human medicines.

P.T.O.

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

a) Explain in detail regulatory approval process for investigational new drug. New drug application in United States.

b) Explain in detail a bout legislation & regulations for import manufacture, distribution and sale of cosmetics in Brazil

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

a) Write a note on code of Fedral Regulations

b) Write a note on PANDRH

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

d) Describe Active substance master Files (ASMF) system in EU.

e) Write a note on sale of cosmetics in Australia

Total No. of Questions : 5]

SEAT No. : ____

P2828

[Total No. of Pages : 2

[5855]-214

First Year M. Pharmacy

REGULATORY ASPECTS OF HERBAL & BIOLOGICALS

(2019 Pattern) (Semester-II) (MRA202T)

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 questions. (15 marks each)

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

b) Explain quality, safety & legislation for herbal products in India.

Q2) Answer Any Two (7.5 marks each)

a) What are the post market data requirements for similar biologics as per India?

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

c) Explain what are the CTD module 1 data requirements for market authorization applications as per India.

d) Write a note on GDP.

Q3) Answer any three (5 marks each).

a) Write a note on biological & biosimilars, enlist different biological products.

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

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

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

e) What are the stability requirement' for vaccines as per Guropean Union.

P.T.O.

Q4) Answer any one (15 marks each).

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

b) Explain quality, safety & legislation for herbal products in USA.

Q5) Answer any three (5 marks each)

a) What are the safety requirements for vaccines as per European Union?

b) What are the quality requirements for harbal products as per EU.

c) What are the safety requirements for herbal prodcuts as per EU.

d) What are the applicable regulations & guidelines for vaccines as per India.

e) Write a note on TSE/BSE evaluation.

Total No. of Questions : 5]

SEAT No. :

P2829

[Total No. of Pages : 2

[5855]-215

First Year M. Pharmacy

REGULATORY ASPECTS OF MEDICAL DEVICES

(2019 Pattern) (Semester-II) (MRA 203T)

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

Instructions to the candidates:

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

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

a) Explain in detail summary Technical Document.

b) Explain in detail regulatory registration process of JAPAN.

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

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

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

c) Write a note on investigation device exemption and in vitro diagnostics

d) Write a note on CE certification process.

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

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

b) Write a note on Pre-market approval

c) Explain global medical Devices nomenclature.

d) Explain medical Devices working groups.

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

P.T.O.

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

a) Write a note on regulatory approval process for medical Devices (510k) pre-market notification

b) Explain in detail quality risk management of medical Devices. ISO 14971.

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

a) Write down differences between medical Devices and pharmaceutical

b) Explain in detail ISO 13485.

c) Write a note on clinical investigation of medical devices.

d) Define and classify medical devices as per Indian regulations.

Total No. of Questions : 5]

SEAT No. : ____

P2830

[Total No. of Pages : 2

[5855]-216

First Year M. Pharmacy

REGULATARY ASPECTS OF FOOD & NUTRACEUTICALS

(2019 Pattern) (Semester-II) (MRA 204T)

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

Instructions to the candidates:

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

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

a) Role of research and development in nutraceutical.

b) Explain development of master manufacturing record and fatch record.

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

a) Explain reason for occurence of non -communicable disease? Explain role of nutraceutical in meating non-communicable disease.

b) Explain recommended dietory allowe any in europe.

c) What are cardiac nutraceuticals? Explain in details with examples.

d) Give the duties and responsibilities of food analyst.

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

a) What is NSF? Give its composition and explain how it works.

b) Explain in details what information needs to be on the label along with its importance.

c) Explain responsibilities of USFDA.

d) European regulation on Novel food.

e) Explain safety manufacturing standards and self-regulation in India.

P.T.O.

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

a) Explain in details dietary supplement & health education as per US act.

b) Explain auropean directives and regulations for manufacturing and sale of nutraceutical and dietary supplement.

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

a) Explain good manufacturing practice, compliance and cost.

b) Explain role of glucosamine and chordin in meeting inflammatary disease.

c) What is the functions of food safety and standard act? Give its composition and function.

d) Why Mare dietary supplements are not NSF certified.

e) Explain european regulation on novel food ingredient.

