

Total No. of Questions : 5]

SEAT No. :

P5488

[Total No. of Pages : 2

[5553]-1001

M. Pharmacy (Semester - I)

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES  
(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Discuss principle, theory, instrumentation of Nuclear Magnetic Resonance spectroscopy. Draw the possible structure of the compound (Molecular formula  $C_3H_7Cl$ ) that shows one doublet and one septet in proton NMR spectrum. **[15]**

OR

Explain in detail principle and applications of HPLC. Give an account of columns, degassers, pumps and detectors used in HPLC.

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

- a) Discuss various Ionization used in Mass spectroscopy and give fragmentation rules. Mass spectrum of pentane produced a molecular ion peak at  $m/e$  72. It also showed peaks at  $m/e$  57, 43 and 29. Identify these possible fragments of pentane.
- b) Explain in detail gel electrophoresis.
- c) Write about principle, theory, instrumentation and applications of HPTLC.
- d) Enlist various Hyphenated analytical techniques. Explain any one.

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

- a) Why are IR absorption bands inverted compared to those in uv-visible spectra? Why does Hydrogen molecule not give an IR spectrum?
- b) Discuss on quenching and factors affecting fluorescence intensity.
- c) Write a note on Derivative spectroscopy.
- d) Write comparison of flame emission and Atomic Absorption spectroscopy.
- e) Write about chemical shift and spin-spin coupling and add a note on the factors influencing them.

**P.T.O.**

**Q4)** Discuss bragg's law, different X-ray methods, types of crystals and applications of X-ray diffraction. **[15]**

OR

Write in detail principle, instrumentation, applications of Differential Thermal Analysis. Write a note on Derivative Differential Thermal Analysis. (DDTA.)

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

- a) Ion selective electrodes.
- b) Detectors in GC.
- c) FTIR.
- d) Thermo gravimetric analysis (TGA).
- e) Principle and factors affecting separation of paper Electrophoresis.



Total No. of Questions : 5]

SEAT No. :

P5489

[Total No. of Pages : 2

[5553]-1002

**M. Pharmacy (Semester - I) (Pharmacognosy)**  
**(MPG - 101T) MODERN PHARMACEUTICAL ANALYTICAL**  
**TECHNIQUES**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Give principle of FT-NMR and <sup>13</sup>C NMR, with their applications in herbal research. **[15]**

OR

Discuss fundamental principle and various techniques of affinity chromatography. Describe different components used in affinity medium.

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

- a) Describe use of quantitative TLC in quantitation of phyto constituents
- b) Illustrate various designs and modules of DSC along with its applications.
- c) Explain various ionization techniques and mass analyzers in mass spectroscopy.
- d) Elaborate types of fundamental vibrations in IR along with factors affecting on it

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

- a) Explain choice of solvent and solvent effect in UV-VIS spectroscopy.
- b) Enlist and explain and explain different solid sampling techniques in IR spectroscopy.
- c) Describe principle and applications of Atomic Absorption Spectroscopy (AAS).
- d) Explain principle and instrumentation of Flame Emission Spectroscopy (FES).
- e) Give an account on types of ions formed in mass spectroscopy.

**P.T.O.**

**Q4)** Describe production of X-rays, methods of X-ray diffraction and significance of Bragg's law in finding crystal nature. **[15]**

OR

Describe principle, instrumentation and applications of Ultra Performance Liquid Chromatography (UPLC).

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

- a) Instrumentation and applications of UV-VIS spectrophotometry.
- b) Iso-electric Focusing.
- c) Moving boundary electrophoresis.
- d) Electrodes in potentiometry.
- e) Factors having influence on Fluorescence.



Total No. of Questions : 5]

SEAT No. :

P5490

[Total No. of Pages : 2

[5553]-1003

**M. Pharmacy (Pharmaceutics) (Semester - I)**  
**(MPH 101T) MODERN PHARMACEUTICAL ANALYTICAL**  
**TECHNIQUES (Theory)**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

- 1) *All questions are compulsory. Internal choices are given.*
- 2) *Figures to the right indicate full marks.*
- 3) *Draw neat diagram and structures wherever necessary.*
- 4) *Do not write anything on the question paper.*

**Q1)** Define chromatography. Enlist different types of chromatography. Elaborate on instrumentation and application of HPLC. **[15]**

OR

Explain the principle of UV-Visible Spectroscopy. Elaborate on instrumentation of double beam spectrophotometer. Add a note on type of transition of organic and inorganic molecule.

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

- a) Discuss principle and instrumentation of IR spectroscopy
- b) Discuss general principle of flame photometry and add note on pharmaceutical applications of flame photometry.
- c) Elaborate on detectors use in gas chromatography
- d) Assign the structure to compound for the compound having spectral character:

Molecular weight: 58

UV: no absorption maxima above 210 nm.

IR: 2941-2857cm<sup>-1</sup> CH stretch for alkene, 1458cm<sup>-1</sup> CH bending.

NMR:  $\delta$ -2.75 (quintet, J-7.1 cps, 14.6 squares) and

$\delta$ -4.75 (triplet, J-7.1 cps, 29.4 squares)

**P.T.O.**

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

- a) Discuss applications of gas chromatography.
- b) Elaborate on principle and applications of column chromatography.
- c) Elaborate on atomic absorption spectroscopy.
- d) Explain factors affecting fluorescence.
- e) Compare between dispersive IR and FTIR.

**Q4) Outline the fundamental principle underlying the mass spectrometry. Explain Mc Lafferty rearrangement and add a note on formation of metastable ions.**[15]

OR

Discuss in detail principle and instrumentation of NMR spectroscopy.

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

- a) ELISA.
- b) Application of X-ray diffraction.
- c) Paper chromatograph.
- d) Thin layer chromatography.
- e) Zone electrophoresis.



Total No. of Questions : 5]

SEAT No. :

P5491

[Total No. of Pages : 2

[5553]-1004

**M. Pharmacy (Semester - I) (Pharmacology)**  
**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Classify various techniques in chromatography. Draw a neat labeled diagram of an ideal chromatogram obtained in HPLC analysis of a two-component sample and label following parameters:  $R_t$ ,  $2\sigma$ ,  $V_0$ , and  $K$ . **[15]**

OR

Draw a well labeled diagram of an instrument for Nuclear Magnetic Resonance spectrophotometer, and a high resolution spectrum obtained from PMR analysis of ethanol.

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

- a) Enlist the Factors affecting the chemical shift in a PMR spectrum.
- b) Explain the process of 'Tailing' in HPLC. Give measures to overcome the problem.
- c) Explain the term UV-cut off in the context of UV-spectroscopy. Give its significance.
- d) Differentiate between HPLC and HPTLC.

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

- a) What is a capacity factor? How to calculate it?
- b) What is the significance of isotopic abundance in interpreting mass spectra?
- c) Give detail account on combination bands in IR spectrum.
- d) Enlist different types of ionization techniques in mass spectrometry.
- e) Explain the process of Ion-exchange chromatography.

**P.T.O.**

**Q4)** Write detail account on stationary phases used in HPLC. HPTLC and GC. Give characteristic features of each. **[15]**

OR

Give the principle and working of Ion selective electrodes and write about pharmaceutical applications of potentiometry.

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

- a)  $C^{13}$  NMR
- b) HEPT
- c) DSC
- d) Capillary electrophoresis
- e) Applications of X-ray crystallography.



Total No. of Questions : 5]

SEAT No. :

P5492

[Total No. of Pages : 2

[5553]-1005

M. Pharmacy (Semester - I)

**MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES  
(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Write principle of Infra - Red spectroscopy. Discuss instrumentation of FTIR. What are advantages of FTIR over dispersive IR? **[15]**

OR

Write principle of Flame Emission Spectroscopy. Discuss any two burners used in FES. Comment on ways to minimize interferences in FES.

