Total No. of Questions : 5]

SEAT No. :

PA-2754

[Total No. of Pages :2

[5941]-111
M. Pharmacy
MPAT 101T : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(2019 Pattern) (Semester - I)

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

Instructions to the candidates :

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

Q1) Explain modes of molecular vibrations and factors affecting vibrational frequencies. Give applications of IR spectroscopy.

OR

Explain chemical shift, spin-spin coupling and factors affecting chemical shift. Give applications of NMR spectroscopy.

[15]

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

a) Elaborate electronic transitions in UV/Visible spectroscopy. Discuss solvent effect.

b) Write instrumentation and applications of HPTLC.

c) Discuss different ionization techniques in mass spectrometry.

d) Explain in detail Ion Exchange Chromatography.

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

a) Write instrumentation and applications of Gel electrophoresis.

b) Give a comparative account on HPLC and UPLC.

c) Discuss applications of X-ray crystallography.

d) Describe Time of Flight and Magnetic sector mass analyzers.

e) Write instrumentation of Flame Emission Spectroscopy.

P.T.O.

Q4) Deduce the structure from following given data

Molecular weight : 88,

IR : 3000, 1745, 1250, 1150 cm^{-1}

^{13}CNMR : δ 176, 60, 21, 19

PMR : δ 4.2, quartet (2H),

δ 2.15, singlet (3H),

δ 1.2, triplet (3H)

Mass: m/z 88 (molecular ion), 73, 61, 45, 43 (base peak), 29, 15.

OR

Write in detail principle and instrumentation of gas chromatography.

[15]

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

a) Fourier transform infrared spectroscopy.

b) Factors affecting separation in electrophoresis.

c) Thermogravimetric analysis.

d) Instrumentation of Atomic Absorption Spectroscopy.

e) Derivative differential thermal analysis.

◆◆◆

Total No. of Questions : 5]

SEAT No. :

PA-2755

[Total No. of Pages :2

[5941]-112
M. Pharmacy
MPH 102T : DRUG DELIVERY 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.***

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

a) Explain the need for Gastroretensive drug delivery system with detailed account of various formulation principles/approaches used.

b) Explain in details mechanism of drug release from matrix and membrane controlled drug delivery systems.

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

a) Explain in detail the principle, advantages and disadvantages of mucoadhesive drug delivery systems.

b) Explain in details barriers for protein delivery in-vivo.

c) Give applications and designs of transdermal patches.

d) Classify ocular drug delivery systems and give brief account of intro ocular injections.

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

a) Explain structure of skin and its barriers.

b) Give importance of personalized medicines.

c) Explain in brief enzyme activated drug delivery system.

d) Enlist various evaluation parameters for oral S.R.tablet & explain % CDR determination and its importance.

e) Classify polymers with examples. Give examples of 5 synthetic polymers.

P.T.O.

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

a) Compare sustained released DDS with conventional DDS. Discuss in details prerequisites of drug candidate for development into SRDF.

b) Explain the principle and various designs of osmotic DDS.

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

Write short note on:

a) Biodegradable polymers and their applications

b) Drug delivery systems with zero order drug release.

c) Penetration enhancers in transdermal drug delivery systems.

d) Buccal drug delivery systems.

e) Single shot vaccine.

◆◆◆

Total No. of Questions : 5]

SEAT No. :

PA-2756

[Total No. of Pages : 2

[5941]-113
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 wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Define preformulation. Explain drug excipient interactions with suitable examples. Also add about the techniques to identify them. **[15]**

OR

What are small volume parenterals? Elaborate its formulation components.

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

a) Elaborate on response surface methodology.

b) Give validation of cone blender.

c) Discuss various dissolution models.

d) Describe inventory management & control.

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

a) Explain concept of electrical double layer in dispersion.

b) Discuss self emulsifying drug delivery.

c) Elaborate process of material management.

d) Give significance of similarity (f_2) & dissimilarity (f_1) factor.

e) Explain pharmacokinetic parameters.

P.T.O.

Q4) What are optimization parameters? Add a note on simplex method of optimization. **[15]**

OR

What is pharmaceutical validation? Explain scope & merits of validation.

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

a) Qualification of equipments.

b) Sales forecasting.

c) Budget & Cost Control.

d) Industrial & Personal relationship.

e) Total quality management concept.

◆◆◆

Total No. of Questions : 5]

SEAT No. :

PA-2757

[Total No. of Pages :2

[5941]-114
M. Pharmacy
MPH 104T : REGULATORY AFFAIRS
(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) Attempt any one : **[15]**

Explain in detail the drug approval process in European union (EU) countries.

OR

give elaborate details of drug master file (DMF).

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

a) Explain in detail ANDA regulatory approval process.

b) Explain in detail clinical trial protocols.

c) Give detailed account on Investigator Brochure.

d) Explain in detail the different sections of NDA.

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

a) Explain in detail the Hatch Waxman act.

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

c) Explain the medicinal product dossier (IMPD).

d) Enlist ICHQ guidelines.

e) Explain in detail post marketing Surveillance.

P.T.O.

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

Explain in detail NDA regulatory approval process.

OR

Explain in detail scale up process approval changes.

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

a) Short note on informed consent process.

b) Write note on ECTD.

c) Enlist is ICHS guidelines.

d) What is TGA, write note on its objectives.

e) Write short note on HIPAA.

◆◆◆

Total No. Of Questions : 5]

SEAT No. :

PA-2758

[Total No. Of Pages : 2

[5941]-118
M. (Pharmacy)
MPC - 102T : Advanced Organic Chemistry - 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) ***Do not write anything on question paper except seat number.***
4) ***Draw neat diagrams and structures wherever necessary.***

Q1) a) Explain the reaction mechanism and applications of Dieckmann reaction, Suzuki reaction and Michael addiction reaction. **[15]**

OR

b) Explain the basic principles of retrosynthesis and synthon approach. Elaborate on strategies for synthesis of four and five membered rings.

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

a) Describe the method of formation, stability and synthetic applications of carbenes and nitrenes.

b) Discuss the theory, mechanism and synthetic applications of Hantzsch reaction.

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

d) What is multicomponent synthesis? Discuss about Ugi reaction and Passerini reaction.

P.T.O.

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

a) Discuss Functional Group Interconversion (FGI) and Functional group addition (FGA) with suitable examples.

b) Discuss any two methods of determining reaction mechanism.

c) Write synthesis of Sulfamerazine and Celecoxib.

d) Elaborate on synthetic applications of Aluminium isopropoxide and N- bromosuccinamide in organic reactions.

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

Q4) Write synthesis of Ketoconazole, Antipyrine and Alprazolam. **[15]**

OR

Explain the protection of carboxyl and carbonyl groups with suitable examples.

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

a) Ozonolysis

b) Rearrangement reactions.

c) Knorr pyrrole synthesis and Pinner Pyrimidine synthesis.

d) Hoffmann and Saytzeff rules of elimination reaction.

e) Synthetic applications of Diazomethane and Witting reagent.

Total No. Of Questions : 5]

SEAT No. : [ ]

PA-2759

[Total No. Of Pages : 2

[5941]-119

F.Y. M. Pharmacy

MPC - 103T : Advanced Medicinal Chemistry - 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) ***Do not write anything on question paper except seat number.***

Q1) Classify antihypertensive agents with examples and mechanism of action.Give an account of calcium channel blockers. **[15]**

OR

Enlist various types of receptors and discuss about various theories of drug receptor interactions.

Q2) **Attempt any <u>Two</u> :** **[15]**

a) Classify anticonvulsants and enlist their structural requirement.

b) Explain design of stereoisomers and geometric isomers in Analog design.

c) Discuss chemistry of drugs used in the treatment of Alzheimer's and Parkinson's disease.

d) Discuss chemistry of psychoactive drugs.

P.T.O.

Q3) **Attempt any <u>Three</u> :** **[15]**

a) Explain chemistry of Cox-1 and Cox-2 inhibitors.

b) Write mode of action of salicylates and profens.

c) Explain Rationale of prodrug design and practical consideration.

d) What is drug resistance? Explain it's causes in light of anticancer antibiotics with examples.

e) Stereoisomers influence ADME properties of drug: justify with example.