Total No. of Questions : 5]

SEAT No. : ____

P2831

[Total No. of Pages : 2

[5855]-217
First Year M. Pharmacy
PROTEIN & PROTEIN FORMULATION
(2019 Pattern) (Semester-II) (MPB201T)

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 a note on Biophysical characterization of proteins.

b) Briefly discuss various sequencing methods for protein.

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

a) What is PGEylation? Write properties.? benefits of PEG ylation in protein formulations.

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

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

d) Discuss the role of X-Ray (Crystallography) in protein structure determination.

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

a) Explain various chromatographic techniques in protein purification.

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

c) Defination classification & evoluation of peptidomimetics.

d) Write a note on design of peptidomimetics.

e) A note on ACE I in hibitors.

P.T.O.

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

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

b) How proteins can be purified & Enlist? explain the different methods used for the protein purification.

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

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

b) Explain different types of proteomics.

c) Discuss ICA A Labelling technique for protein quantification

d) Gene shuffling

e) Tryptic peptide mapping.

Total No. of Questions : 5]

SEAT No. : ____

P2832

[Total No. of Pages : 2

[5855]-218
First Year M. Pharmacy
IMMUNO TECHNOLOGY
(2019 Pattern) (Semester-II) (MPB202T)

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 and labeled diagram whenever necessary.***

Q1) Answer Any One out of Two. **[1×15=15]**

a) Discuss in detail about primary and secondary lymphoid organs.

b) What are immunoglobulins? Explain in details about their nomenclature, classes and their biological functions.

Q2) Answer Any Two out of Four. **[2×7.5=15]**

a) What are cytokines? Discuss their biological rule.

b) Discuss detail structure and functions of antibody.

c) Explain various types of Auto immune disorders.

d) What is vasculitis? Write different classes of Vasculitis.

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

a) Give basic characteristics of complement system.

b) Write functions of cytokines.

c) Enlists cytokines that regulate innate immune response.

d) Write examples of various traditional vuccines.

e) Explain subunit vaccine with suitable examples.

P.T.O.

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

a) Discuss in detail about Recombinant vaccines with suitable examples.

b) What is RIA? Write principle, procedure and applications of RIA.

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

a) Tumor Necrosis factor (TNF)

b) Complement Fixation Reaction.

c) Peptide vaccine.

d) Opsonization.

e) Principles and applications of ELISA.

Total No. of Questions : 5]

SEAT No. : ____

P2833

[Total No. of Pages : 2

[5855]-219

First Year M. Pharmacy (Pharmaceutical Biotechnology)
BIOINFORMATICS AND COMPUTER TECHNOLOGY
(2019 Pattern) (Semester-II) (MPB203T)

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

a) Define bioinformatics. What are bioinformatics databases? Discuss five major types of bioinformatics databases.

b) Explain in detail sequence Analysis.

Q2) Attempt Any Two out of four. **[2×7.5=15]**

a) What is data mining. Give its applications.

b) What is FASTA and BLAST?

c) What is drug designing? Explain its principle.

d) What is lead discovery? Explain application of bioinformatics in micro array analysis?

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

a) Write a note on protein databases

b) Write about five types of data used in bioinformatics

c) Write a note on Nucleic acid databases.

d) Write application of Bioinformatics.

e) Write about high throughput screening and virtual screening.

P.T.O.

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

a) What is force Field methods, of protein informatics? Explain in detail protein informatics.

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

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

a) Discuss methods of protein ligand docking.

b) Explain in detail genetic mapping.

c) Explain laboratory based approaches method of gene prediction.

d) Write a note on Nematode biology.

e) What is importance of nucleotide sequence and write about pattern of nucleotide.

Total No. of Questions : 5]

SEAT No. : [ ]

P2834

[Total No. of Pages : 2

[5855]-220

First Year M. Pharmacy

BIOLOGICAL EVALUTION OF DRUG THERAPY

(2019 Pattern) (Semester-II) (MPB 204T)

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

Instructions to the candidates:

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

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

a) Explain the principle, advantages, disadvantages, and types of bioassay.

b) Define biological medicines. Explain in detail the role of biological medicines concerning cardiovascular diseases and digestive disorders.