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

- a) What factors should be considered while selecting solvent for UV spectroscopy experiment? What is the effect of solvent polarity on  $\lambda_{\text{max}}$  value?
- b) Explain the concept of spin-spin coupling in NMR with suitable examples.
- c) Give an exhaustive account of APCI and ESI in Mass Spectrometry. What are different X-ray methods?

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

- a) Explain the term "Coupling constant" using suitable examples.
- b) What is the principle of Affinity chromatography?
- c) Discuss factors affecting separation of mixture of components by GC.
- d) Discuss principle and instrumentation of paper electrophoresis.
- e) Radiation source in AAS.

**P.T.O.**

**Q4)** Write principle, instrumentation and applications of HPLC. [15]

OR

State principle and instrumentation of NMR. Add note on Magnetic Anisotropy.

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

- a) Quantum efficiency of fluorescence.
- b) Columns in Gas chromatography.
- c) Applications of X-ray diffraction.
- d) McLafferty rearrangement.
- e) Isoelectric focusing.

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Total No. of Questions : 5]

SEAT No. :

P5493

[Total No. of Pages : 2

[5553]-1006

**M. Pharmacy (Semester - I) (Pharmaceutical Chemistry)**  
**ADVANCED ORGANIC CHEMISTRY- I**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Discuss briefly the following reactions with mechanism and giving relevant applications involved in the synthesis of drugs. **[15]**

- a) Pinner Pyrimidine synthesis.
- b) Bernthsen acridine synthesis.
- c) Traube purine synthesis.

OR

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

- a) Mannich reaction.
- b) Brook rearrangement.
- c) Ozonolysis.

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

- a) Explain the preparation, salient features of Aluminium Isopropoxide and diazopropane explain their applications in organic synthesis.
- b) Discuss Stereochemistry and factors that influence the mechanism of bimolecular substituents.
- c) Write synthesis of Miconazole and Quinine.

**P.T.O.**

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

- a) Explain any two methods of determining reaction mechanisms.
- b) Explain Combes Quinoline synthesis and Traube Purine Synthesis.
- c) Strategies for synthesis of four membered ring systems through synthon approach.
- d) Explain unimolecular elimination reaction with example.
- e) Explain the preparation, salient features of diazomethane and mention its applications in organic synthesis.

**Q4) Write synthesis of Metronidazole; Triamterene & Alprazolam.** [15]

OR

Explain protection for Amino & Amino acids with suitable example.

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

- a) Discuss stability of carbanions.
- b) Write a note on free radicals.
- c) Explain Synthetic application of Wilkinson and Wittig reagent.
- d) Discuss the Ugi reaction and its synthetic applications.
- e) Write a note on Sharpless asymmetric epoxidation with example.



Total No. of Questions : 5]

SEAT No. :

P5494

[Total No. of Pages : 2

[5553]-1007

**M. Pharmacy (Semester - I) (Pharmacognosy)**  
**MPG 102 T : ADVANCED PHARMACOGNOSY - I**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Discuss AYUSH guidelines for safety monitoring of natural medicine. **[15]**

OR

Discuss occurrence, isolation and characteristic features of flavonoids.

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

- a) Write method of isolation, chemical properties and medicinal and health benefits of Taxol
- b) Discuss in detail Marine toxins.
- c) Discuss the Current trends and future scope of nutraceuticals.
- d) Write a note on Current good cultivation and collection practices.

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

- a) Discuss the importance of pharmacognosy in herbal drug industry.
- b) Discuss antioxidants as nutraceuticals.
- c) Explain the isolation, medicinal and health benefits of Vitamins.
- d) Write a note on Garlic
- e) Discuss on Conservation of medicinal plants.

**P.T.O.**

**Q4)** Discuss the current trends and future scope of nutraceuticals. Add a note on green and herbal Tea. **[15]**

OR

Write method of isolation, chemical properties and medicinal and health benefits of

- a) Shatavarins
- b) Andrographolide

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

- a) Spirulina.
- b) Carotenoids.
- c) Regulatory aspects of nutraceuticals.
- d) Isolation and uses of andrographolide.
- e) Formulation of nutraceuticals.



Total No. of Questions : 5]

SEAT No. :

P5495

[Total No. of Pages : 2

**[5553]-1008**  
**M. Pharmacy (Semester - I) (Pharmaceutics)**  
**DRUG DELIVERY SYSTEMS**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Discuss in detail challenges faced in ocular drug delivery and nanotechnology based ocular delivery systems. **[15]**

OR

Discuss various approaches for formulating gastro retentive drug delivery system.

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

- a) Write in detail about ophthalmic inserts.
- b) Discuss formulation approaches for protein/peptide delivery.
- c) Discuss structure of buccal mucosa and barriers to penetration across buccal mucosa.
- d) Discuss feedback regulated drug delivery systems.

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

- a) What is the drug selection criteria for transdermal drug delivery system (TDDS). Enumerate advantages and disadvantages of TDDS.
- b) Explain the mechanisms of mucoadhesion.
- c) Elaborate upon role of Ion exchange resins as controlled drug delivery carriers.
- d) Discuss mechanism of action of penetration enhancers.
- e) Elaborate upon “polymers used in mucoadhesion”.

**P.T.O.**

**Q4)** Discuss mechanism of drug release from SR/CR formulations. **[15]**

OR

Elaborate on the techniques for formulation of transdermal drug delivery system

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

- a) Microneedles.
- b) Theriform Technology (3D Printing technology).
- c) Personalised medicine.
- d) Raft forming systems.
- e) Mucosal delivery of vaccines.



Total No. of Questions : 5]

SEAT No. :

P5496

[Total No. of Pages : 2

[5553]-1009

**M. Pharmacy (Semester - I) (Pharmacology)**  
**MPL-102T: ADVANCED PHARMACOLOGY - I**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Classify antihypertensive drugs. Explain the pharmacology of drugs acting on renin angiotensin system. **[15]**

OR

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

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

- a) Classify antiparkinsonian drugs. Describe the pharmacology of L-dopa.
- b) Classify antihyperlipidemic agents. Explain the therapeutic utility of statins in hyperlipidemia.
- c) Describe the pharmacology of thiazide diuretics.
- d) Explain the pharmacology of oral anticoagulants.

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

- a) Write a note on Histamine.
- b) Give an account on G-protein coupled receptors.
- c) Write about stages of general anaesthesia.
- d) Explain the pharmacology of vasodilators.
- e) Give an account on haematinics.

**P.T.O.**

**Q4)** Give a detailed account on pharmacology of adrenaline. **[15]**

OR

Classify opioid analgesics. Explain in detail pharmacology of morphine.

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

- a) Biotransformation of drug.
- b) Pharmacology of 1-Dopa.
- c) GABA.
- d) 5 HT-antagonists.
- e) Organophosphate compounds poisoning.

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Total No. of Questions : 5]

SEAT No. :

P5497

[Total No. of Pages : 2

[5553]-1010

**F.Y. M. Pharmacy (Pharmaceutical Quality Assurance)  
QUALITY MANAGEMENT SYSTEM  
(2018 Pattern) (Semester - I)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Explain the steps involved in ISO 9000 certification. What is ISO 9001: 2008? **[15]**

OR

Explain the customers' perception of quality. Explain dimensions of product and service quality. **[15]**

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

- a) Explain cost of quality and models of cost of quality
- b) Highlight the process of quality risk assessment.
- c) Explain IPQC testing
- d) Discuss benchmarking process

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

- a) Elaborate concept of process capability.
- b) Explain role of self inspection in pharmaceutical quality management
- c) Discuss need and implementation of vendor certification process.
- d) Define and give the advantages of statistical process control
- e) Describe HACCP in brief.