Q4) Explain enantio selectivity in drug absorption, distribution, metabolism and elimination with case studies and role of chirality in selective and specific therapeutic agents. **[15]**

OR

Explain chemistry of prostaglandins, Leukotrienes and thromboxanes.

Q5) **Write short notes on (any <u>Three)</u> :** **[15]**

a) Carrier linked prodrugs.

b) Classical and non-classical bioisosteric replacement strategies.

c) Classification and detail account of H_1 and H_2 receptor antagonists.

d) Generic principles of drug resistance.

e) Enzyme inhibitors in medicine.

Total No. Of Questions : 5]

SEAT No. : ____

PA-2760

[Total No. Of Pages : 2

[5941]-120
M. Pharm
MPC - 104T : Chemistry Of Natural Products
(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) **Solve any <u>One</u> question out of <u>Two</u>:** **[15]**

Explain how antimalarial drug development has progressed from plant products.

OR

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

Q2) **Solve any <u>Two</u> questions out of <u>Four</u>:** **[2×7.5=15]**

a) What are characterization details for Digitalis glycosides?

b) Explain development of paclitaxel as anticancer agent.

c) Define and classify terpenoids. Elucidate the structure of Camphor.

d) Discuss in brief about oligonucleotide therapy.

Q3) **Answer any <u>Three</u> questions out of <u>Five</u> :** **[3×5=15]**

a) Write structure elucidation methods for alkaloids.

b) Explain chemistry of macrolide antibiotics

c) Explain the significance of isoprene rule.

d) Discuss the chemistry of progesterone.

e) Discuss physiological significance of Folic acid and vitamin C.

P.T.O.

Q4) **Answer any <u>One</u> question out of <u>Two</u>:** **[15]**

Explain nomenclature and chemistry of contraceptive agents giving their structures.

OR

What is gene therapy? Explain clinical applications and recent advances in gene therapy.

Q5) **Write short notes on any <u>Three</u> out of <u>Five</u>:** **[3×5=15]**

a) Physiological significance of vitamin A.

b) Development of curare alkaloids as neuromuscular blocking agents.

c) Describe the active constituents in phyllanthus niruri for liver dysfunction and curcuma longa linn for antitumor property.

d) Describe the structural elucidation of Quercetin.

e) Explain principles of RNA & DNA estimation.

Total No. Of Questions : 5]

SEAT No. :

PA-2761

[Total No. Of Pages : 2

[5941]-124

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA - 102T : 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 side indicate full marks.***
3) ***Draw neat labeled diagrams wherever necessary***

Q1) Describe types of benchmarking and explain benchmarking process. Give advantages and limitations of bench - marking. **[15]**

OR

Explain pharmaceutical quality management as per ICH Q10

Q2) **Attempt any <u>Two</u> :** **[15]**

a) Explain statistical control charts. Give its concepts and general aspects.

b) Explain CAPA in pharma industry.

c) Elaborate on NABL certification and accreditation.

d) Explain ISO 9001 : 2008

P.T.O.

Q3) **Attempt any <u>Three</u>:** **[15]**

a) Define benchmarking. Give reasons for benchmarking.

b) Give advantages of statistical control.

c) Principles of six sigma.

d) Principles of TQM.

e) Quality metrics of pharmaceutical industry.

Q4) Explain in detail six system inspection model. **[15]**

OR

Explain ICHQ8 in detail.

Q5) **Write short note on any <u>Three</u> :** **[15]**

a) Dimensions of quality.

b) Concept of self inspection.

c) Change control, deviations and out of trend with respect to quality systems.

d) HACCP.

e) Photostability testing of drug and drug products.

Total No. Of Questions : 5]

SEAT No. :

PA-2762

[Total No. Of Pages : 2

[5941]-125

M. Pharmacy (Pharmaceutical Quality Assurance)

MQA - 103T : Quality Control And Quality Assurance

(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) ***Neat diagrams must be drawn wherever necessary***

Q1) Discuss in detail about CGMP guidelines as per schedule M in pharmaceutical industry. **[15]**

OR

Explain about CPCSEA guidelines with protocol for conduct of nonclinical testing. **[15]**

Q2) **Attempt any <u>Two</u> questions:** **[15]**

a) Explain about scope and importance of Good laboratory practices.

b) Discuss importance of environmental control utilities and maintenance of sterile area in pharmaceutical unit.

c) Elaborate in brief about hygiene and personal records in pharmaceutical unit.

d) Discuss about batch manufacturing record in manufacturing of solid dosage forms.

P.T.O.

Q3) **Attempt any <u>Three</u> questions:** **[15]**

a) Elaborate about CDER,CBER and EMEA.

b) Explain about mix-ups and cross contamination.

c) Discuss about analysis of raw material and finished products.

d) Differentiate in between Quality control and Quality assurance department.

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

Q4) Discuss about IPQC and finished product quality control test for capsules as per I.P and B.P. **[15]**

OR

What do you mean by documentation. Explain about three tier and master batch record. **[15]**

Q5) **Write a short note on any <u>Three</u> :** **[15]**

a) Pharmaceutical inspection Convention.

b) Quality audit plan and reports.

c) Quality certification.

d) Good warehousing practices.

e) Reprocessing and salvaging.

Total No. of Questions : 5]

SEAT No. :

PA-2763

[Total No. of Pages :2

[5941]-126

M. Pharmacy

MQA 104T : PRODUCT DEVELOPMENT AND 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 indicate full marks.***

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

Explain solubility. Enlist method to improve solubility and discuss in detail any one method to improve solubility of drug.

OR

Explain in detail stages of drug discovery and development.

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

a) Explain concept and significance of pilot plant scale up and give details of large scale manufacturing tech with respect to equipment process and quality control of tab lets.

b) Explain the concept of pre-formulation studies and discuss pre formulation parameter for drug substance.

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 plastic used in pharmaceutical packaging and explain medical device packaging.

P.T.O.

Q3) Attempt any three: **[3 × 5 = 15]**

a) Explain the stability testing process while product development.

b) What is polymorphism? Explain technique to study polymorphism of drug substance.

c) Explain various issues facing modern drug packaging.

d) Explain technique to study crystal properties of drug substance.

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

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

Discuss in detail manufacturing, manufacturing flowchart and in process quality control tests for parenteral dosage form.

OR

Explain in detail documentation in technology transfer and in process quality control test for parenteral forms.

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

a) Write short note on Investigational New Drug Application (INDA).

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

c) Write short note on abbreviated new drug application (ANDA).

d) Write short note on post marketing surveillance.

e) Write short note on supplemental new drug application (SNDA).

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Total No. of Questions : 5]

SEAT No. :

PA-2764

[Total No. of Pages :2

[5941]-127
M. Pharmacy
MRA 101T : GOOD REGULATORY PRACTICES
(2019 Pattern) (Semester - I)

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

Instructions to the candidates :

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

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

a) Explain in detail cGMP.

b) Explain in detail GLP subpart A to K.

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

a) Explain future of GLP regulations.

b) Explain principles of GALP regulations and GALP requirements.

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

d) Write in detail about analytical method validation.

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

a) What are the legal GDP requirements?

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 requirements?

P.T.O.

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

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

b) Explain in detail 21 CFR part 11.

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

a) Write a note on GHTF working groups.

b) Explain product lifecycle of medical devices.

c) Explain in brief Bracketing and Matrixing design for stability testing of new drug substance and products.

d) Enlist ICH quality guidelines.

e) Explain quality by design.

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Total No. of Questions : 5]

SEAT No. : [ ]

PA-2765

[Total No. of Pages : 2

[5941]-128

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) Explain in detail CTD module 3.

b) Explain in detail site master file.

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

a) Explain in detail DMF.

b) Write a note on preparation and Conduct of Audit.

c) Write a note on inspection of pharmaceutical manufacturer.

d) Write a note on ISO risk management standard.

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

a) Write a note on exploratory product development, brief for drug substance and product.

b) What are the types of audit, explain it.

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

d) Write a note on corrective and preventive action.

e) Write a note on root cause analysis.

P.T.O.