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

a) Write a note on mutagenicity toxicity studies.

b) Explain various methods to calculate ED50.

c) Briefly describe the need for bioequivalence studies in the case of conventional dosage forms.

d) Describe bioassay of D-tubocurarine.

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

a) Describe the bioassay of streptokinase.

b) Define bioequivalent and the concept of equivalent.

c) Explain mammalian pharmacokinetic modeling.

d) Describe the regulatory considerations for pre-clinical and clinical testing of biologics.

e) Explain in detail the role of biological medicines concerning blood disorders.

P.T.O.

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

a) Explain OECD guidelines for acute toxicity studies.

b) Explain in detail the role of biological medicines concerning vaccines and growth factors.

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

a) Explain sources, chemistry and properties of pyrogens.

b) Write a note on preclinical drug evaluation.

c) Explain the various methods of measuring bioavailabiltiy.

d) Explain the various methods of the microbial assay.

e) Write a short note on the assay of antibiotics.

Total No. of Questions : 5]

SEAT No. :

P2835

[Total No. of Pages : 2

[5855]-221
First Year M. Pharmacy
ADVANCED PHARMACOLOGY-II
(2019 Pattern) (Semester-II) (MPL201T)

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

Instructions to the candidates:

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

Q1) Define and classify anti-asthmatics. Write the pharmacology of salbutamol and theophylline as anti-asthmatic drugs. **[15]**

OR

Define and classify antibiotics. Explain mechanism of action, mechanism of resistance, adverse effects and therapeutic uses of Penicillin.

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

a) Pharmacology and therapeutic uses of growth hormone.

b) Explain in detail pharmacology of Insulin.

c) Explain pharmacology of PPIs.

d) Write the pharmacotherapy of COPD.

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

a) Write the advancement in the treatment of diabetes mellitus.

b) Explain mode of action, toxicities and therapeutic uses of fluoroquinolones.

c) Write the application of chronopharmacology in the treatment of diabetes.

d) Write the pharmacotherapy of irritable bowel syndrome.

e) Explain the mechanisms of antibiotic resistance.

P.T.O.

Q4) Classify anticancer drugs. Explain in details the role of antimetabolites in the management of cancer. **[15]**

OR

Define free radicals and antioxidants. Explain the role of free radicals in the etiopathology of diabetes. Write a note on vitamin E as an antioxidant.

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

a) Lipoic acid as an antioxidant.

b) Immunosuppressant

c) Comment on Antithyroid agents

d) Oral contraceptives

e) Pharmacotherapy of diarrhea.

Total No. of Questions : 5]

SEAT No. :

P2836

[Total No. of Pages : 2

[5855]-222

First Year M. Pharmacy

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - II

(2019 Pattern) (Semester-II) (MPL 202T)

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

Instructions to the candidates:

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

Q1) Attempt Any One. **[15]**

a) Discuss briefly the OECD principles of GLP.

b) Discuss study design and importance of male reproductive toxicity testing.

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

a) Write a note on *in vitro* and *in vivo* studies for genotoxicity

b) How are inhalational products tested for their toxic effects?

c) Describe in detail the Tier1 and Tier2 safety pharmacology studies.

d) Discuss the Principles of Toxicokinetics.

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

a) Write the alternative methods to animal toxicity studies.

b) Write about ICH guidelines for toxicity studies.

c) Explain the Inhalation studies as per OECD guidelines.

d) Discuss the In vivo methods of assessing female reproductive toxicity studies.

e) Write about acute eye irritation toxicity studies.

P.T.O.

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

a) Define safety pharmacology? Explain the scope, importance and principles of safety pharmacology.

b) Define IND. Discuss the studies needed for IND submission.

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

a) Skin sensitization

b) HERG assay

c) Teratogenicity studies.

d) Dermal toxicity

e) Importance of IND

Total No. of Questions : 5]

SEAT No. : ____

P2837

[Total No. of Pages : 2

[5855]-223
First Year M. Pharmacy
PRINCIPLES OF DRUG DISCOVERY
(2019 Pattern) (Semester-II) (MPL203T)

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

Instructions to the candidates:

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

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

Explain the general techniques used in combinatorial synthesis.