**P.T.O.**

**Q4)** Describe the principles, types and applications of six sigma. **[15]**

OR

Discuss ICH Q10 guidelines

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

- a) McKinsey 7S Model
- b) Line Clearance
- c) Quality by Design
- d) NABL Certification
- e) Out of specifications



Total No. of Questions : 5]

SEAT No. :

P5498

[Total No. of Pages : 2

**[5553]-1011**  
**M. Pharmacy**  
**PHARMACEUTICAL CHEMISTRY**  
**MPC 103T : Advanced Medicinal Chemistry**  
**(2018 Pattern) (Semester - I) (Theory)**

**Time : 3 Hours]**

**[Max. Marks : 75**

**Instructions to the candidates:**

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

**Q1)** Give the classification and detail account of first generation  $H_1$  receptor antagonists. **[15]**

OR

Discuss about Target identification and validation in drug development. What are the challenges encountered in developing a clinically useful drug? **[15]**

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

- a) Describe anticonvulsants interacting with  $GABA_A$  receptor.
- b) Give focus on antineoplastic antibiotics.
- c) Classify antivirals with suitable example. Write chemistry and mode of action of amantadine.
- d) Theories of drug receptor interaction.

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

- a) Comment on neuraminidase inhibitors as antivirals
- b) What is drug resistance? Explain its causes in light of antibiotics.
- c) Explain lead identification and optimization.
- d) How aspirin is selective  $COX_1$  antagonist? Write mode of action of salicylates.
- e) Explain chemistry of prostaglandins.

**P.T.O.**

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

OR

Which are the types of peptidomimetics? Explain functional mimetics with examples. Add a short note on designing of peptidomimetics.

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

- a) Carrier linked prodrugs.
- b) Stereochemistry and pharmacokinetics of drug.
- c) Selective  $\alpha$ -adrenergic antagonists.
- d) ACE inhibitors as antihypertensive agents.
- e) Explain the significance of High Throughput Screening in drug development.



Total No. of Questions : 5]

SEAT No. :

P5499

[Total No. of Pages : 2

**[5553]-1012**  
**F.Y. M. Pharmacy (Semester - I)**  
**PHYTOCHEMISTRY**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Elaborate a detail account of spectroscopic characterization for structural elucidation of Glycyrrhizin. **[15]**

OR

Elaborate a detail account of phytochemical finger printing in the characterization of herbal extracts using LCMS along with its application in structure elucidation of phytoconstituents.

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

- a) Explain in detail the lead structure selection process and structure development in drug discovery and development.
- b) Explain isolation, purification, characterization and industrial importance of Bacosides.
- c) Explain in detail separation of phytoconstituents by preparative HPLC.
- d) Elaborate a detail account of spectroscopic characterization of Nicotine for structural elucidation.

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

- a) Explain isolation, purification and industrial importance of guggulosterone.
- b) Explain in detail spectroscopic characterization for structural elucidation of citral.
- c) Explain application of HPTLC in characterization of herbal extracts.
- d) Provide principle and working of microwave assisted extraction.
- e) Explain in detail drug registration.

**P.T.O.**

**Q4)** Describe in detail principle, working, Applications of CCCET along with its merits and demerits. **[15]**

OR

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

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

- a) Artemesin in drug discovery and development.
- b) Umbelliferone.
- c) Structural Elucidation of Kaempferol.
- d) Methods of fractionation.
- e) Protocol design for clinical studies of lead molecules.



Total No. of Questions : 5]

SEAT No. :

**P5500**

[Total No. of Pages : 2

**[5553] - 1013**

**M.Pharmacy (Semester - I)**

**MPH 103T - MODERN PHARMACEUTICS**

**(2018 Pattern)**

***Time : 3 Hours]***

***[Max. Marks : 75***

***Instructions to the candidates:***

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

***Q1)*** What is the importance of preformulation studies? Explain preformulation studies for dispersion. Give an account of theories of dispersion. **[15]**

**OR**

Define Validation. Discuss Validation and Calibration of Master plan.

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

- a) Discuss cGMP requirements regarding building premises, sanitation and hygiene for pharmaceutical products.
- b) Differentiate between compression and consolidation. Highlight effect of friction and discuss about distribution of forces in compression and consolidation.
- c) Explain validation using any one unit process in the manufacture of solid dosage form.
- d) Explain ICH & WHO guidelines for calibration and validation of equipments.

***P.T.O.***

**Q3) Attempt any three :**

**[15]**

- a) Drug excipients compatibility studies.
- b) TQM.
- c) Sales forecasting.
- d) Heckel plot.
- e) Concept and objectives of stability of pharmaceuticals.

**Q4) Describe the use of 'students T-test' and 'standard deviation' in evaluation of data.**

**[15]**

OR

Describe briefly the importance of experimental design. Add note on contour plots.

**Q5) Write short notes on any three :**

**[15]**

- a) Stability testing.
- b) Inventory management and control.
- c) Handling of rejected material.
- d) Application of Factorial designs in formulation.
- e) Physics of tablet compression.



Total No. of Questions : 5]

SEAT No. :

P5501

[Total No. of Pages : 2

[5553] - 1014

M.Pharmacy (Semester - I)

PHARMACOLOGY

MPL 103T - Pharmacological and Toxicological Screening Methods - I  
(2018 Pattern)

Time : 3 Hours

[Max. Marks : 75

*Instructions to the candidates:*

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

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

OR

Discuss the various methods employed in the screening of anti-inflammatory agents. [15]

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

- a) Describe in detail the different in vivo models employed in the screening of anti-arrhythmic drugs.
- b) Discuss the various methods employed in the screening of anti-diabetic agents.
- c) Discuss the various methods employed in the screening of analgesic agents.
- d) Describe the screening methods for anti-parkinsonian agents.

**P.T.O.**

**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 hepatoprotective agents.
- e) Explain various methods used in screening of immunomodulators.

**Q4) Discuss the various methods employed in the screening of antiepileptic agents.**  
**[15]**

OR

Discuss the various methods employed in the screening of sedative, hypnotic and anxiolytic agents.  
**[15]**

**Q5) Write short note on any three :**

**[15]**

- a) Transgenic animals.
- b) General principles of bioassay.
- c) Screening methods of nootropics.
- d) CPCSEA guidelines.
- e) Immunoassay.



Total No. of Questions : 5]

SEAT No. :

P5502

[Total No. of Pages : 2

[5553] - 1015

M.Pharmacy (Semester - I)

PHARMACEUTICAL QUALITY ASSURANCE

MQA 103T - Quality Control and Quality Assurance

(2018 Pattern) (Theory)

Time : 3 Hours]

[Max. Marks : 75

*Instructions to the candidates:*

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

**Q1)** What is Pharmaceutical manufacturing documentation? Write about objectives, importance and storage of documents. **[15]**

OR

Explain IPQC and FPQC for capsule dosage form in Pharma Industry according to Indian Pharmacopoeia.

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

- a) Discuss the components of Quality Assurance and Quality Control.
- b) Comment on scope and importance of various intellectual property rights.
- c) Explain Purchase specifications and maintenance of stores for raw materials.
- d) Write principle of Quality Audit. How checklists are important during audits?

**P.T.O.**

**Q3) Attempt any three :**

**[15]**

- a) State precautions to avoid mix-ups and cross contamination during manufacturing.
- b) Write a note on “Waste and Scrap disposal”.
- c) Discuss significance of Calculation of yield at various stages of manufacturing.
- d) State procedure of release of finished goods.
- e) Briefly describe the importance of Training in Pharmaceutical manufacturing.

**Q4) Discuss in detail CPCSEA guidelines for non clinical testing along with protocol for the same.**

**[15]**

OR

Discuss in detail the location, design and plant layout of Pharmaceutical industry.

**Q5) Write short note on (any three) :**

**[15]**

- a) Three tier documentation.
- b) Drug Product salvaging.
- c) CTD and eCTD.
- d) Environmental control in sterile areas.
- e) Time limitations on Production.