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

a) Explain indetail submission in sugam system of CDSCO.

b) Explain in detail ACTD

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

a) Write a note on post approval labeling changes.

b) Write a note EIR and warning letter.

c) Write a note on seizure and injunctions.

d) Explain print pack specifications and COA.

e) Explain Batch manufacturing record and its calculations.

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Total No. of Questions : 5]

SEAT No. :

PA-2766

[Total No. of Pages : 2

[5941]-129

F.Y. M. Pharm.

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) ***Figures to the right indicate full marks.***

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

a) What is CDSCO guidelines? Explain in detail.

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

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

a) Explain in detail about CFR 21 812.

b) Explain Regulatory Guidance on Efficacy & Safety ICH guidance.

c) What is GCP? Explain in detail about Indian GCP guidelines.

d) What is Belment Report? Explain Ethics of clinical research in special populations.

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

a) IND application

b) CFR21 part 320

c) Guidelines for Efficacy & safety.

d) General consideration of clinical trial.

e) Significance of ANDA.

P.T.O.

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

a) What is EMA? Explain in detail about clinical research regulations in Europe.

b) Explain the origin of ICH and add a note on "Good Clinical Practice". guidelines.

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

a) NDA.

b) Declaration of Helsinki

c) Phase I studies in Clinical Trial.

d) Post Marketing surveillance.

e) Patient Information sheet and Informed consent form.

Total No. of Questions : 5]

SEAT No. : [ ]

PA-2767

[Total No. of Pages : 2

[5941]-130

M. Pharmacy

MRA-104 T : REGULATIONS AND LEGISLATION FOR DRUGS AND COSMETICS, MEDICAL DEVICES, BIOLOGICALS AND HERBALS, AND FOOD NEUTRACEUTICALS 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 ony one. **[15]**

a) Write about Indian patent Scenario.

b) Give regulatory requirements and approval procedures for drugs and cosmetics, medical devices, biologicals & herbals & food & neutraceuticals.

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

a) Mention the conditions of import license for schedule C and schedule X drugs.

b) Give the constitution of Drug Technical Advisory Board (DTAB) & its functions.

c) What is Berne Convention for the protection of Literary & Artistic works?

d) Offences & penalites in narcotic drugs & psychotropic substances.

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

a) Write a brief note on schedule M framed under D & C act rules there under.

b) Guidelines for approval of drugs and cosmetics.

P.T.O.

c) Comment on prohibition of misleading advertisement relating to drugs under drugs & magic remedies act 1955.

d) What international conventions protect patent rights?

e) Give regulatory requirements of Bioequivalence study.

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

a) What is IPR? Discuss various components of IPR.

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

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

a) How retail price of formulation is calculated? As per drug price control order 1995.

b) Describe copyright & work protected under copyright act.

c) Write in brief about Patent Act 1970 & its ammendments.

d) Give rules, regulations, guidelines & standards for regulatory filing of biological and herbals.

e) What is trademark? Explain the different types of trademarks with examples. Differentiate between trademark & desgin. What is the process of registering a trademark?

Total No. of Questions : 5]

SEAT No. : [ ]

PA-2768

[Total No. of Pages : 2

[5941]-131

M. Pharmacy

PHARMACEUTICAL BIOTECHNOLOGY

MPB 102 T : Microbial and Cellular Biology

(2019 Pattern) (Semester-I)

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

Instructions to the candidates:

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

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

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

b) What are the features of pathogenic bacteria, fungi and virus and explain the mechanism of action of antimicrobial agent.

Q2) Attempt any two out of four. **[2×7½=15]**

a) What are the various cellular components? How prokaryotic cells are different from eukaryotic cells?

b) What is gene regulation? How transcriptional and tanslational controls occur?

c) Enlist and explain the factors affecting on stability of microbial culture.

d) Explain in detail cytotoxicity, anti-tumour and anti-viral assays.

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

a) Write a short note on mutagenesis.

b) Discuss carcinogens and repair mechanisms.

c) What are bacteriophages? Explain the genetic organization of bacteriophages

d) What is chemotherapy?

e) What is cytotoxicity?

P.T.O.

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

a) Explain the etiology and pathology of common microbial disease and currently recommended therapies for bacteria, fungi and viral infections.

b) Write a note on cell cycle, apoptosis, tumaur cells, carcinogens and oncogenes.

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

a) What are embryonic germ cells and stem cells? What are their applications?

b) Write a note on fertilization and events in fertilization.

c) What is chemotherapy?

d) Define microbial growth and enlist the factor affecting on it.

e) Differentiate between prokaryotes and eukaryotes.

Total No. of Questions : 5]

SEAT No. : ____

PA-2769

[Total No. of Pages : 2

[5941]-132

M. Pharmacy

PHARMACEUTICAL BIOTECHNOLOGY

MPB 2027 : Bioprocess Engineering and Technology

(2019 Pattern) (Semester-I)

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

Instructions to the candidates:

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

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

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

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

Q2) Attempt any two out of four. **[2×7½=15]**

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

b) Discuss various techniques used for presentation of stock culture.

c) Explain theories associated with mass transfer with respect to fermentation

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

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

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

b) Discuss regulatory a spects of biological products.

c) Explain batch cultivation process.

d) Outline bioautographic technique.

e) What are primary culture and secondary culture?

P.T.O.

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

a) Explain Biosynthetic pathways for any one secondary metabolities.

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

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

a) Computer control of fermentation process.

b) Immobilization of enzymes.

c) Bioproduction of Vitamin-B12

d) Bubble column bioreactor

e) Cell disruption techniques.

Total No. of Questions : 5]

SEAT No. : ____

PA-2770

[Total No. of Pages : 2

[5941]-133

F.Y. M. Pharmacy

PHARMACEUTICAL BIOTECHNOLOGY

MPB 104 T : Advanced Pharmaceutical Biotechnology

(2019 Pattern) (Semester-I)

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

Instructions to the candidates:

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

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

a) Discuss various sources of enzymes and their therapeutic and clinical applications.

b) What are biosensors? Discuss various mechanisms and types of biosensors.

Q2) Attempt any two out of four. **[2×7½=15]**

a) Write the principle of genetic engineering. Discuss various applications of genetic engineering.

b) Explain microbias production, purification & isolation of glucose isomerse enzyme.

c) Explain biotransformation process for chiral drugs.

d) Briefly explain role of various oncogenes proteins.

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

a) Write ideal properties of cloning vectors.

b) Discuss inflammatory responses in cell.

c) Write the applications of biotransformation.

d) What are restriction endonucleus enzymes? Write their various classess.

e) Write the significant of human genome project.

P.T.O.

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

a) What are transgenic animals? Write their applications in production of Therapeutic proteins.

b) Explain in details about kinetics of enzyme activity.

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

a) Biodegradation of xenobiotics

b) Recombinant DNA production of interferon

c) Expression vectors in r-DNA

d) Write a note on C-DNA

e) Production of trypsin

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Total No. of Questions : 5]

SEAT No. : [ ]

PA-2771

[Total No. of Pages : 2

[5941]-138

F.Y. M. Pharmacy

ADVANCED PHARMACOLOGY-I

(2019 Pattern) (Semester-I) (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 your seat no.***

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

a) What is CCF? Explain in detail pharmacology of Digitalis glycosides.

b) Define Autocoids. Explain mechanism of action and pharmacological actions of serotonin on its receptors.

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

a) Describe Pharmacology of CCBs.

b) Classify Opioid Analgesics. Explain mechanism of action of Morpine on its receptors.

c) What are the pharmacological actions of glycine.

d) Classify Fibrinolytics. Describe Pharmacology of Streptokinases.

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

a) Differentiate between Local and General Anaesthetics.

b) Explain mechanism of action and adverse effects of Imipramine.

c) What is role of ACE inhibitors in the management of hypertension?

d) Write a note on NANC transmission.

e) "Benzodiazepines are preferred more over barbiturates in Insomina" State true or false. Justify your answer.

P.T.O.

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

a) What is Parkinson's disease? Describe the pharmacology of L-Dopa

b) Classify anticoagulants. Describe Pharmacology of Low Molecular weight Heparins.