OR

Explain in detail the pharmacophore based approach in drug design.

Q2) Medium Length Answers solve any two. **[2×7.5=15]**

a) Describe in detail about microarray techniques.

b) Explain in brief stages involved in drug discovery.

c) Explain in detail the structure based drug design.

d) Write in detail about QSAR protocols.

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

a) Write about applications of Biomarkers in drug discovery.

b) Describe in short about docking based screening.

c) What is hologram QSAR (HQSAR) Explain in details.

d) Explain in detail about scaffold hopping.

e) What are the basic principles of drug design.

P.T.O.

Q4) Long answer questions (Solve any one out of two) **[1×15=15]**

Define rational drug design & explain types of drug design.

OR

Write in detail about physicochemical parameters used in QSAR studies.

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

a) Add a note on in-silico lead discovery techniques.

b) Write a note about molecular docking.

c) Write a note on proteomics.

d) Give a shot note on lead optimization.

e) Give the short account on linear Regression.

Total No. of Questions : 5]

SEAT No. : ____

P2838

[Total No. of Pages : 2

[5855]-224

First Year M. Pharmacy

CLINICAL RESEARCH AND PHARMACOVIGILANCE

(2019 Pattern) (Semester-II) (MPL 204T) (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) ***Neat diagrams must be drawn wherever necessary.***

Q1) Long answer questions. **[15]**

Define Adverse drug reactions (ADRs). Write in Detail Types of ADRs, Mechanism of 'Type A' ADRs with suitable examples.

OR

Write a note on ICH-GCP guidelines for clinical trials. note on concept of informed consent in clinical trial with suitable example.

Q2) Medium Length Answers solve any two. **[15]**

a) Schedule Y.

b) Phase '0' and phase 'l' in clinical trial.

c) Clinical trial investigator.

d) Clinical trial monitoring.

Q3) Short Answer questions solve any three. **[15]**

a) Responsibilities of clinical Research organisation.

b) Note on clinical trial study team.

c) Roles of ICMR in clinical trial study.

d) Note on Roles of sponsor in clinical trial study.

e) Note on suspected adverse drug reaction with examples.

P.T.O.

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

Guidelines for preparation of clinical trial document. Describe in detail components for preparation of clinical trail protocol.

OR

Explain history and progress of pharmacovigilance. Write on roles and responsibilities involved for pharmacovigilance.

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

a) Case report forms.

b) Methods of Detection of Adverse drug reactions.

c) Clinical trials.

d) Significance of safety monitoring.

e) Institutional review board (IRB) in clinical trial.

Total No. of Questions : 5]

SEAT No. :

P2839

[Total No. of Pages : 2

[5855]-225
First Year M. Pharmacy
MEDICINAL PLANT BIOTECHNOLOGY
(2019 Pattern) (Semester-II) (MPG201T)

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

Instructions to the candidates:

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

Q1) What is the genetic code? What are its silent features? Explain regulation of gene expression with suitable example. **[15]**

OR

What is transgenic plant? Explain various methods used in gene identification, localization and sequencing of genes.

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

a) Explain different methods of cloning and its applications.

b) Explain DNA recombinant technology with its applications.

c) Write a note on 'Single cell protein'.

d) Explain production of enzymes of pharmaceutical interest by fermentation technology.

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

a) Explain DNA replication with its applications.

b) Give applications of immobilization techniques in secondary metabolite production.

c) Write a note on 'Transgenic plants'

d) What is Protoplasm? Explain the process of protoplast fusion with example.

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

P.T.O.

Q4) What is RNA? Explain RNA and Protein replication in detail. **[15]**

OR

What is fermentation? Explain various applications of fermentation technology.

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

a) Protoplast fusion

b) Applications of plant biotechnology in pharmacy and allied fields.

c) Cloning of plant cell.

d) Applications of PCR in plant genome analysis.

e) Sterilization methods used in tissue culture.

