Registration No : | 2 | 1 | 0 | 8 | 2 | 5 | 7 | 0 | 4 | 2 |

Total Number of Pages : 02

M.Pharm

MPA101T/ MPC101T/ / MPG101T/ MPH101T/ MPL101T/ MQA101T

1st Semester Regular / Back Examination: 2021-22

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

BRANCH(S): ANALYSIS & QUALITY ASSURANCE, PHARMACEUTICAL ANALYSIS/ CHEMISTRY/ PHARMACOGNOSY/ PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS/ PHARMACOLOGY/ PQA

Time : 3 Hour

Max Marks : 75

Q.Code : OF587

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.

The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions :** **(2×10)**

a) What are chromophores and Auxochromes. Give examples?

b) At wave number 1710 to 1740 cm–1 what are the functional groups that may appear for an organic compound in IR spectrum.

c) What is quenching? Give two examples of quencher.

d) Define chemical shift. Write the significance TMS.

e) What is the difference between the base peak and the molecular ion peak?

f) What is HPLC and UHPLC. Write the advantages of UHPLC over HPLC.

g) What is theoretical plate. Write its significance.

h) Write the sources of X-Rays. Write the importance of X-Ray crystallography in structure elucidation.

i) Why is nitrogen gas used in TGA analysis?

j) When and why, for a pharmaceutical preparation, one can proceed for DTA or DSC analysis.

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** **(5×7)**

a) Briefly discuss the electronic transition in UV spectroscopy.

b) Explain the principle and application of capillary electrophoresis.

c) Explain about spin-spin coupling and its importance in NMR.

d) Explain Bragg's equation.

e) What is shielding and de-shielding write the importance of J constant.

f) Write the criteria for fluorescence and its pharmaceutical application.

g) Write the principle instrumentation and application of flame photometry.

h) Explain the principle involved in Gas-chromatography.

i) Explain the functional group region of IR spectrum. How will you proceed for an IR spectrum. Interpretation

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Discuss instrumentation and principle of mass spectroscopy with a diagram **(10)**

Q4 Write a note on any two. **(10)**

a) Paper electrophoresis.
b) Ion exchange chromatography
c) MALDI
d) HPTLC

Q5 Explain solvents and selection criteria for UV spectroscopy. Discuss various sample preparation techniques for IR spectroscopy. **(10)**

Q6 What are the electrodes used in potentiometry. Write the principle of DSC and application of TGA. **(10)**

Registration No : | 2 | 1 | 0 | 8 | 2 | 5 | 7 | 0 | 4 | 2 |

Total Number of Pages : 01

M.Pharm
MPH102T

1st Semester Regular / Back Examination: 2021-22
DRUG DELIVERY SYSTEM
BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS
Time : 3 Hour
Max Marks : 75
Q.Code : OF629

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions :** **(2×10)**

a) What are toxoids?
b) Why permeation enhancers are used for TDDS?
c) What is pharmacogenetics?
d) What is the importance of adhesive rims for TDDS?
e) Differentiate proteins and peptides.
f) Classify pH-sensitive drug delivery systems.
g) Mention the importance of swelling index?
h) What is wicking agent? Give an example.
i) Define rate limiting step of a dosage form.
j) What do you mean by Fickian diffusion?

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** **(5×7)**

a) Personalized medicine
b) Various approaches for SR/CR formulations.
c) Polymer application in pharmacy
d) Osmotic activated Drug Delivery Systems
e) 3-D printing
f) Single shot vaccines
g) Telepharmacy
h) Approaches to extend GI transit.
i) Barriers for protein delivery.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Name various skin barriers for penetration of drug. Discuss in detail the technologies involved in TDDS. **(10)**

Q4 Differentiate between CR and SR; Discuss various mechanisms of Drug Delivery from SR/CR formulations in detail. **(10)**

Q5 Write the Principle of muco-adhesion, discuss in detail about formulation and evaluation of buccal drug delivery systems **(10)**

Q6 Mention the drawbacks for ocular permeation. Discuss various drug delivery systems for eye. **(10)**

Registration No : | 1 | 7 | 0 | 3 | 2 | 5 | 7 | 0 | 5 | 8 |

Total Number of Pages : 01

M.Pharm
MPH103T

1st Semester Regular / Back Examination: 2021-22
MODERN PHARMACEUTICS
BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS
Time : 3 Hour
Max Marks : 75
Q.Code : OF679

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions :** (2×10)

a) What are the objectives of preformulation studies?
b) Why is Real-Time stability testing performed?
c) What is SMEDDS?
d) State the scope of validation.
e) What do you mean by Quality by Design?
f) What is a Contour Plot?
g) Define multiple emulsion and microemulsion.
h) What are the main objectives of cGMP?
i) How does decompression affect the quality of tablets?
j) What is Chi square test?