Total No. of Questions : 5]

SEAT No. :

P5503

[Total No. of Pages : 2

[5553] - 1016

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

**MPC-104T : CHEMISTRY OF NATURAL PRODUCTS**

**(2018 Pattern) (Theory)**

*Time : 3 Hours*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** What are alkaloids? Explain general methods of isolation and classification of alkaloids with examples from each class. Elucidate the structure of reserpine. **[15]**

OR

What are terpenoids? Explain isolation methods and classification of terpenoids with examples. Comment on isoprene rule and general methods of structural elucidation of drugs containing terpenoids. **[15]**

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

- a) What are glycosides? Explain chemistry of cardiac glycosides.
- b) Write elaborative note on neuromuscular blocking drugs.
- c) Write elaborative note on macrolid antibiotics.
- d) Discuss chemistry of Adrenocorticoids.

**P.T.O.**

**Q3) Attempt any three :**

**[15]**

- a) Write note on curare alkaloids.
- b) Note on  $\beta$ -lactum antibiotics.
- c) Explain principle of RNA and DNA estimation.
- d) Elucidate structure of morphine.
- e) Explain active chemical constituents of curcuma longa with antitumor view point.

**Q4) What are flavonoids? Explain general methods of structure determination of flavonoids. Elucidate structure of quercetin.** **[15]**

OR

What is gene therapy? Write elaborative note on gene therapy. Explain various advancement of gene therapy and various applications of gene therapy. **[15]**

**Q5) Write short note on any three :**

**[15]**

- a) Explain physiological importance of Vitamin A and Vitamin C.
- b) Explain chemical constituents of Swertia chirata in diabetic therapy.
- c) Explain significance of IR spectroscopy in structure elucidation.
- d) Comment on stereochemistry and structure elucidation of ephedrine.
- e) Comment on natural CNS drugs.



Total No. of Questions : 5]

SEAT No. :

**P5504**

[Total No. of Pages : 2

**[5553] - 1017**

**M.Pharmacy (Pharmacognosy) (Semester - I)**

**MPG 104T - INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY**

*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)** Describe WHO guidelines for quality assessment of herbal drugs. **[15]**

OR

Describe Indian and international patent laws and amendments applicable to herbal and natural products and their process. **[15]**

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

- a) Explain national and international regulatory status of herbal drugs.
- b) Write note on Foreign Trade Policy of India.
- c) How stability testing of natural products is performed?
- d) What are set of international standards on quality management?

**P.T.O.**

**Q3) Attempt Any Three :**

**[15]**

- a) Describe Procedure for Indian Patent filing.
- b) What are pilot plant and scale up techniques?
- c) What are Rights of patents?
- d) How natural local resources are protected legally?
- e) What are the methods of selecting projects?

**Q4) Describe in detail about the Good Manufacturing Practices (GMP) for the production of herbal formulations.**

**[15]**

OR

Explain requirements of herbal industry involved in production of phytomedicines.

**[15]**

**Q5) Write short note on Any Three :**

**[15]**

- a) Monograph of herbal drugs.
- b) Constraints of herbal formulations.
- c) Total Quality Management.
- d) Plant Design Steps.
- e) Trade-Related Aspects of Intellectual Property Rights.



Total No. of Questions : 3]

SEAT No. :

**P5505**

[Total No. of Pages : 2

**[5553] - 1018**

**M.Pharmacy (Semester - I)**

**REGULATORY AFFAIRS**

**(2018 Pattern)**

*Time : 3 Hours*

*[Max. Marks : 75*

*Instructions to the candidates:*

- 1) *All questions are compulsory.*
- 2) *Figures at right indicate full marks.*

**Q1)** Answer the following :

**[20]**

- a) What kind of application can be submitted as a 505(b)(2) application?
- b) Highlight the examples of changes to approved drug products for which 505(b)(2) application should be submitted?
- c) Give the chemical classification codes for NDA.
- d) What are the differences between NDA and 505 (b)(2) application?
- e) What is a Marketing Authorization Application?
- f) Explain what is an ASMF.
- g) What are the types of active substances for which ASMFs are submitted?
- h) Give the difference between DMF and ASMF (with respect to submission).
- i) What is ICH?
- j) Focus on CTD.

**P.T.O.**

**Q2) Solve Any Two :**

**[20]**

- a) Give the regulatory requirements for product approval API and Biologics.
- b) Give detail account on Investigator Brochure (IB).
- c) Explain in details about Regulation for combination products and medical devices.

**Q3) Answer the following Any Five :**

**[35]**

- a) Regulatory requirements of EU.
- b) ICH guidelines for S.
- c) Give DMF and its types.
- d) Institutional review board.
- e) Note on CRO.
- f) ICH guidelines of M.
- g) Focus on various regulatory agencies for the drug.



Total No. of Questions : 5]

SEAT No. :

**P5506**

[Total No. of Pages : 2

**[5553] - 1019**

**M.Pharmacy (Pharmacology) (Semester - I)**  
**CELLULAR & MOLECULAR PHARMACOLOGY**  
**(2018 Pattern)**

*Time : 3 Hours*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Define Pharmacogenomics. Explain in details the role of genetic variation in Pharmacology. **[15]**

OR

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

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

- a) Explain the role of Caspases in apoptosis.
- b) Explain in detail principles and applications of cell viability assay.
- c) Discuss the techniques for western blot with its applications.
- d) Write detailed account on gene therapy and its clinical applications.

**P.T.O.**

**Q3) Attempt Any Three :**

**[15]**

- a) Explain in detail gene expression and its regulation.
- b) Write the types of immunotherapeutic.
- c) Discuss in details cell cycle and its regulation.
- d) Explain the principles and applications of flow cytometry.
- e) Discuss in detail intercellular signaling.

**Q4) Discuss the principles and applications of recombinant DNA technology.**

**[15]**

OR

Explain the types of ELISA with its advantages and disadvantages. Write note on its applications.

**[15]**

**Q5) Write short note on Any Three :**

**[15]**

- a) JAK/STAT Signaling pathway.
- b) Organization of genome.
- c) Humanization of antibody therapy.
- d) Nitric Oxide Signaling.
- e) SDS PAGE.



Total No. of Questions : 5]

SEAT No. :

**P5507**

[Total No. of Pages : 2

**[5553] - 1020**

**M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - I)**

**MQA 104T - PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER**

**(2018 Pattern)**

*Time : 3 Hours*

*[Max. Marks : 75*

**Instructions to the candidates:**

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

**Q1)** What is product registration? Discuss registration of bulk drugs and finished formulations in India as per CDSCO. **[15]**

OR

How is technology transferred from R & D to production? Give detailed overview of various quantitative models in technology transfer.

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

- a) What are Phase IV studies? How do they differ from Phase I/II/III clinical studies.
- b) What is importance of Technology Transfer? What are the factors influencing Technology Transfer?
- c) Write a note on medical Device packing.
- d) Discuss the challenges in scale up of new drug products.

**P.T.O.**

**Q3) Attempt Any Three :**

**[15]**

- a) What is polymorphism? Discuss any two techniques for evaluation of crystal properties.
- b) Describe the registration guidelines for dosage forms as per USFDA.
- c) Enlist types of Pharmaceutical Packaging. Discuss any two Quality control tests for secondary packing material.
- d) Discuss various issues faced in modern drug packaging.
- e) Differentiate INDA, ANDA and NDA.

**Q4) What are SUPAC and BACPAC? Discuss in detail SUPAC guidelines for changes in formulation, site, equipment and process along with suitable examples.**

**[15]**

OR

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

**Q5) Write short notes on Any Three :**

**[15]**

- a) Quality control tests for plastic and rubber container-closure systems.
- b) Qualitative technology models for technology transfer.
- c) Importance of micromeritics and flow properties in preformulation.
- d) SUPAC.
- e) Design of Pilot plant.



Total No. of Questions : 5]

SEAT No. :

**P5508**

[Total No. of Pages : 3

**[5553] - 2001**

**M.Pharmacy (Pharmaceutical Chemistry) (Semester - II)**

**MPC 201T - ADVANCED SPECTRAL ANALYSIS**

**(2018 Pattern)**

*Time : 3 Hours*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Discuss the mass fragmentation patterns for the following class of organic compounds **[15]**

- a) Alcohols.
- b) Alkyl benzenes.
- c) Carbonyl compounds.