Total No. of Questions : 5]

SEAT No. : ____

P2840

[Total No. of Pages : 2

[5855]-226
First Year M. Pharmacy
ADVANCED PHARMACOGNOSY-II
(2019 Pattern) (Semester-II) (MPG202T)

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

Instructions to the candidates:

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

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

a) Discuss the process of herbal drug discovery. what is the role of ethnopharmacology in herbal drug discovery.

b) What is the significance of phytopharmacological screening in new drug development? Discuss various assays used in In-Vitro evaluation of anticancer drug.

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

a) Explain how DNA finger printing techniques can be used in identification of drugs of natural origin.

b) Give analytical profile of Psoralea Corylifolia state its pharmacological significance.

c) Discuss In Vitro screening methods for antidiabetic herbal drugs.

d) Describe the protocol for toxicity studies of herbal drugs as per OECD guidlines.

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

a) Write about 'wound healing herbs and their screening'.

b) Give chemical and analytical profile of Curcuma longa.

c) Discuss In Vitro screening techniques for antioxidants.

d) Write a note on reverse pharmacology.

e) Explain the role of ethnobotany in herbal drug evaluation.

P.T.O.

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

a) Comment on efficacy of herbal drugs. Describe various pharmacokinetic and pharmacodynamic issues involved in validation of herbal therapies.

b) Enlist various techniques for assessing quality of herbal drugs. Describe in brief estimation of following parameters as per WHO protocol;

i) Pesticide residue

ii) Heavy metals.

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

a) Microbial contamination in herbs/formulations.

b) In Vivo anti inflammatory screening.

c) Herbal Drug Regulation.

d) Analytical profile of Coleus Forskohlii.

e) Antifertility screening.

Total No. of Questions : 5]

SEAT No. :

P2841

[Total No. of Pages : 2

[5855]-227

First Year M. Pharmacy (Pharmacognosy)

MPG203T : INDIAN SYSTEM OF MEDICINE

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

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

Instructions to the candidates:

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

Q1) Explain Quality Assurance in ISM formulation **[15]**

OR

What is Naturopathy? Write a note on treatment modalities in naturopathy.**[15]**

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

a) Discuss standard operating procedure as per GMP

b) What is Gunapadam. Explain in detail?

c) Explain various meditation and meditation techniques.

d) Elaborate government in CRAS.

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

a) Explain about documentation process as per GMP

b) Elaborate Unani system of medicine.

c) Write in short about Suddhi.

d) Write in brief about GAP.

e) Discuss Homeopathic science.

P.T.O.

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

a) Explain principles of treatment in Ayurvedic system of medicines

b) Discuss challenges in safety monitoring of herbal medicines.

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

a) AYUSH

b) Carrier oils

c) Pranayama

d) GLP

e) CRU

Total No. of Questions : 5]

SEAT No. :

P2842

[Total No. of Pages : 2

[5855]-228

First Year M. Pharmacy (Pharmacognosy)

HERBAL COSMETICS

(2019 Pattern) (Semester-II) (MPG 204T)

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

Instructions to the candidates:

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

Q1) Explain the significance of pre-formulation studies of cosmetics. Elaborate on compatibility studies and possible interactions between chemicals and herbs. **[15]**

OR

Discuss method of prepration and standardization of dentifrices and mouth washes. **[15]**

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

a) Describe formulation and evaluation of conditioners.

b) Explain hair growth formulation. Enlist various hair growth promoters.

c) Discuss formulation and standardization of baby product.

d) Explain in details about manufacturing and Evaluation of Cleansing cream.

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

a) Enlist quality control methods of herbal shampoo.

b) Explain Lipstics as herbal cosmetics.

c) Explain formulation and evaluation of face powder.

d) Comment on humectants incorporated in herbal cosmetics.

e) Write in detail about natural colourants used in cosmetics.

P.T.O.

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

a) Discuss in details formulation and optimization of herbal cosmetic.

b) Explain the formulation and evaluation of herbal shampoos.

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

a) Toxicity screening in animals.

b) Herbs used in cosmetics as an active ingredient.

c) Bleaching cream.

d) Offences and penalties related to cosmetics.

e) Herbal deodorants.