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

a) Haematinics

b) Adrenaline

c) Atropine Poisoning

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Total No. of Questions : 5]

SEAT No. : [ ]

PA-2772

[Total No. of Pages : 2

[5941]-139

F.Y. M. Pharmacy

MPL 103 T : 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-diabetic agents. **[15]**

OR

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

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. **[15]**

Q5) Write a short note 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.

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Total No. of Questions : 5]

SEAT No. :

PA-2773

[Total No. of Pages : 2

[5941]-140

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 side indicate full marks.***
3) ***Draw well labelled diagrams wherever necessary.***

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

OR

Write detail account on gene therapy and its clinical applications.

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

a) What do you mean by recombinant DNA technology?Discuss its applications

b) Explain the mechanism of apoptosis.

c) How cell cycle is regulated?

d) Write note on gene transfer techniques.

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

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

b) Explain the principles and applications of cell viability assays.

c) Describe inter cellular signaling.

d) Explain mitogen activated protein kinase signaling.

e) Differentiate between necrosis and apoptosis.

Q4) What are second messengers? Explain role of cyclic AMP. Calcium ion and nitric oxide as second messengers. **[15]**

OR

Explain in detail polymerase chain reaction and its applications.

P.T.O.

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

a) Cellular aging and death.

b) DNA based diagnosis of diseases.

c) Protein engineering.

d) Nuclear receptors.

e) Applications of biosimilars.

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Total No. of Questions : 5]

SEAT No. :

PA-2774

[Total No. of Pages : 2

[5941]-141

F.Y. M. Pharmacy

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) Explain in detail about recent advances in research in marine drugs.

b) Elaborate detail account of Current Good Agricultural practices.

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

a) Write a note on importance of Pharmacognosy in herbal drug Industry.

b) Write a note on conservation of medicinal plants.

c) Write a note on Marine toxins.

d) Discuss chemical nature, medicinal uses and health benefits of Flax seeds.

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

a) Antioxidants

b) Isolation of Withanolides

c) Regulatory aspects of Nutraceuticals

d) Health benefits of Vitamins.

e) Current trends and future scope on Nutraceuticals

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

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

b) Write in detail about the occurrence, isolation and characteristic feature of Rutin and Hesperidin.

P.T.O.

Q5) Short note (Slove any three) **[15]**

a) Occurrence and isolation of α and β-Carotene

b) Bio drug-food interaction with suitable examples.

c) Medicinal uses and health benefits of Green and Herbal tea.

d) Classification of Functional food with suitable examples

e) Occurrence and Characteristic features of Andrographolides.

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Total No. of Questions : 5]

SEAT No. :

PA-2775

[Total No. of Pages : 2

[5941]-142

F.Y. M. Pharmacy

MPG 103 T : PHYTOCHEMISTRY

(2019 Pattern) (Semester-I)

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 indicates full marks.***

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

OR

Elaborate a detail account of phytochemical fingerprinting in the characterisation of herbal extracts using LCMS along with its application in structural elucidation of phyto constituents.

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

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

b) Explain isolation, purification, characterisation and industrial importance of digitoxin.

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

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

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

a) Describe isolation, purification and industrial importance of Quercetin.

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

c) Elaborate in detail applications of LCMS in characterization of herbal extracts.

d) Explain clinical studies emphasizing on phases of clinical trials.

e) Explain detail spectroscopic characterization for structural elucidation of carvone.

P.T.O.

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

OR

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

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

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

b) Methods of fractionation.

c) Radiotracer techniques

d) Structural elucidation of kaempferol.

e) Umbelliferone

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Total No. of Questions : 5]

SEAT No. :

PA-2776

[Total No. of Pages : 2

[5941]-143

M. Pharmacy

MPG 104 T : INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY

(2019 Pattern) (Semester-I)

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

Instructions to the candidates:

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

Q1) What are WHO guidelines for assessing quality of herbal medicines with reference to contaminants & residues.? **[15]**

OR

Describe the process for obtaining patent for herbal drug formulation or natural product. **[15]**

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

a) Explain fundamentals of quality management systems in ISO 9000.

b) What are guidelines and instructions established by DGFT related to import and export of goods in India?

c) What are challenges in stability testing of natual products? Explain importance of stability testing?

d) Explain global regulatory status of herbal medicines.

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

a) Describe principles and importance of Total Quality Management (TQM).

b) Explain stability protocal for natural products.

c) What are rights of patent holder in India?

d) Write note on “Geographical Indication”

e) Describe process of project selection.

P.T.O.

Q4) "The manufactured herbal medicine should have acceptable quality". Explain this sentence in context to GMP. **[15]**

OR

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

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

a) Scale up techniques for optimization, maximization of productivity.

b) American Herbal Pharmacopoeia.

c) Exclusive Rights.

d) International legal agreement for intellectual property.

e) Patentability requirements.

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Total No. of Questions : 5]

SEAT No. : ____

PA-2777

[Total No. of Pages : 2

[5941]-211

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

MOLECULAR PHARMACEUTICS

(Nano Tech and Targeted DDS) (MPH 201T)

(2019 Pattern)

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) Intranasal formulation development in light of anatomical and physiological aspects of nasal cavity.

OR

b) Write in detail on nucleic acid based therapeutic delivery system.

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

a) Discuss the advantages and disadvantages of Aerosols as drug delivery system.

b) Monoclonal antibodies as drug delivery system

c) Methods for preparation of liposomes

d) What are the strategies for tumor targeting?

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

a) Explain nonviral gene transfer

b) Write a note on ex-vivo gene therapy

c) Write a note on propellants

d) Write a note on niosomes

e) Evaluation of nanoparticles

P.T.O.

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

a) Write in detail on preparation and evaluation of microspheres

b) What are the advantages and disadvantages of nanoparticles & liposomes?

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

a) Aquasomes

b) Containers for aerosols

c) In-vivo gene therapy

d) Electrosomes

e) Phagocytosis and pinocytosis

Total No. of Questions : 5]

SEAT No. :

PA-2778

[Total No. of Pages : 2

[5941]-212
M. Pharmacy
MPH 202T : ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS
(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) Explain various biopharmaceutics factors that limit oral bloavailability of drug from its dosage form. **[15]**

OR

How various pharmacokinetic parameters can be estimated when a drug is given as an i.v. bolus injection and follows one compartmental model?

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

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

b) Compare bioavailability and bioequivalence. Elaborate on various study designs used for bioequivalence study.

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) Describe in detail the importance of IVIVC and various types of IVIVC.

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

a) Describe briefly active transport of drug.

b) Enlist various applications of pharmacokinetic principles.

P.T.O.

c) If the drug is given by i.v. bolus route and the elimination rate constant K_E. of drug is 0.173 hr^{-1} and total clearance is found to be 57.17 L/hr. Calculate half - life and volume of distribution of drug V_d.

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

e) Discuss method of residuals along with its importance, advantages & limitations.

Q4) Explain the pH - partition hypothesis for drug absorption throught GIT. Give its importance and limitations. **[15]**

OR

What are pharmacokinetic models? Explain various types with their significance.

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

a) Biosimilar drug products.

b) CDSCO guidelines for BA/BE

c) Tight junction complex

d) Pharmacokinetic applications to modified drug release products

e) Reasons of non-linearity in pharmacokinetics.

Total No. of Questions : 5]

SEAT No. :

PA-2779

[Total No. of Pages : 2

[5941]-213
F.Y. M.Pharmacy
MPH203T : COMPUTER AIDED DRUG DEVELOPMENT
(2019 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.***

Q1) Answer in detail (Solve 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 (Solve 2 out of 4) : **[2 × 7.5 = 15]**

a) Explain in brief computational modelling for drug disposition.

b) Write a detailed account on AI & robotics.

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

d) Give historical perspective of application of computers in pharmaceutical industry.

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

a) Compare population and non-population PV/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, Life cycle & Risk assessment.

e) Explain BCRP and HPEPTI.

P.T.O.

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

a) Explain in detail feel Vs. fasted state and biowaiver considerations.

b) Write the significance of In-Vitro-In-vivo correlation in Biopharmaceutical characterization.

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

a) Write a short note on legal protection of innovative uses of computers in R & D.