OR

Give mass fragmentation patterns for the following compounds.

- a) n-Butane.
- b) Benzaldehyde.
- c) Cyclohexanone.
- d) Benzamide.

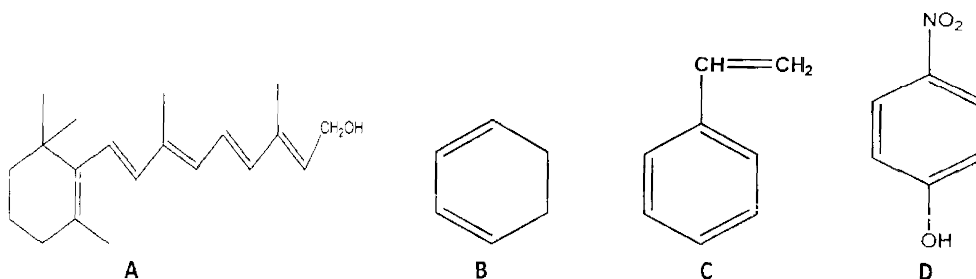
**Q2)** Attempt **Any Two** :

**[15]**

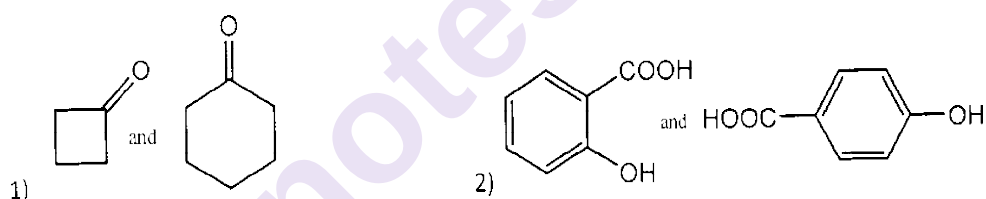
- a) Predict and explain the NMR spectra of following compounds
  - i) m-cresol.
  - ii) p-anisidine.
  - iii) butanol.
  - iv) 2-chloropropane.

**P.T.O.**

- b) The UV spectra of following compounds displayed  $\lambda_{\max}$  at 256, 318, 282 and 325 nm. Assign the appropriate  $\lambda_{\max}$  for the compounds shown below with justification.



- c) Discuss NOESY and COSY techniques.
- d) How will you distinguish between following pairs of compounds on the basis of IR spectroscopy?



**Q3) Attempt Any Three :**

**[15]**

- a) How will you calculate the wavelength of maximum absorption for dienes using Woodward's rule?
- b) Write a note on Mc-Lafferty rearrangement.
- c) Discuss suitable atmospheric pressure ionization interfaces in LC-MS.
- d) 1,3, pentadiene absorbs at higher wavelength in UV spectroscopy than 1,4 pentadiene. Explain.
- e) Write a note on TGA.

**Q4) Answer the following :**

**[15]**

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

Molecular formula :  $C_8H_8O$

**IR :**  $1703\text{cm}^{-1}$ ,  $2733\text{cm}^{-1}$ ,  $2828\text{cm}^{-1}$ ,  $2922\text{cm}^{-1}$ ,  $3048\text{cm}^{-1}$ .

**$^1\text{H}$  NMR :** 2.4  $\delta$  (singlet, 3H)

7.3-7.8  $\delta$  (symmetric multiplets, 4H)

9.9  $\delta$  (singlet, 1H)

- b) Write a detailed note on 2D NMR.

OR

**Answer the following :**

Explain in detail principle, instrumentation and applications of HPTLC.

**Q5) Write short notes on Any Three :**

**[15]**

- a) Write a note on radioimmunoassay of digitalis.
- b) Discuss how LC-FTIR technique can assist in structural elucidation of an unknown compound.
- c) Explain the instrumentation in SFC.
- d) Add a note on Raman spectroscopy.
- e) Explain instrumentation and applications of DSC.



Total No. of Questions : 5]

SEAT No. :

P5509

[Total No. of Pages : 2

[5553] - 2002

M.Pharmacy (Semester - II)

PHARMACOGNOSY

MPG 201T - Medicinal Plant Biotechnology

(2018 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 well labelled diagram wherever necessary.*
- 4) *Do not write anything on question paper except seat number.*

**Q1)** Describe different plant tissue culture techniques and role of plant tissue culture in biosynthesis of secondary metabolites. **[15]**

OR

Describe in detail enzyme immobilization and its applications.

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

- a) Explain recombinant DNA technique.
- b) What is protoplast? Explain isolation and culture of protoplast.
- c) What are applications of biotechnology in Pharmacognosy?
- d) What is organogenesis? Describe factors affecting organogenesis.

**P.T.O.**

**Q3) Attempt Any Three :**

**[15]**

- a) Write about RAPD markers for genetic mapping.
- b) What are gene transfer techniques in transgenic plants?
- c) What are different parameters that can be measured during bioprocessing?
- d) What are applications of rDNA technology in pharmaceutical field?
- e) Write note on 'Biosensors'.

**Q4) How secondary metabolite production in plant cell culture is manipulated?**

**[15]**

OR

What are different types of bioreactors used in fermentation technique for production of secondary metabolites?

**Q5) Write short notes on Any Three :**

**[15]**

- a) Hairy root culture.
- b) RFLP.
- c) Gene sequencing.
- d) Molecular pharmacognosy.
- e) Transgenic plants.



Total No. of Questions : 5]

SEAT No. :

**P5510**

[Total No. of Pages : 2

**[5553] - 2003**

**M.Pharmacy (Pharmaceutics) (Semester - II)**

**(MPH 201T) MOLECULAR PHARMACEUTICS (Nano Tech. and Targeted DDS)**

**(2018 Pattern)**

*Time : 3 Hours*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Compare and Contrast various approaches for development of novel drug delivery systems. **[14]**

**Q2)** Solve any two : **[2 x 8 = 16]**

- a) Describe barriers to brain targeted drug delivery system.
- b) What are the advantages of Dry Powder Inhalers?
- c) Describe different techniques for preparation of nano particles with special reference to large scale manufacturing.

**Q3)** Write Short Notes on (any three) : **[3 x 5 = 15]**

- a) Monoclonal Antibodies.
- b) Therapeutic antisense molecules.
- c) Propellents.
- d) Intra Nasal Route.

**P.T.O.**

**Q4)** Explain pressurized meter dose inhalers with reference, to formulation, packaging and evaluation. **[15]**

**Q5)** Explain in detail gene therapy. **[15]**



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Total No. of Questions : 5]

SEAT No. :

P5511

[Total No. of Pages : 2

[5553] - 2004

M.Pharmacy (Semester - II)

MPL 201T - ADVANCED PHARMACOLOGY - II

(2018 Pattern)

Time : 3 Hours

[Max. Marks : 75

*Instructions to the candidates:*

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

**Q1)** Explain in detail mode of action, mechanism for development of resistance, adverse effects and therapeutic uses of Penicillins. **[15]**

OR

Classify anticancer agents with examples. Discuss in detail pharmacology of alkylating agents.

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

- a) Write in detail pharmacotherapy of bronchial asthma.
- b) Discuss mode of action, adverse effects and therapeutic uses of Ciprofloxacin.
- c) Describe role of immunomodulatory in Immunopharmacology.

**P.T.O.**

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

- a) Classify antiemetic drugs. Write pharmacology of prokinetic agents.
- b) Explain in detail clinical practice guidelines of Tuberculosis.
- c) Describe mode of action, toxicities and uses of aminoglycoside antibiotics.
- d) Give a detailed account on oral hypoglycemic agents.
- e) Explain role of parathyroid hormone, calcitonin and vitamin D in maintaining calcium homeostasis.

