

Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmacology) (Sem-2)
CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T

M.Code : 74946

Date of Examination : 05-06-2023

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Discuss about origin of International Conference on Harmonization. Discuss about Good Clinical Practice guidelines and their principles.
2. Describe the salient features of Schedule Y. Discuss in detail the composition, functions and responsibilities of Institutional Review Board.
3. Discuss the role and responsibilities of investigator in a clinical trial. Describe about contract research organization, its functions and management.
4. Describe in detail, about the objectives and contents of clinical trial protocol and investigator brochure in a clinical trial.
5. Define and classify the various types of adverse drug reactions. Describe about their predictability and preventability assessment.
6. Discuss about pharmacovigilance programme of India. Describe about Argus, Aris G and Vigiflow.

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(S31)-2001

July-2023.

Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmacology) (Sem-2)
PHARMACOLOGICAL & TOXICOLOGICAL SCREENING

Subject Code : MPL-202T

M.Code : 74944

Date of Examination : 07-06-2023

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) Write a note on safety pharmacology, its origin, concept and significance. (8)
b) Add a note on IND studies and highlight submission parameters. (7)
2. Discuss in detail, OECD guidelines for acute, sub-acute and chronic oral toxicity studies. (15)
3. Give a detailed account on the toxicokinetic evaluation in preclinical studies and applications of toxicokinetic studies. (15)
4. Write notes on following : (5×3=15)
a) HERG Assay
b) Segment I and II female reproductive toxicity studies
c) Skin sensitization studies
5. a) Write a note on *in vivo* carcinogenicity studies. (8)
b) Write a note on alternative methods to animal toxicity testing. (7)
6. Discuss following as per OECD guidelines : (8)
a) Dermal toxicity studies (7)
b) Inhalational toxicity studies.

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July-2023

Roll No. _____

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy. (Pharmacology/Pharmaceutical Analysis) (Sem.-2)

CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T

M.Code : 74946

Date of Examination : 12-07-22

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
 2. Each question carries FIFTEEN marks.
-
1. A) What is meant by informed consent? Discuss the ethical issues concerning informed consent for clinical trials.
B) Give an account of the storage provisions to be provided in a pharmaceutical plant for raw materials and finished products.
 2. A) Enumerate the different types of personnel required for a clinical trial. Mention their responsibilities in brief.
B) Enumerate the different study designs for clinical trials. Describe any one.
 3. A) Discuss the protocol for conducting a clinical trial. How is clinical study report documented?
B) Differentiate between side effect and adverse drug reaction. How is severity and seriousness of ADRs assessed and recorded?
 4. What are pharmacovigilance studies? Enumerate the approaches used for these studies. Give a detailed account of WHO regulations for this purpose.
 5. Discuss the regulatory guidelines for ADRs reporting in India. Outline the procedure used for this purpose.
 6. Write notes on (any three) :
A) Vaccine safety surveillance
B) Pharmacoepidemiology
C) Statistical methods for evaluating medication safety data.
D) Non RCT and its significance.

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Total No. of Pages : 01

M.Pharmacy(Pharmacology) (Sem.-2)
PHARMACOLOGICAL & TOXICOLOGICAL SCREENING

Subject Code : MPL-202T

M.Code : 74944

Date of Examination : 06-07-22

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Write a note on genotoxicity studies.
2. Write a note on ICH and schedule Y.
3. What is HERG assay? Write a note on safety pharmacology of drugs acting on the respiratory system.
4. What do you understand by toxicokinetics? Write its importance and applications.
5. Write a note on acute toxicity studies for oral products.
6. What is toxicology? What is its importance in drug development? What are its different branches?

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Roll No.
Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmacology) (Sem.-2)
ADVANCED PHARMACOLOGY -II
Subject Code : MPL-201T
M.Code : 74943
Date of Examination : 04-07-22

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

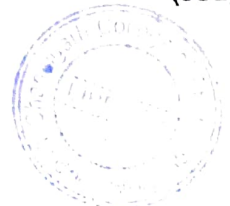
1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. A. Discuss pharmacology of insulin in detail.
B. Write a short note on anti-thyroid drugs and their uses.
2. A. Discuss events of acute inflammation.
B. Discuss pharmacotherapy of asthma.
3. A. Classify anti-viral drugs in detail.
B. Write a detailed note on superbugs.
4. A. Write a detailed note on hypersensitivity reactions.
B. Outline chemotherapy of cancer.
5. A. Define diarrhea and outline its management.
B. Discuss implications of chrono-pharmacology.
6. A. Write a detailed note on diabetic complications.
B. Classify anti-cancer drugs in detail.

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1 | M-74943

(S31)-135



Roll No

Total No. of Questions : 06

Total No. of Pages 01

M.Pharmacy (Pharmacology) (Sem.-2)

ADVANCED PHARMACOLOGY -II

Subject Code : MPL-201T

M.Code : 74943

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. A. Explain cellular and molecular mechanism of T3.
B. Write a detailed note on oral hypoglycemic agents.
2. A. Classify anti-viral drugs in detail.
B. Discuss cellular events of inflammation.
3. A. Write a detailed note on beta-lactams.
B. Outline management of tuberculosis.
4. A. Outline process of free radical generation
B. Outline management of COPD.
5. A. Write a detailed note on circadian rhythms.
B. Discuss role of free radical in pathophysiology of diabetes.
6. A. Outline pharmacological management of Parkinson's disease.
B. Discuss pathophysiology of Alzheimer's disease.