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** (5×7)

a) Write about the theories of dispersion.
b) Write a short note on accelerated stability testing.
c) How is pyrogen testing of parenterals performed?
d) What are the different types of process validation?
e) Write about the ICH guidelines for calibration of equipments.
f) Give a brief note on master formula record.
g) Write about the principles of GMP.
h) Explain product recall system.
i) Give a brief note on ANOVA test.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Describe briefly about the compression force-time profiles of tablets. (10)

Q4 Illustrate the different concepts of Total Quality Management. (10)

Q5 Discuss about the optimization techniques in pharmaceutical formulations. (10)

Q6 Describe briefly about the URS, DQ, IQ, OQ, and PQ processes of facilities. (10)

Registration No: | 2 | 1 | 8 | 8 | 2 | 5 | 7 | 0 | 4 | 2 |

Total Number of Pages: 01

M. Pharm
MPH104T

1st Semester Regular / Back Examination: 2021-22
REGULATORY AFFAIR
BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS
Time: 3 Hour
Max Marks: 75
Q. Code: OF728

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions:** **(2×10)**

a) Enlist the importance of documentation in pharmaceutical industry?
b) How is innovator drug different from generic?
c) What is NDA in drug development?
d) Write down the objectives of ICH.
e) What is global submission of IND?
f) How do the regulatory requirements in ROW countries harmonise?
g) What do you mean by IMPD dossier?
h) Write down the role of Data and Safety Monitoring Board in clinical trial.
i) What is the role of HIPPA in clinical trial?
j) What is triage in pharmacovigilance?

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** **(5×7)**

a) Give details note on NDA.
b) Write a note on ANDA. Explain PARA I to IV filling in ANDA.
c) Explain in details Master Formula Record. (MFR).
d) Explain guidelines of ICH-Q.
e) How to develop clinical trials protocol at institute level?
f) Give details note on MHRA.
g) Define CTD and eCTD. Explain in detail.
h) Give in details of Pharmacovigilence safety monitoring in Clinical Trials.
i) Define orange book. Explain investigator brochure (IB).

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Give important of CRO. What about out sourcing of BA & BE studies to CRO? **(10)**

Q4 Explain the various components of FDA. **(10)**

Q5 What is dossier? Explain regulatory requirements of dossier for ROW countries. **(10)**

Q6 What is Post Marketing Surveillance (PMS)? Give it's important in clinical trials. **(10)**

Registration No : | 2 | 1 | 0 | 8 | 2 | 5 | 7 | 0 | 0 | 9 |

Total Number of Pages : 02

M.Pharm
MPA102T

1st Semester Regular/Back Examination: 2021-22
ADVANCED PHARMACEUTICAL ANALYSIS
BRANCH(S): ANALYSIS & QUALITY ASSURANCE, PHARMACEUTICAL ANALYSIS

Time : 3 Hour
Max Marks : 75
Q.Code : OF621

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions :** **(2×10)**

a) Define identified and unidentified impurities.
b) What are mutagenic impurities? Give two examples.
c) Classify the different types of residual solvents.
d) Name two factors that affect the stability testing of drugs and drug products.
e) Signify the importance of accelerated stability testing of pharmaceuticals.
f) Name two advanced instrumentation techniques used for impurity profiling.
g) What are Haptens?
h) What are resolution and RF factor?
i) What are antigens and antibodies? Give examples of each.
j) Enumerate different types of radio immune assays.

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** **(5×7)**

a) Discuss on different classes residual solvents with suitable examples.
b) Outline the instrumentation used in analysis of C,H, N and S elements.
c) Write short notes on sampling and storage of stability samples.
d) Write short notes on Shelf life calculation of pharmaceuticals with suitable examples.
e) Compare the advantages and disadvantages of HPLC and HPTLC phytopharmaceutical analysis.
f) Classify the different stability zones and storage guidelines as per ICH guideline.
g) Describe the bioassay of Rabies vaccine.
h) Describe the bioassay of Oxytocin.
i) Write a short notes on optical immunoassay.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Describe in detail about the regulatory requirements and various stability testing protocols for phytopharmaceuticals. **(10)**

Q4 Discuss in detail about the photostability testing of drugs as per ICH guideline. **(10)**

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Q5 Define PCR and describe its instrumental components and operational procedure for study of gene regulation. **(10)**

Q6 Define immunoassays. Classify them and discuss in detail about radio immune assay and enzyme immune assay. **(10)**

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$K = Ae^{-Ea/RT}$

$\log K = \log A - \frac{R}{2.303KT}$

$K = Ae^{-RT/K}$

① - centrifuge

② - Radio labelled immunology

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M.PHARM
MPA103T

1st Semester Regular / Back Examinations – 2021-22
PHARMACEUTICAL VALIDATION
BRANCH: ANALYSIS & QUALITY ASSURANCE, PHARMACEUTICAL ANALYSIS
Time: 3 Hours
Max marks: 75
Q Code: OF680