**Q4) Classify antiviral agents. Discuss in detail pharmacotherapy of HIV.** [15]

OR

Write pharmacological actions, mode of action, adverse effects and therapeutic applications of Corticosteroids.

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

- a) Oral contraceptives.
- b) Antithyroid agents.
- c) Explain the therapeutic applications of antioxidants.
- d) Management of constipation.
- e) Imidazoles as antifungal agent.



Total No. of Questions : 5]

SEAT No. :

**P5544**

[Total No. of Pages : 2

**[5553]-2005**

**M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - II)**  
**HAZARDS AND SAFETY MANAGEMENT (MQA - 201T)**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Define Industrial hazard and risk. Discuss sources of fire hazards and control strategy for preventive and protective management from fires and explosions. **[15]**

OR

Discuss in detail the air circulation maintenance in pharmaceutical company for sterile area. Add a note on HVAC system.

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

- a) Explain in detail the TLV concept. Discuss its significance and various threshold limits.
- b) Explain components of Fire triangle and classification of Fire.
- c) Discuss various control measures while handling flammable material, dust explosions and pyrophoric material.
- d) Write a note on sources and management of air based hazards.

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

- a) Write a note on various self-protective measures against workplace hazards.
- b) Explain role of Emergency services in Hazard management.
- c) Discuss the hazards and control strategies while using sulphonating reagents.
- d) Write in brief about BOD and COD.
- e) Enlist and explain various renewable and non-renewable natural resources.

**P.T.O.**

**Q4)** Explain in detail the various hazards which can occur due to soil and radioisotopes and suitable measures to prevent them. [15]

OR

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

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

- a) Explain various control strategies to prevent chemical hazards.
- b) Explain various Elements of Safety Management Programme.
- c) Elaborate in brief about factory act and rules.
- d) Explain in brief about Preliminary Hazard Analysis.
- e) Discuss the functions of ecosystem.



Total No. of Questions : 5]

SEAT No. :

P5512

[Total No. of Pages : 2

[5553] - 2006

**M.Pharmacy (Pharmaceutical Chemistry) (Semester - II)**

**MPC 202T - ADVANCED ORGANIC CHEMISTRY - II**

**(2018 Pattern) (Theory)**

*Time : 3 Hours*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Elaborate on methods of asymmetric synthesis using chiral pool and chiral auxiliaries with suitable examples. Add a note on asymmetric catalysis.  
[15]

OR

What is solid phase synthesis? Explain various solid supports and linkers used for the solid phase synthesis. Add a note on Fmoc strategy for protection.  
[15]

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

- a) Explain working principle and applications of Continuous flow reactors.
- b) Discuss [3, 3] Sigmatropic rearrangement with respect to its stereochemistry and applications.
- c) Elaborate on the twelve Principles of Green Chemistry.
- d) Explain the methods of racemic resolution.

**P.T.O.**

**Q3) Attempt Any Three :**

**[15]**

- a) Describe the solution phase peptide synthesis.
- b) Explain the mechanism of cycloaddition-Diels Alder reaction with respect to its Frontier Orbitals.
- c) Explain how the Ziegler-Natta catalyst is used for polymerization of alkenes.
- d) Give synthetic applications of Ultrasound assisted reactions.
- e) Discuss the CIP sequence rules.

**Q4)** Elaborate on homogenous catalysis with respect to hydroformylation. Explain the advantages and disadvantages of homogenous catalysis and heterogeneous catalysis. **[15]**

OR

Describe the principle involved in Microwave assisted reactions. Write applications of Microwave assisted reactions in heterocyclic synthesis. **[15]**

**Q5) Write short notes on Any Three :**

**[15]**

- a) Phase Transfer catalysis.
- b) Use of enzymes in organic synthesis.
- c) Electrocyclic reactions.
- d) Photochemical reactions.
- e) Transition metal catalysed reactions.



Total No. of Questions : 5]

SEAT No. :

P5513

[Total No. of Pages : 2

[5553] - 2007

M.Pharmacy (Semester - II)

MPG 202T - ADVANCED PHARMACOGNOSY - II

(2018 Pattern)

Time : 3 Hours

[Max. Marks : 75

Instructions to the candidates:

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

**Q1)** Discuss in detail *in vivo* screening techniques of anticancer herbal drugs with suitable examples. [15]

OR

Elaborate natural products that make them appropriate in new drug discovery. [15]

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

- a) Write impact of pesticide residue, heavy metals and microbial contamination on natural drugs.
- b) Explain herbals versus convention drugs.
- c) Discuss analytical profile of *Emblica officinalis*.
- d) Discuss the role of validation in herbal products.

P.T.O.

**Q3) Attempt Any Three :**

**[15]**

- a) Discuss adulteration and its types with suitable examples.
- b) Write *in vitro* evaluation techniques for antioxidants.
- c) Write comment on analytical profile of Turmeric.
- d) Explain different causes and measures of adulteration.
- e) Comment on pharmacodynamic and pharmacokinetic drug interactions with suitable examples.

**Q4) Discuss the impact of ethnobotany in development of new drugs from natural origin.** **[15]**

OR

Explain OECD guidelines for acute toxicity studies. **[15]**

**Q5) Write short notes on Any Three :**

**[15]**

- a) DNA Fingerprinting.
- b) Analytical profile of *Andrographis paniculata*.
- c) Reverse pharmacology.
- d) Sampling techniques.
- e) Screening of antidiabetic activity.



Total No. of Questions : 5]

SEAT No. :

P5514

[Total No. of Pages : 2

[5553] - 2008

M.Pharmacy (Semester - II)

MPH 202T -ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS

(2018 Pattern)

Time : 3 Hours

[Max. Marks : 75

*Instructions to the candidates:*

- 1) All questions are compulsory.
- 2) Neat diagrams must be drawn wherever necessary.
- 3) All questions carry equal marks.

**Q1)** Discuss various factors that affect the drug absorption from gastrointestinal tract. [15]

OR

Describe two compartment open model and estimate hybrid first order constants ( $\alpha$  and  $\beta$ ).

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

- a) Describe in detail protein and tissue binding drug interactions.
- b) What is the purpose of BA/BE studies? Describe methods for assessment of bioavailability.
- c) Describe in detail active transport of drug.
- d) How dissolution profiles of two dosage forms are compared?

**P.T.O.**

**Q3)** Attempt any three :

**[15]**

- a) Biosimilar drug products.
- b) Presystemic metabolism.
- c) Levels of IVIVC.
- d) Study designs in BA/BE studies.
- e) Tight junction complex.

**Q4)** What is non linear kinetics? Give reasons and examples for non-linear kinetics. Add a note on estimation of  $V_{\max}$  and  $K_m$ . **[15]**

OR

Discuss BCS and add a note on in vitro methods for permeability studies.

**Q5)** Write notes on any three :

**[15]**

- a) pH-partition hypothesis.
- b) Wagner-Nelson method.
- c) Noyes-Whitney equation.
- d) Compartment modeling.
- e) Pharmacokinetic applications to modified drug release products.



Total No. of Questions : 5]

SEAT No. :

P6102

[Total No. of Pages : 2

**[5553]-2009**  
**M. Pharmacy (Semester - II)**  
**PHARMACOLOGICAL & TOXICOLOGICAL SCREEN-**  
**ING METHODS - II**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Discuss importance of documents to be submitted to the regulatory authorities as per schedule 'Y' before carrying out the clinical trial of a new drug in India. **[15]**

OR

Explain toxicokinetic evaluation in preclinical studies with its importance.

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

- a) Discuss OECD principles of good laboratory practices.
- b) Explain in brief acute dermal toxicity studies.
- c) Explain various studies for carcinogenicity testing.
- d) Discuss acute inhalation toxicity studies.

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

- a) Describe in brief male reproductive toxicity studies.
- b) Discuss ocular toxicity studies.
- c) Explain in brief genotoxicity studies.
- d) Write in brief about female reproductive toxicity studies.
- e) Explain concept and importance of safety pharmacology.