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

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

d) Write a short note on BBB choline transporter.

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

Total No. of Questions: 5]

SEAT No. : ____

PA-2780

[Total No. of Pages : 2

[5941]-214
M. Pharmacy
MPH-204T: COSMETIC AND COSMECEUTICALS
(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.***
3) ***Draw well labeled diagrams wherever necessary.***
4) ***Do not write anything on question paper except seat number.***

Q1) Write in detail about structure of hair and comment on hair growth cycle. Add a note on the ingredients used in the preparatin of hair care cosmetics. **[15]**

OR

Write in detail about the biological aspects of skin problems like dry skin, acne, pigmentation, wrinkles and body odor and cosmetic preparations used to tackle these skin problems.

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

a) Discuss in detail about types of surfactants and their applications in cosmetics.

b) Discuss in detail about the problems associated oral cavity.

c) Building blocks for Soaps

d) Write in detail about formulation and evaluation of lipsticks.

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

a) Prohibition of manufacturing and sale of certain cosmetics

b) Perfumes used in cosmetics

c) Building blocks for cream formulation

d) Antidandruff formulations.

e) Preservatives used in cosmetic industry, their merits and demerits.

P.T.O.

Q4) Explain the causative factors of sunrays causing skin damage. Describe formulation of sunscreen products. Add a note on measurement of SPF.

OR

Define cosmetics? Give the detail classification of cosmetics. Explain regulatory provisions related to the manufacture and packaging of cosmetics. **[15]**

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

a) Antiperspirants and deodorants.
b) COSMOS Guidelines for foaming agents
c) Labeling of cosmetics
d) Loan license conditions for cosmetics
e) Preservative efficacy testing

Total No. of Questions : 5]

SEAT No. :

PA-2781

[Total No. of Pages : 2

[5941]-219
M. Pharmacy
MPC 201 T : ADVANCED SPECTRAL ANALYSIS
(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

Q1) Elaborate 2D-NMR Technique. **[15]**

OR

Compile the principle, instrumentation and applications of GC-MS.

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

a) Explain principle and instrumentation of supercritical Fluid chromatography.

b) How will you differentiate the following pair of compounds from their IR spectra?
   i) Acetaldehyde and acetone
   ii) Methylamine and aniline
   iii) Ethanol and acetic acid

c) Discuss instrumentation and applications of CE-MS.

d) Predict and explain NMR spectra of following compounds. (Any Three)
   i) p - toludine
   ii) 1 - Nitropropane
   iii) p - hydroxy acetophenone
   iv) t - butyl Chloride

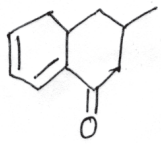
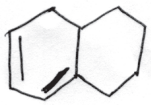
Q3) Attempt any Three. **[15]**

a) Elaborate Attenuated total Reflectance in IR spectroscopy.

b) Explain Mc-Lafferty rearrangement with suitable example.

P.T.O.

c) Predict the uv absorption maxima for following substances.

I]  II] 

d) Explain electrospray ionization in LC-MS.

e) Discuss metastable ion peaks and Isotopic peaks in mass spectrometry.

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

MF : $C_9H_{10}O$

uv : 280 nm (ethanol)

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

^{1}HNMR (δ ppm) :

i) δ : 2.09, singlet, 3H

ii) δ : 3.65, singlet, 2H

iii) δ : 7.29, singlet, 5H

b) Elaborate LC - FTIR Technique.

OR

Compile different rules used in mass fragmentation of organic compounds. Discuss the mass fragmentation patterns of following class of organic compounds.

i) Amines.

ii) Aliphatic and Aromatic acids

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

a) ELISA

b) Ring Rule in MS

c) Applications of LC-MS

d) Radioimmunoassay of Digitalis

e) Flash chromatography

Total No. of Questions : 5]

SEAT No. :

PA-2782

[Total No. of Pages : 2

[5941]-220
M. Pharmacy (Pharmaceutical Chemistry)
ADVANCED ORGANIC CHEMISTRY - II
(2019 Pattern) (Semester - II) (MPC 202 T) (Theory)

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

Instructions to the candidates:

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

Q1) What are pericyclic reactions? Explain with suitable example, cycloaddition reaction and sigmatropic rearrangement. **[15]**

OR

Elaborate on the rules for R/S nomenclature of stereoisomers with suitable examples. Add a note on resolution of racemic modification.

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

a) Elaborate on principles of Green chemistry.

b) Explain various phases of heterogeneous catalysis with suitable example.

c) Discuss solid phase synthesis and add a note on various solid supports and linkers used.

d) Elaborate on applications of phase Transfer catalysis.

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

a) Describe energy transfer in photochemical reaction.

b) Write applications of Microwave assisted reactions in Synthesis.

c) Elaborate on uses of enzymes in organic synthesis.

d) Example of reaction with Wilkinson catalyst.

e) Discuss uses of Transition metal catalysts with examples.

P.T.O.

Q4) Elaborate on various protection and deprotection strategies in solid phase peptide synthesis. **[15]**

OR

Explain Chiral auxiliary method of asymmetric synthesis with suitable examples.

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

a) Ionic Liquids and their applications.

b) Principle of Microwave assisted reactions

c) Ultra sound assisted reactions

d) Homogenious Catalysis

e) Continuous flow reactors

Total No. of Questions : 5]

SEAT No. :

PA-2783

[Total No. of Pages : 2

[5941]-221

F.Y. M. Pharmacy (Pharmaceutical Chemistry)

MPC203T : COMPUTER AIDED DRUG DESIGN

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

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) Citing suitable examples explain the development of agents acting on HMG-CoA reductase using CADD. **[15]**

OR

Give a detailed account on the use of CADD for predicting ADMET properties of new chemical entities for drug likeliness. **[15]**

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 *Hansch* analysis employed in Molecular Modeling and Docking.

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

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

a) Free Wilson analysis.

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

c) Describe the process of identifying Ligand Binding Domain in receptor/enzyme.

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 conformational analysis in drug design. **[15]**

OR

Describe the advancement of drug design in the field of HMG-CoA reductases focusing on the role of CADD. **[15]**

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

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

b) Molecular and quantum mechanics.

c) Contour map analysis.

d) Give a shot account on the success of CADD in drug discovery.

e) Energy Minimization Methods.

▽▽▽▽

Total No. of Questions: 5]

SEAT No. :

PA-2784

[Total No. of Pages : 2

[5941]-222

M. Pharm. (Pharmaceutical Chemistry)
MPC 204T : PHARMACEUTICAL PROCESS CHEMISTRY
(Credit 2019 Pattern) (Semester-II) (Theory)

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

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

OR

b) Explain in detail in-process control and validation of large-scale process.

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

a) What is halogenation? Mention case study on Industrial halogenation Process.

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

c) Define crystallization Give principle and general methods of preparation of polymorphs.

d) Comment in detail on Production of penicillin..

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

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

b) Comment on types of fire and fire extinguisher

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

d) Comment on azeotropic and steam distillation methods.

e) Define evaporation. Enlist and explain factors affecting evaporation.

P.T.O.

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

a) Define fermentation. Give its types. Explain the procedure for production of Lovastatin.

b) What do you mean by industrial safety? write a detailed note on OHSAS-1800 and ISO-14001.

Q5) Wrie a short note on any Three **[15]**

a) Production of vitamins

b) Pressure and vacuum filtration

c) Reaction progress kinetic analysis

d) Material safety Data sheet (MSDS)

e) Theory of filtration

Total No. of Questions : 5]

SEAT No. :

PA-2785

[Total No. of Pages : 2

[5941]-227

M.Pharm. (Pharmaceutical quality Assurance)

MQA-201T : HAZARDS AND SAFETY MANAGEMENT

(2019 Pattern) (Semester-II)

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

Instructions to the candidates:

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

Q1) Explain air circulation in pharmaceutical industry for non-sterile avca .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 to toxic gases and oxygen displaning gases.

b) Discuss the hazards related to Radio isotopes.

c) Describe various physico chemical parameters for measurment of effluents.

d) Explain strategies for accident prevention.

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

a) Enlist 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.

P.T.O.