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part- I

Q1 Objective Answer Type Questions (Answer All) **(2×10)**

a) Differentiate between Trade secret and Trademark with suitable example.
b) Define calibration and mention its significance in Pharmaceutical industry.
c) Enlist the different types of patent.
d) What is the limit of conductivity and limit of endotoxin in pure steam?
e) Define sterile water for injection
f) Storage condition of steam sample if not analyzed within 2 hours.
g) Differentiate Ruggedness and Robustness.
h) What is TOC?
i) Mention four disinfectants used in Pharmaceutical industry.
j) Give the significance of user requirement specification.

Part- II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven) **(5x7)**

a) Explain Validation Master Plan.
b) Enumerate about Storage of Pharmaceutical water.
c) HVAC system in Pharmaceutical industry.
d) Role of IP in Pharmaceutical industry.
e) Differentiate between FAT and SAT.
f) Write notes on cleaning validation.
g) What are penalties for violation of intellectual property?
h) Give out significance of TOT.
i) Describe the qualification of pipette and measuring cylinder.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Define Validation. Explain the general principles involved in Validation of Analytical method as per ICH guidelines and USP. **(10)**

Q4 Explain the different types of Pharmaceutical water and their purification techniques. Write a note on pure steam. **(10)**

Q5 Define and mention the advantages and streamlining of qualification and Validation process. **(10)**

Q6 Enumerate the detail process of filing a patent application. **(10)**

Registration no: | 2 | 1 | 0 | 8 | 2 | 5 | 7 | 0 | 0 | 9 |

Total Number of Pages: 01

M.PHARM

MPA104T

1st Semester Regular Examinations 2021-22

FOOD ANALYSIS THEORY

BRANCH: ANALYSIS & QUALITY ASSURANCE, PHARMACEUTICAL ANALYSIS

Time: 3 Hours

Max marks: 75

Q Code: OF718

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any twofrom Part-III.

The figures in the right hand margin indicate marks.

Part- I

Q1 Objective Answer Type Questions (Answer All) **(2x10)**

a) Why is defatting of samples for carbohydrate analysis being done?
b) Give importance of saponification value and iodine value for lipids?
c) What are types of preservatives used in food products?
d) Classify vitamins based on lipophilicity.
e) Define sweeteners. Give examples of sweeteners obtained from nature.
f) Enumerate common adulterants of milk.
g) Give the examples of monosaccharide and disaccharides.
h) Explain Ninhydrin test?
i) Give methods for determination of ethyl alcohol in fermentation products.
j) What is AGMARK?

Part- II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven) **(5x7)**

a) Comment in brief on hydrogenation of vegetable oils.
b) Give an account of pharmacokinetics of carbohydrates.
c) Enumerate the protein structure.
d) Explain the principle and procedure for analysis of Vitamin C.
e) How will you quantitatively determinestarch and urea in milk?
f) Write notes on organophosphorus and organochloride pesticides.
g) Explain the determination of rancidification of food.
h) Describe about analysis of protein by Biuret assay method.
i) Summarize the functions of USFDA.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Discuss the principle of microbial assay ofVitamins of B series. **(10)**

Q4 Illustrate the types and methods of detection of Synthetic and Natural Dyes usedin food industry. **(10)**

Q5 What do you mean by crude fibre and dietary fibre? How they are estimated? **(10)**

Q6 Describe the procedures for determination of adulterations in fat and oils. **(10)**

Registration No : | 2 | 1 | 0 | 8 | 2 | 5 | 7 | 0 | 1 | 9 |

Total Number of Pages : 02

M.Pharm
MPC102T

1st Semester Regular Examination: 2021-22
ADVANCED ORGANIC CHEMISTRY -I
BRANCH(S): CHEMISTRY
Time : 3 Hour
Max Marks : 75
Q.Code : OF620

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions :** (2×10)

a) Enumerate the synthesis of Metronidazole
b) Differentiate synthon and retron with suitable example.
c) How do you deprotect the MOM and Trityl protection of primary alcohol?
d) Write the formation of Vilsmeyer-Haack reagent.
e) How do you know if a reaction is SN1 or SN2?
f) Write the structure and one application of dicyclohexyl carbodimide (DCC).
g) What is an allylic shift? What is its importance in organic reactions?
h) What is Bernthsen Acridines synthesis?
i) Why are the products derived out of Saytzeff's rule more stable?
j) Why is the Sharpless asymmetric epoxidation enantioselective?