**P.T.O.**

**Q4)** Describe in detail acute oral toxicity studies as specified in the OECD guidelines. **[15]**

OR

Enumerate and explain alternative methods to animal toxicity studies.

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

- a) Teratogenicity studies.
- b) ICH guidelines.
- c) Schedule Y
- d) Applications of INDs
- e) Emergency use INDs



Total No. of Questions : 5]

SEAT No. :

**P5560**

[Total No. of Pages : 2

**[5553] - 2010**

**M.Pharmacy (Pharmaceutical Quality Assurance) (Semester - II)**

**MQA 202T - PHARMACEUTICAL VALIDATION**

**(2018 Pattern)**

*Time : 3 Hours*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Elaborate types of process validation. Explain process validation of coated tablets. **[15]**

OR

Elaborate the concept of Intellectual Property, Intellectual Property Protection and Property Intellectual Rights in pharmaceutical industry.

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

- a) Discuss cleaning validation protocol.
- b) Explain Validation Master Plan.
- c) Explain qualification of tablet compression machine.
- d) Explain computer system validation.

**P.T.O.**

**Q3) Attempt any Three :**

**[15]**

- a) Explain significance of Transfer of Technology (TOT).
- b) Explain qualification of autoclave.
- c) Discuss Site Acceptance Test (SAT) and Factory Acceptance Test (FAT).
- d) Explain difference between Calibration and Validation.
- e) Elaborate qualification of Hardness Tester.

**Q4) Discuss validation of HVAC system in detail.**

**[15]**

OR

Explain types of qualification. Describe qualification of HPLC.

**Q5) Write short note on (Any Three) :**

**[15]**

- a) Qualification of pure steam system.
- b) Process validation of ointment.
- c) LOD and LOQ of an analytical method.
- d) Media fill validation.
- e) Selection of acceptance limits for contamination during cleaning validation.



Total No. of Questions : 5]

SEAT No. :

P5515

[Total No. of Pages : 2

[5553]-2011

**M.Pharmacy (Pharmaceutical Chemistry)**  
**(MPC203T) : COMPUTER AIDED DRUG DESIGN (Theory)**  
**(2018 Pattern) (Semester - II)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** State the parameters which are commonly used as measures of electronic and lipophilic properties in QSAR study. Elaborate on experimental and theoretical approaches for determination of these properties. **[15]**

OR

Explain the methodology and applications of molecular docking in drug design. Discuss with examples of drugs acting on choline esterase or HMG CoA reductase.

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

- a) Outline the fundamental principle underlying the 2D-QSAR approach to drug design.
- b) Discuss structure based in silico virtual screening protocols and its significance.
- c) Elaborate on the concept of de novo drug design and its applications.
- d) Write a note on 3D – QSAR and contour map analysis.

**P.T.O.**

**Q3)** Write short notes on **any three** of the following : **[15]**

- a) Homology modelling.
- b) Fragment based drug design.
- c) Importance of ADMET in drug design
- d) Free Wilson Analysis.
- e) Quantum mechanics.

**Q4)** What is QSAR? Give advantages and disadvantages of QSAR. Explain Hansch analysis and its applications in drug design. **[15]**

OR

What is pharmacophore mapping? Elaborate on its process, advantages, limitations and applications in drug design.

**Q5)** Answer **any three** of the following : **[15]**

- a) How steric features of the drug molecule are important in QSAR study?
- b) What is in silico drug design? Explain its principle.
- c) What is Craig plot? What is its use in drug design?
- d) Add an account on statistical parameters in QSAR equation.
- e) Discuss various methods of energy minimization.



Total No. of Questions : 5]

SEAT No. :

P5516

[Total No. of Pages : 2

[5553]-2012

**M.Pharmacy (Pharmacognosy)**  
**(MPG 203T) : INDIAN SYSTEM OF MEDICINE**  
**(2018 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)** Elaborate fundamental principle of treatment in Ayurvedic systems of Medicines. **[15]**

OR

Elaborate GMP components for ISM with its objectives.

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

- a) What are the challenges for monitoring safety aspects of herbal medicines?
- b) What are 'Astang Yoga'? Elaborate it.
- c) What is 'aromatherapy'? Explain its benefit for ailments.
- d) Explain Homeopathic Science and describe potentization method for homeopathic medicines.

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

- a) Explain GAP with respect to quality assurance aspects for herbals.
- b) Brief about 'Government bills' in AYUSH.

**P.T.O.**

- c) Brief about various 'Asanas' techniques in Yogic science.
- d) Write in short about Siddha Gunapadam.
- e) How documents are prepared for new drug application and export registration for herbals?

**Q4)** Elaborate stability studies of ISM formulations. **[15]**

OR

Explain Naturopathy principle and treatment modalities in detail.

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

- a) TKDL.
- b) Standard Operating Procedures as per GMP.
- c) Meditation and relaxation Techniques.
- d) Unani principles of treatment.
- e) CCRH.



Total No. of Questions : 5]

SEAT No. :

P5517

[Total No. of Pages : 2

[5553]-2013

F.Y. M.Pharmacy

**(MPH 203T) : COMPUTER AIDED DRUG DELIVERY SYSTEM  
(2018 Pattern) (Semester - II)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Answer the following (any one) : **[1 × 15 = 15]**

- a) Explain CADD. Write history of computers in pharmaceutical research and development and elaborate population modeling in detail.
- b) Elaborate regulatory and industry view on QbD in pharmaceutical development.

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

- a) Write a note on computational modeling of drug disposition.
- b) Explain in detail Nucleoside Transporters, OCT and OATP.
- c) Explain in detail Development of pharmaceutical emulsion & microemulsion as drug carriers.
- d) Write a note on gastrointestinal absorption simulation.

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

- a) Write a short note on *In -vitro* dissolution and IVIVC.
- b) Explain in detail Computer simulation in Isolated Tissues and organ.
- c) Write the advantage, disadvantage and Current challenges for Robotics.

**P.T.O.**

- d) Write a short note on P-gp and BBB-Choline Transporter.
- e) Explain in detail Artificial Intelligence (AI)

**Q4)** Answer the following (any one) : **[1 × 15 = 15]**

- a) Explain in detail Fed vs. Fasted state and Bio Waiver Considerations.
- b) Explain in detail Clinical data collection and management. Short note on Proteins and gene.

**Q5)** Write Short note on (Any three) : **[3 × 5 = 15]**

- a) Sensitivity analysis and Optimal design.
- b) Optimization and factorial design.
- c) ICH Q8 guideline.
- d) Modeling techniques.
- e) Ethics of computing in pharmaceutical research and computer in market analysis.



Total No. of Questions : 5]

SEAT No. :

**P5110**

[Total No. of Pages : 2

**[5553]-2015**

**M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - II)**  
**AUDITS AND REGULATORY COMPLIANCE**  
**(2018 Pattern)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Write the role of quality systems and audits in Pharmaceutical Manufacturing. **[15]**

OR

Discuss in details about auditing of vendors and production department.

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

- a) Discuss cGMP regulations regarding premises, sanitation, personnel and manufacturing of sterile preparations.
- b) Describe quality assurance functions in Pharmaceutical manufacturing.
- c) Describe the audit checklist for drug industries.
- d) Explain the cGMP requirements with respect to labels and printed materials.

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

- a) Describe management responsibilities in the audit of Pharmaceutical manufacturing.
- b) Comment on designing of water and steam system for manufacturing of sterile preparations.
- c) Discuss the significance of Corrective and Preventive Action (CAPA).
- d) Describe the importance of contents of Standard Operating Procedure (SOP).
- e) Describe audit components of HVAC System.

**P.T.O.**

**Q4)** Discuss the measures for auditing of Microbiological laboratory. **[15]**

OR

Enlist the documents related to Materials Management in Pharmaceutical Industry.