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

OR

Explain the fire triangle and discuss the strategies for fire extinguishment.**[15]**

Q5) Write short notes 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 physico chemical measurment of effluents.

Total No. of Questions : 5]

SEAT No. :

PA-2786

[Total No. of Pages : 2

[5941]-228
M. Pharmacy
PHARMACEUTICAL VALIDATION
(2019 Pattern) (Semester - II) (MQA 202 T)

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) ***All questions carry equal marks.***

Q1) Attempt Any One of the following. **[1×15=15]**

a) What is the concept of cleaning method development and validation? How to use analytical method to ensure cleaning of equipment.

b) Discuss in detail about validation of "Pharmaceutical water system".

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

a) Write protocol for process validation of ointment and creams.

b) Explain facility validation for sterile and non-sterile production plant.

c) Discuss tests to qualify UV-visible spectrophotometer as per Indian Pharmacopoeia.

d) Write in brief about validation of compressed air system in pharmaceutical industry.

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

a) What are the factors affecting choice of IP protection?

b) Explain cleaning validation protocol.

c) How are acceptance limits for residue decided during validation of cleaning method?

d) Compare purified water and water for injection with respect to method of generation & specifications.

e) Define validation. Enlist scope & advantages.

P.T.O.

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

a) Elaborate types of process validation. Explain process validation of coated tablets.

b) Explain working of HVAC system. How is it validates?

Q5) Write short notes on (Any Three) **[3×5=15]**

a) Rights & Responsibilities of patentee.

b) Computerized system validation.

c) Qualification of Membrane filtration process.

d) Qualification of Friability test apparatus and disintegration tester.

e) FTIR qualification as per Indian Pharmacopoeia.

Total No. of Questions : 5]

SEAT No. :

PA-2787

[Total No. of Pages : 2

[5941]-229
F.Y.M. PHARMACY(Semester - II)
MQA 203 T : AUDITS AND REGULATORY COMPLIANCE
(Theory)
(2019 Pattern)

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

Instructions to the candidates:

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

Q1) Discuss significance of audit in pharmaceutical industry. Give a brief overview of auditing procedure. **[15]**

OR

Explain parts and subparts of cGMP.

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

a) Describe the process of auditing a production department.

b) Discuss types of audit with its scope, objective and advantages.

c) Explain the auditing parameters in general areas of interest in the building and raw materials in microbiology laboratory.

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

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

a) What is HVAC? Discuss its components.

b) Outline vendor audit of bulk pharmaceutical chemicals.

c) Discuss audit of ETP.

d) Describe management responsibilities.

e) Enumerate the objectives of an audit. What are responsibilities of an auditor?

P.T.O.

Q4) Discuss importance of water for injection systems auditing in a sterile manufacturing plant. Give a detailed account of auditing these systems. **[15]**

OR

Explain elements of quality system model described in the FDA's pharmaceutical quality system guidance.

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

a) Classification of deficiencies.

b) FEFO and FIFO

c) Audit report.

d) Personnel and sample handling audit involving microbiological laboratory.

e) Auditee's responsibility.

Total No. of Questions: 5]

SEAT No. :

PA-2788

[Total No. of Pages : 2

[5941]-230

First Year M.Pharmacy (Pharmaceutical Quality Assurance)
PHARMACEUTICAL MANUFACTURING TECHNOLOGY
(2019 Pattern) (Semester-II) (Theory) (MQA204T)

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

Instructions to the candidates:

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

Q1) Explain in detail about coating process and problem encountered in coating technology. **[15]**

OR

What is Quality by Design (QbD)? Explain its necessity and advantages. Also describe various elements of QbD with example.

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

a) Explain evaluation of stability of packaging material.

b) Explain QbD for excipients.

c) Explain lyophilization techniques.

d) Describe materials used for making containers.

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

a) IPQC test for sterile emulsion and suspension.

b) Comment on drug plastic interaction.

c) Explain types and quality of glass as packaging material.

d) Comment on risk assessment and risk management.

e) Granulators.

P.T.O.

Q4) Discuss in detail how to select pharmaceutical plant location? Explain factors influencing plant location and plant layout. **[15]**

OR

Describe layout of sterile and aseptic area for manufacturing of parental product.

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

a) PAT
b) IPQC test for capsules
c) Blister and bubble pack
d) SVP and LVP
e) Spheronizers

Total No. of Questions : 5]

SEAT No. :

PA-2789

[Total No. of Pages : 2

[5941]-231

M.Pharmacy

PHARMACEUTICAL QUALITY ASSURANCE

MRA-201T : Regulatory Aspects of Drugs & Cosmetics

(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 neat labelled diagram wherever necessary.***

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

a) Explain in detail about legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA.

b) Explain Hatch Waxman act in detail.

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

a) Describe regulatory pre-requisites related to marketing authorization requirements for drugs in UAE.

b) Enlist the regulations of import, manufacture and distribution of cosmetics in Canada.

c) Explain the organisation, structure and functions of EDQM.

d) Explain regulatory considerations for manufacturing, packaging and labelling of pharmaceuticals in Japan.

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

a) Write a note on purple book.

b) Write a note on SADC.

c) Write a note on content and approval process of IMPD in European union.

d) Describe certificate of pharmaceutical product.

e) Write a short note on certificate of suitability in European Union.

P.T.O.

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

a) Explain in detail regulation approval process for AMDA and SNDA.

b) Explain the organisation, structure and functions of EMA.

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

a) Write a note on Fedral Register.

b) Enlist the regulations of import manufacture and distributions of cosmetics in ECC countries.

c) Write a note on supplemental New Drug Application.

d) Enlist the regulatory requirements for registrations of drug in South Africa.

e) Write a note on orange book.

Total No. of Questions : 5]

SEAT No. :

PA-2790

[Total No. of Pages : 2

[5941]-232
First Year M. Pharmacy
REGULATORY ASPECTS OF HERBAL & BIOLOGICALS
(2019 Pattern) (Semester - II) (MRA 202 T)

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

Instructions to the candidates:

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

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

a) Write in detail about GMP requirements for biologicals as per Indian regulations.

b) Write in detail about packing & labelling requirements for biologicals as pe USFDA.

Q2) Answer any two. **[7.5 each]**

a) Write a note on pharmacovigillance.

b) What are preclinical & clinical development considerations for biologics as per USFDA.

c) What are the principles for the development of simmilar biologics as per India.

d) Write a note on pluma master file.

Q3) Answer any three. **[5 each]**

a) What are the data requirements for clinical trial application as per Indian regulations.

b) Write down difference between generic drugs? biosimilars.

c) Write a note on TSE / BSE evaluat?

d) Write a note on advertising regulations as per USA.

e) What are regulatory requirements for blood products as per Indian regulations.

P.T.O.

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

a) Explain in detail IND process as per USA.

b) Explain in detail BLA application process as per USA.

Q5) Answer any three. **[5 each]**

a) What are the regulatory requirements for blood products as per USA regulations.

b) What are the data requirements for preclinical studies as per Indian regulations.

c) Write a note on choice of the reference product as per EU.

d) What are the applications of biosimilars approach as per EU?

e) What are the principles for establishing biosimilarity.

Total No. of Questions : 5]

SEAT No. :

PA-2791

[Total No. of Pages : 2

[5941]-233
M. Pharmacy
MRA - 203 T : 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) ***Draw neat and well labeled diagram wherever necessary.***
3) ***Figures to the right indicates full marks.***

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

a) Explain in detail summary Technical Document.

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

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

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

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

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

d) Write a note on CE certification process.

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

a) Explain global medical device nomenclature.

b) Explain medical devices working group.

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

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

e) Write a note on clinical investigational plan for medical devices.

P.T.O.

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

a) Write a note on regulatory approval process for medical devices as per EV.

b) Write a note on regulatory approval process for medical devices (510K) premarket notification.

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

a) Explain indetail ISO 13485.

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

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

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

e) Write a note on pre-market approval.

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Total No. of Questions : 5]

SEAT No. :

PA-2792

[Total No. of Pages : 2

[5941]-234

M.Pharmacy

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS

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

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

Instructions to the candidates:

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

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

a) What are Good manufacturing practices? Explain in details with its importance.

b) What are the duties and responsibilities of food safety and standard authority of India.