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** (5×7)

a) Write the mechanism and synthetic applications of Mitsunobu reaction.
b) Describe in detail about the factors influencing bimolecular substitution reactions.
c) Explain the effect of substituents on reactivity and orientation of mono substituted benzene.
d) Write a note on Debus-Radziszewski imidazole synthesis.
e) Compare E1 and E2 reactions. Discuss the factors affecting E2 reactions.
f) Discuss the chemistry and uses of Wittig reagent.
g) Describe the protection and deprotection methods for 1,2- diols.
h) Outline the synthesis of Celecoxib with reagents used and reaction conditions followed.
i) Write a short note on Functional group interconvertion (FGI) with examples.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Discuss the method of formation, stability, relative reactivity and synthetic applications of carbocations. (10)

Q4 Explain the retrosynthetic strategies for synthesis of three, four and five membered rings. (10)

Q5 Mention the heterocyclic nucleus present and also the steps involved in the synthesis of Chloroquine and Trimethoprim. **(10)**

Q6 Discuss the protection and deprotection techniques used for amino acids with suitable examples. **(10)**

Registration No : | 2 | 1 | 6 | 8 | 2 | 5 | 7 | 0 | 2 | 9 |

Total Number of Pages : 02

M.Pharm
MPC103T

1st Semester Regular / Back Examination: 2021-22
ADVANCED MEDICINAL CHEMISTRY
BRANCH(S): Chemistry
Time : 3 Hour
Max Marks : 75
Q.Code : OF673

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions :** (2×10)

a) Define hit, lead and candidate in drug Discovery?
b) What is the significance of eudysmic ratio (eudismic ratio)?
c) What are the challenges of making COX-1 selective inhibitors?
d) Write the applications of leukotrienes?
e) Name a local constraint and write its benefit in the design of peptidomimetics.
f) What is the difference between neutral antagonist and inverse agonist?
g) Differentiate between carrier linked prodrugs and bioprecursors.
h) What is the significance of analog design?
i) What is the difference between cofactor & prosthetic group?
j) Write the chemical structure and uses of any one ACE inhibitor?

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** (5×7)

a) Is it true that the active site of an enzyme can be synthetically developed? If true, illustrate. If false, substantiate with reasons.
b) Discuss the role of bioisosterism in drug research.
c) What are indirect acting sympathomimetic agents? Write the structure and uses of any one indirect acting sympathomimetic drug.
d) Explain various forces involved in drug-receptor interactions.
e) Write a brief note on genetic principles of drug resistance.
f) How does rigid analog and alteration of chain branching help in analog design.
g) Give an account on chemistry of prostaglandin.
h) Write a short note on design of non-covalently binding enzyme inhibitors.
i) Briefly discuss the role of enantioselectivity in drug metabolism.

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Write the classification and SAR of H1 receptor antagonists. Give the mode of action and synthesis of any one new generation H1 receptor antagonist. (10)

Q4 What is a prodrug? Explain the attempts made on drug molecules to enhance the aqueous solubility, gastrointestinal absorption and CNS specific delivery with suitable examples. (10)

Q5 Define peptidomimetics. What are their advantages over peptides as drugs? Discuss the design of peptidomimetics by incorporating conformational constraints. **(10)**

Q6 What are different stages of drug discovery? Discuss in detail the lead identification techniques. **(10)**

Registration No :

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M.Pharm
MPC104T

1st Semester Regular Examination: 2021-22
CHEMISTRY OF NATURAL PRODUCTS
BRANCH(S): CHEMISTRY
Time : 3 Hour
Max Marks : 75
Q.Code : OF717

Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

Part-I

Q1 **Answer the following questions :** **(2×10)**

a) Biological source and uses of Morphine
b) Structure of Paclitaxel
c) Structure of Lovastatin
d) Biological source and uses of Ergot
e) Structure of Testosterone
f) Structure of Squalene
g) Biological source and uses Gymnema sylvestre
h) Name some anti-diabetic drug of plant origin
i) What is hybridoma technology - Form of hybrid cell, B-lymphatic cell & tumor cell
j) What is gene therapy

Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** **(5×7)**

a) Describe about one Anticancer Drugs
b) What isCurare alkaloids. Describe about its Pharmacological activity.
c) Describe in brief about the methods of structural elucidation of Alkaloid
d) Describe the structural elucidation and stereochemistry of ephedrine
e) Discuss the structural elucidation and stereochemistry of reserpine
f) Enumerate isolation and purification of flavonoids
g) Describe the chemistry of sterols
h) Discuss the structural elucidation of citral
i) What is Recombinant DNA technology

Alkaloid Curare Curarine

Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Discuss about drug affecting of nervous system with example **(10)**

Q4 Enumerate in detail about the chemistry of macrolid antibiotic with a suitable example **(10)**

Q5 What is alkaloid, classify and describe about the isolation, purification and molecular modification **(10)**

Q6 Give a note on clinical application and recent advances in gene therapy **(10)**