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

- a) Regulatory guideline to Personal qualification and training.
- b) Classification of deficiencies.
- c) ETP (Effluent Treatment Plant) and audit components.
- d) Quality Assurance Maintenance.
- e) Transitioning of quality system approach.



Total No. of Questions : 5]

SEAT No. :

P5519

[Total No. of Pages : 2

[5553]-2016

**M.Pharmacy (Pharmaceutical Chemistry)**

**MPC 204T : PHARMACEUTICAL PROCESS CHEMISTRY**

**(2018 Pattern) (Semester - II) (Theory)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Give an account of different stages, equipments involved in the large scale manufacturing of APIs with suitable examples. **[15]**

OR

Write about principle of extraction process in the manufacturing of APIs and discuss in details about counter current extraction.

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

- a) Elaborate on Industrial halogenation process with suitable examples.
- b) Write an account of different types of oxidation reactions. Discuss mechanism of oxidation process.
- c) Discuss various types of crystallization techniques. Comment on various factors affecting crystallization.
- d) Give an account of different types of impurities in API and discuss about their sources and strategies to reduce impurities of API.

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

- a) Discuss in-process Quality Control tests for APIs.
- b) Discuss role of Industrial Centrifuges in API manufacturing process.
- c) Elaborate ISO-14001 guidelines.

**P.T.O.**

- d) Explain route selection strategies in chemical process during API synthesis.
- e) Write in detail about industrial reduction scale up process including mechanism, examples.

**Q4)** Write in detail account of principle and process involved in fermentation process. Explain production of Penicillin and streptomycin using fermentation process. [15]

OR

Discuss the principle and mechanism involved in Nitration reaction. Comment on nitrating agents. Write about scale up process for manufacturing of products containing nitro group.

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

- a) Ozonolysis.
- b) Importance of effluent treatment for API manufacturing plant.
- c) MSDS for API.
- d) Fire hazards, types and its prevention.
- e) Catalysts used in oxidation process.



Total No. of Questions : 5]

SEAT No. :

P5520

[Total No. of Pages : 2

**[5553]-2017**  
**M.Pharmacy**  
**HERBAL COSMETICS**  
**(2018 Pattern) (Semester - II)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** Discuss in details Regulatory Provisions in relation to manufacturing of cosmetics. **[15]**

OR

Explain in details toxicity screening and test methods for analysis of cosmetics.

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

- a) Write in details about preparation and standardization of Tooth pastes.
- b) Explain Herbal Hair Growth formulation.
- c) Explain in details manufacturing and evaluation of Cleansing cream.
- d) Write a note on preservatives used in herbal cosmetics.

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

- a) Elaborate a detail account on Lipstick as a herbal cosmetics.
- b) Elaborate a detail account of Quality control methods for herbal shampoo.
- c) Explain different functional herbs used in cosmetics.
- d) Explain in details Natural Colourants for cosmetics.
- e) Explain in details export of herbal/natural cosmetics.

**P.T.O.**

**Q4)** Explain in details designing of herbal cosmetic.

**[15]**

OR

Explain Physiology and chemistry of Skin and pigmentation.

**Q5)** Write a short note on (Any three) :

**[15]**

- a) Industries involved in production of herbal cosmetics.
- b) Vanishing cream.
- c) Offences in relation to herbal cosmetics.
- d) Deodorants.
- e) Quality control of herbal cosmetics for Hairs.

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Total No. of Questions : 5]

SEAT No. :

P5521

[Total No. of Pages : 2

[5553]-2018

**M.Pharmacy (Pharmaceutics)**

**MPH 204T: COSMETICS AND COSMECEUTICALS**

**(2018 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 the ingredients used in the preparation of herbal skin care cosmetics. Add a note on challenges in formulating herbal cosmetics.[15]

OR

What is shampoo? Give the desired properties of shampoo and explain the formulation development of shampoo.

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

- a) Discuss about the building blocks for cream formulation.
- b) Discuss in detail about the common problems associated with oral cavity and cosmetics used to tackle them.
- c) Write in detail about the thickeners used in cosmetic industry.
- d) Explain about the Surfactants used in cosmetics.

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

- a) Explain in detail about the Dental Products.
- b) Discuss about the Sunscreen cosmetics.
- c) Describe in detail about anti acne formulation.
- d) Elaborate on classification of cosmetics with examples.
- e) Write in detail about the moisturizing cream.

**P.T.O.**

**Q4)** What do you mean by Misbranded and spurious cosmetics. Write in detail about the Indian regulatory requirements for labeling of topical cosmetics.[15]

OR

Explain antimicrobial preservatives with their merits and demerits. Elaborate the factors influencing efficacy of preservatives. [15]

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

- a) Conditions for Loan license for cosmetics manufacturing.
- b) Enlist the emollients used in skin care cosmetics with their mechanism of action.
- c) Lipsticks-preparation and evaluation.
- d) COSMOS members and their rules.
- e) Herbal hair care products.



Total No. of Questions : 5]

SEAT No. :

P5522

[Total No. of Pages : 2

[5553]-2019

**M.Pharmacy (Semester - II)**  
**EXPERIMENTAL PHARMACOLOGY PRACTICAL - II**  
**(Clinical Research and Pharmacovigilance**  
**(2018 Pattern) (MPL204T)**

*Time : 3 Hours]*

*[Max. Marks : 75*

*Instructions to the candidates:*

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

**Q1)** What do you mean by clinical research? Describe phases of clinical research. **[15]**

OR

What do you mean by Adverse Drug Reactions? Explain its types and factors affecting Adverse Drug Reactions.

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

- a) Comment on ethical issues related to clinical trials.
- b) What do you mean by safety monitoring in clinical research?
- c) Discuss methods of detection and reporting of Adverse Drug Reactions.
- d) Comment on roles and responsibilities of clinical trial personnel.

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

- a) Explain the role of Institutional Review Board in clinical research.
- b) Write note on severity and seriousness assessment.
- c) Explain the guidelines for preparation of documentation of clinical trials.
- d) Discuss aggregate report.
- e) What do you mean by passive and active surveillance?

**P.T.O.**

**Q4)** Define Pharmacovigilance. Write about data collection and reporting methods in pharmacovigilance. [15]

OR

Discuss in detail periodic safety update report of marketed product. [15]

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

- a) Pharmacoepidemiology.
- b) International classification of diseases.
- c) Vigiflow and Argus.
- d) Methods of causality assessment of Adverse Drug Reactions.
- e) The Nuremberg Code.



Total No. of Questions : 5]

SEAT No. :

**P5111**

[Total No. of Pages : 2

**[5553]-2020**

**M. Pharmacy (Pharmaceutical Quality Assurance) (Semester - II)**  
**PHARMACEUTICAL MANUFACTURING TECHNOLOGY**  
**(2018 Pattern) (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 well labelled diagrams wherever necessary.*
- 4) Do not write anything on question paper except seat number.*

**Q1)** Discuss in detail how to select pharmaceutical plant location? Explain factors influencing plant location and plant layout. **[15]**

OR

Describe the process of film coating. Describe in detail problems encountered in tablet coating alongwith remedies to each problem.

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

- a) Explain primary drying and secondary drying in lyophilization.
- b) Describe wet granulation process in tablet manufacturing technology.
- c) Describe types of containers and qualities of good container.
- d) Describe extrusion - spheronization process.

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

- a) Describe IPQC tests for sterile emulsion and suspensions.
- b) Describe coating pans used in tablet coating.
- c) What are closure liners? Explain factors to be considered While selecting closure liners.
- d) Describe materials used for making containers.
- e) Explain drug-plastic interactions.

**P.T.O.**

**Q4)** Describe in detail environment control in sterile product manufacturing. Explain area planning in sterile product manufacturing with advantages. [15]

OR

What is Quality by Design (QbD)? Explain its necessity, advantages and elements. Also describe various terminologies used with examples.

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

- a) Clean in place (CIP)
- b) Types and quality of glass for containers
- c) Blister packs and bubble packs
- d) PAT
- e) Production Planning