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

a) What is the function of food safety and standard act explain in details.

b) Explain role of NSF testing and certification.

c) Explain recommended dietary allowance and in os.

d) Explain european food safety authority's organization and function.

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

a) Why should customer give importance to purchase NSF certified food.

b) What are probiotics? Give their application in management of disease.

c) Composition of food authority and qualification.

d) Explain european nutrition labelling.

e) Explain testing of finished products.

P.T.O.

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

a) Explain USFDA food safety modernization act.

b) Explain european directives and regulations for manufacture & sale of natra ceuticals & dietary supplements.

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

a) Micronutrients in management of disease

b) Role of Flauonoids in management of cardio vascular disease.

c) European regulation on novel food.

d) Role of Nutraceutical in Alzheimers disease.

e) Role of symbiotics in management of disease.

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Total No. of Questions : 5]

SEAT No. :

PA-2793

[Total No. of Pages : 2

[5941]-235

M.Pharmacy

MPB-201T : PROTEINS AND 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 labelled diagram wherever necessary.***

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

a) What do you mean by protein engineering? What are the different methods of protein engineering?

b) Define and classify Peptidomimetics with example.

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

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

b) Describe in detail CADD techniques in Peptidomimetics.

c) What are the various methods of gel electrophoresis?

d) Discuss about Analytical and biophysical parameters of proteins.

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

a) Describe in brief liposomes in protein formulation.

b) How does Edman degradation help in protein sequencing?

c) What is the purpose of PEGylation?

d) What kind of inhibitors are transition state analogs?

e) What is directed evolution in protein engineering?

P.T.O.

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

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

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

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

a) Tryptic Peptide Mapping.

b) Forced degradation studies of protein.

c) 2-Dimensional gel electrophoresis.

d) Development of non-peptide Peptidomimetics.

e) Gene shuffling.

Total No. of Questions : 5]

SEAT No. :

PA-2794

[Total No. of Pages : 2

[5941]-236
First Year M. Pharmacy (Pharmaceutical Biotechnology)
IMMUNO TECHNOLOGY
(2019 Pattern) (Semester - II) (MPB 202 T)

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

Instructions to the candidates:

1) ***All Quetions are compulsory.***
2) ***Figures to the right side indicate full marks.***
3) ***Draw neat and clean diagram wherever necessary.***

Q1) Attempt any One out of Two. **[1×15=15]**

a) Write structure and general functions of antibody.

b) Discuss in detail about Hypersensitivity types - I - IV reactions.

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

a) Write the impact of genetic engineering on vaccine Technology.

b) Discuss on MHC.

c) Write the principle, working and applications of Western Blot Analysis.

d) Explain Pathophysiology of Systemic Lupus Erythematosus.

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

a) Differentiate between primary and secondary lympnoid orgars.

b) Explain compliment activation and its types.

c) Write functions of different types of T-cells.

d) Explain vaccine vectors.

e) Give different types of organolseptic autoimmune diseases.

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

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

b) Outline difference types of vaccines. Discuss on Anti-idiotypic vaccine.

P.T.O.

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

a) Antigen presenting cells.

b) DNA vaccine

c) Principle and applications of ELISA.

d) Therapeutic applications of Monoclonal Antibodies.

e) Applications of stem cells in immunology.

Total No. of Questions : 5]

SEAT No. : ____

PA-2795

[Total No. of Pages : 2

[5941]-237
F.Y. M.Pharmacy
PHARMACEUTICAL BIOTECHNOLOGY
Bioinformatics & Computer Technology (MPB203T)
(2019 Pattern) (Semester - II)

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

Instructions to the candidates:

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

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

a) Discuss in detail protein structure prediction.

b) Write a note on sequence Analysis.

Q2) Attempt any two out of Four : **[2 × 7.5 = 15]**

a) What is multiple sequence alignment?

b) Discuss homology modelling.

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) Define bioinformatics. What are bioinformatics databases?

b) Discuss Five major types of bioinformatics data bases.

c) What is BLAST?

d) Write a note on "internet and bioinformatics"

e) Write a note on structural databases.

P.T.O.

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

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

b) Discuss kind of docking methods of protein & ligand.

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

a) What is CLUSTALX?

b) What is MUSCLE?

c) Enlist methods of alignment. What is multiple sequence alignment?

d) Explain the principle of drug design.

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

Total No. of Questions : 5]

SEAT No. : ____

PA-2796

[Total No. of Pages : 2

[5941]-238

First Year M.Pharmacy

BIOLOGICAL EVALUATION OF DRUG THERAPY

(2019 Pattern) (Semester-II) (MPB204T)

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

Instructions to the candidates:

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

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

a) Define biologic medicines. Explain detail the role of biologic medicines. concerning organ transplantation and cancer.

OR

b) Explain in detail various types of bioequivalence study designs.

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

a) Explain pyrogen testing of parenteral.

b) Describe the regulatory considerations for preclinical and clinical testing of medical devices.

c) Explain OECD guidelines for acute toxicity studies.

d) Explain the various types of microbial assays in detail.

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

a) Write a note on the principle of assay of vitamins.

b) Describe a bioassay of oxytocin

c) Write a note on mutagenicity toxicity studies.

d) Explain the bioassay of heparin sodium.

e) Briefly describe the need for bioequivalence studies in the case of controlled drug delivery systems.

P.T.O.

Q4) Answer any one. (15 marks Each) **[15]**

a) Define LD 50. Explain various methods to calculate LD 50.

b) Define bioavailability in short. Explain the various methods of measuring bioavailability.

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

a) Write a note on teratogenicity toxicity studies.

b) Write a note on the bioassay of digitalis.

c) Explain compartmental pharmacokinetic? Modelling.

d) Write a note on gene therapy.

e) Write a note on biologic medicines concerning interferons.

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Total No. of Questions : 5]

SEAT No. :

PA-2797

[Total No. of Pages : 2

[5941]-243

M.Pharmacy

MPL-201T : ADVANCED PHARMACOLOGY-II

(2019 Pattern) (Semester-II)

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

Instructions to the candidates:

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

Q1) Define and classify antibiotics. Explain mechanism of action, mechanism of resistance, adverse effects and therapeutic uses of Penicillin. **[15]**

OR

Discuss in details Pharmacological actions, mechanism of action, therapeutic effects and adverse effects of Insulin. Write a note on insulin preparations.**[15]**

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

a) Discuss the recent advancement in the management of cancer.

b) Write pharmacological actions of thyroid hormone.

c) Discuss mode of action, adverse effects and therapeutic uses of aminoglycoside antibiotics.

d) Write the mechanism of action, therapeutic uses and adverse effects of Isoniazid.

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

a) Write the pharmacotherapy of protozoal infection.

b) Discuss mode of action, therapeutic uses of Ciprofloxacin.

c) Describe role of parathyroid hormone and calcitonin in maintaining calcium homeostasis.

d) Write pharmacology of prokinetic agents.

e) Brief on the therapeutic uses and adverse effects of metronidazole.

P.T.O.

Q4) Define and classify anti-ulcer drugs. Write the pharmacology of H_2 receptor antagonists. **[15]**

OR

Define and classify anti-asthmatics. Write the pharmacology of salbutamol and theophylline as anti- asthmatic drugs.

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

a) Vitamine E as an antioxidant.

b) Immunomodulators.

c) Imidazoles and triazoles as antifungal agent.

d) Management of constipation.

e) Chronopharmacology.

Total No. of Questions : 5]

SEAT No. :

PA-2798

[Total No. of Pages : 2

[5941]-244
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 quetions are compulsory.***
2) ***Neat labeled diagrams must be drawn wherever necessary.***
3) ***Figures to the right indicate full marks.***

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

a) Explain the toxicokinetic evaluation in preclinical studies.

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

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

a) Acute eye irritation toxicity studies.

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

c) What is animal toxicity study? Describe alternative methods of animal toxicity studies.

d) Explain in detail the regulatory requirement of ICH for the new drug safety assessment.

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

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

b) Explain the types of toxicity studies.

c) Inhalation studies as per OECD guidelines.

d) What is carcinogenicity? How will you test the compound for carcinogenicity?

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

P.T.O.

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

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

b) Discuss the determination of LD50 in acute toxicity testing of drugs as per OECD.

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

a) HERG assay

b) Importance of safety pharmacology

c) Importance of Toxicokinetics

d) Importance of IND

e) Dermal toxicity

Total No. of Questions : 5]

SEAT No. : ____

PA-2799

[Total No. of Pages : 2

[5941]-245

F.Y. M.Pharmacy

MPL-203T : Principles of Drug Discovery

(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 questions : **[15]**

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

OR

a) Explain Rational approach for drug design and write on role of bioinformatics in target identification.

Q2) Medium length Answers solve any two : **[2 × 7½ = 15]**

a) What is QSAR? Give advantages and dis-advantages of QSAR.

b) Explain Hantzsch analysis and free Wilson analysis.

c) Characteristics and impact of biomarkers.

d) Describe types of protein structure.

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

a) Note on ELISA.

b) Write electrophysiological patch clamp process.

c) Importance of radio ligand assay system.

d) Applications of Biomarkers in drug discovery.

e) Importance of Molecular Docking.

P.T.O.

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

a) Write a note on prediction of protein structure and Describe various lead seeking methods in drug design.

OR

b) Explain G-protein coupled receptors (GPCRS). Note on pharmacophore based screening.

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

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

b) Application of NMR in protein structure prediction.

c) Definition of Biomarkers and their classification.

d) Note on proteonomics.

e) Role of Enzyme inhibition in drug discovery process.

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Total No. of Questions : 5]

SEAT No. : ____

PA-2800

[Total No. of Pages : 2

[5941]-246

First Year M.Pharmacy

CLINICAL RESEARCH AND PHARMACOVIGILANCE

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

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

Instructions to the candidates:

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

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

Explain in details on types of ADRs write on type 'B' adverse drug reactions with suitable examples.

OR

Define clinical trial. Write in brief on ICH-GCP guidelines.

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

a) Importance of schedule 'y'

b) Explain in detail clinical trial phase '2' and phase '3'

c) Note on International Classification of Diseases. (ICDs)

d) Significance of safety monitoring in pharmacovigilance.

Q3) Short Answer questions solve any three. **[3×5=15]**

a) Write on clinical research organisations (CROs)

b) Note on adverse events (AEs)

c) Roles of ICMR in clinical trial study.

d) Responsibilities of Institutional review board.

e) Note on suspected adverse drug reactions with two examples.

P.T.O.

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

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

OR

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

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

a) Case report forms.

b) Pharmaco economics.

c) Detection and reporting of ADRs.

d) Informed consent in clinical trial study.

e) Note on pharmacovigilance center in hospitals and industry.

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Total No. of Questions : 5]

SEAT No. :

PA-2801

[Total No. of Pages : 2

[5941]-247

M.Pharmacy

MPG-201T : MEDICINAL PLANT BIOTECHNOLOGY

(2019 Pattern) (Semester-II)

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

Instructions to the candidates:

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

Q1) Explain secondary metabolism in plant tissue cultures for the prodcution of medicinal agents. **[15]**

OR

What is the genetic code? What are its silent features? Explain regulation of gene expression with suitable example.

Q2) Solve Any two: **[15]**

a) What is fermentation? Explain various applications of fermentation technology in pharmacy and allied fields.

b) Enlist different methods of tissue culture techniques. Describe organogenesis and embryogenesis with its significance.

c) Explain structure and complicity of genome with cell singling.

d) What is protoplast? Explain somatic hybridization with suitable example.

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

a) Explain Immobilization techniques of plant cell with its applications.

b) Write a note on 'Transgenic plants'.

c) Explain gene transfer in plants and their applications.

d) Give an account of production of ergot alkaloids.

e) What is cloning of plant cell? Give its advantages and dis-advantages.

P.T.O.

Q4) What is r-DNA? Describe DNA recombinant technology with its applications. **[15]**

OR

Describe different steps involved in plant tissue culture techniques along with various sterilization methods. Give its applications in pharmacy and allied fields.

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

a) Synthetic seed and monoclonal variation.

b) Single cell proteins.

c) Transgenic plants.

d) Biotransformation.

e) Applications of PCR in plant genome analysis.

Total No. of Questions : 5]

SEAT No. :

PA-2802

[Total No. of Pages : 2

[5941]-248
First Year M. Pharmacy
ADVANCED PHARMACOGNOSY - II
(2019 Pattern) (Semester - II) (MPG 202T)

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

Instructions to the candidates:

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

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

a) Define 'Adulteration' Explain the relative terms; 'Substitution' and 'Sophistication'. Mention various causes of adulteration highlighting intentional and unintentional adulteration.

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

i) Pesticide Residue

ii) Heavy Metals

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

a) Discuss the role of ethnobotany in herbal drug evaluation.

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

c) Give analytical profile of Embelica officinalis. State its pharmacological significance.

d) Discuss in vivo screening methods for hepatoprotective drugs of natural origin.

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

a) Give analytical profile of curcuma longa.

b) Describe a procedure recommended by WHO for 'determination of Microbial Load'.

P.T.O.

c) Write a note on 'efficacy of herbal drugs.

d) Discuss In-Vitro screening techniques for antioxidant herbs.

e) Write about 'Wound healing herbs' and their screening.

Q4) Attempt <u>any one</u> question. **[15]**

a) Describe in details the process of drug discovery, highlighting on various tools and techniques used in herbal drug discovery and development.

b) What is the need of Phyto-pharmacological screening in new drug development. Discuss various assays used for Invitro evaluation of anticancer drugs.

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

a) Toxicity studies of herbal drugs / formulations as per OECD guidelines.

b) In vivo anti-inflammatory screening.

c) Reverse Pharmacology.

d) Herbal Drug Regulation.

e) Analytical profile and signifance of Andrigraphis peniculata.

Total No. of Questions : 5]

SEAT No. :

PA-2803

[Total No. of Pages : 2

[5941]-249
F.Y. M.Pharmacy
PHARMACOGNOSY
MPG 203 T : Indian System of Medicine (Theory)
(2019 Pattern) (Semester - II)

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

Instructions to the candidate:

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

Q1) Explain Document preparation for new drug application and export registration. **[15]**

OR

Explain principles of treatment in Homeopathy system of medicines.

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

a) Explain TKDL in detail.

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

c) Elaborate Ayurveda system of medicine?

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

a) Explain CCRS in detail.

b) Explain different dosage of ISM.

c) Explain basic principle of Naturotherapy practice.

d) Explain AYUSH in detail.

P.T.O.

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

a) Explain Good manufacturing practice of Indian system of medicine.

b) Explain shelf life and stability studies of ISM formulation.

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

a) GLP

b) What is Gunapadam. Explain in detail.

c) Elaborate raw drugs in Siddha system of medicine.

d) Explain Asanas and Pranayama in detail.

e) Explain Preparation technique as per Unani Pharmacopeia.

Total No. of Questions : 5]

SEAT No. :

PA-2804

[Total No. of Pages : 2

[5941]-250

First Year. M.Pharmacy
HERBAL COSMETICS
(2019 Pattern) (Semester-II) (MPG 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) a) Discuss method of preparation and standardization of dentifrices and mouth washes. **[15]**

OR

b) Explain the formulation and evaluation of herbal shampoos.

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

a) Elaborate on design of herbal cosmetic formulation.

b) Explain toxicity of cosmetics.

c) Describe formulation and standardization of baby products.

d) Explain physiology and chemistry of hair.

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

a) Give classification of herbal cosmetics.

b) Write about physiology of face powder.

c) Explain in details about manufacturing and evaluation of cleansing cream.

d) Describe Sprading ability test for semsolid formulations.

e) Enlist quality control methods for herbal ointment.

P.T.O.

Q4) Attempt any one questions of following **[15]**

a) Write in detail about regulatory provisions related to import and export of herbal cosmetics.

b) Describe the quality control methods of herbal cosmetics.

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

a) Herbal industries involved in herbal cosmetics.

b) Hair oils.

c) Natural colourants.

d) Herbal lipstick.

e) Toxicity screening in Animals.