Dec 19.

DEC 19

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(S31)-2366

Roll No. _____

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy(Pharmacology) (Sem.-2)
PHARMACOLOGICAL & TOXICOLOGICAL SCREENING

Subject Code : MPL-202T

M.Code : 74944

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Write a note on teratogenicity studies.
2. Write a note on OECD principles of Good laboratory Practice.
3. What is IND? What is its importance? What are the studies to be included for IND submission?
4. Write a note on alternative methods to animal toxicity studies.
5. Write a note on chronic toxicity studies for oral products.
6. What is safety pharmacology? Explain its origin, concept and significance.



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(S31)-2430

Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmacology) (2017 Batch) (Sem.-2)

ADVANCED PHARMACOLOGY -II

Subject Code : MPL-201T

M.Code : 74943

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

- Q.1 Classify quinolones. Discuss the pharmacology of fluoroquinolones. 15
- Q.2 a. Discuss the clinical management of tuberculosis. 7
- b. Classify anti-cancer drugs. Discuss the pharmacology of alkylating agents and plant based anti-cancer agents. 8
- Q.3 a. Elaborate your views on current clinical pharmacotherapy for asthma. 8
- b. Classify anti-ulcer drugs. Discuss the pharmacology of proton pump inhibitors. 7
- Q.4 Discuss the Pharmacology of oral hypoglycemic agents with suitable examples. 15
- Q.5 Write short notes on the following : 8
- a. Immunosuppressant 7
- b. Oral contraceptives
- Q.6 Discuss the following with suitable examples : 5
- a. Advances in pharmacotherapy of Alzheimer's disease 4
- b. Chronotherapy in diabetes 6
- c. Free radicals in cancer

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May-2019



Roll No.

Total No. of Pages: 01

Total No. of Questions : 06

**M. Pharmacy (Pharmacology) (2017 Batch) (Sem.-2)
CLINICAL RESEARCH & PHARMACOVIGILANCE**

Subject Code : MPL-204T

M. Code : 74946

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Write an extensive note on adverse drug reactions with suitable examples and/or flow charts. 15
2. a. Discuss history, scope and significance of pharmacovigilance. 7
b. Elaborate on roles and responsibilities of contract research organization. 8
3. a. Write a note on ICH-GCP guidelines for clinical trials. 9
b. Discuss the concept of informed consent in clinical trial with suitable examples. 6
4. Give a detailed account on various components of clinical trials. 15
5. Write short notes on the following :
 - a. Pharmacoepidemiology 5
 - b. Phase 0 clinical trial 5
 - c. Schedule Y 5
6. Discuss the following with suitable examples :
 - a. Case report forms 5
 - b. Clinical trial monitoring 6
 - c. Sterile and aseptic area layout 4

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1 | M-74946

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May - 2019

Roll No.

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (2017 Batch) (Sem.-2)

COSMETIC & COSMECEUTICS

Subject Code : MPH-204T

M.Code : 74964

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
 2. Each question carries FIFTEEN marks.
-
1. A) What are misbranded and spurious cosmetics? Give examples of such product and comment on the penal provisions according to Indian regulations.
B) Give an account of the procedure to be adopted for obtaining license for manufacture of cosmetics.
 2. A) What is prickly heat powder? Mention the ingredients used in it with examples and explain their mechanism of action.
B) Enumerate the cleansing formulations for face and eyes. Highlight the essential properties they should possess.
 3. A) What are surfactants? Classify them with examples and justify their use in cosmetics used for cleansing purposes.
B) Give an account of preservatives used in cosmetic formulations.
 4. Give a detailed account of perfumes along with their classification. Why are perfumes listed as allergens in EU regulations?
 5. What are sun screen agents? Classify them with examples and explain the mechanism of action of these agents. Comment on the regulatory guidelines governing them.
 6. Write notes on (any three) :
 - A) Anti-dandruff preparations
 - B) Rheological additives
 - C) Dental cavities and its protection
 - D) Herbal oral care agents



Dcc-19

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Roll No. _____
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M.Pharmacy (Pharmacology) (Sem.-2)
CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T
M.Code : 74946

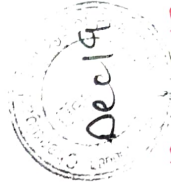
Max. Marks: 75

Time : 3 Hrs.

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) Outline the requirements for a sterile product manufacturing plant. Indicate various areas with the help of an illustration. (7.5)
b) Describe the constitution of IRB. Mention the functions of IRB. (7.5)
c) Write a note on cross sectional observation studies. (7.5)
2. a) Comment on the responsibilities of study coordinator of a clinical trial. (7.5)
b) What is an investigator brochure? Outline the contents of this brochure and mention the purpose of each entry in the form. (7.5)
c) What is ADR? Give five examples of ADRs. How are ADRs detected and reported? Outline the format used for this purpose. (7.5)
4. Outline the importance of safety monitoring in clinical trials. Give a detailed account of safety monitoring in clinical trials. (15)
5. Give a detailed account of passive and active surveillance in pharmacovigilance. Outline the steps involved in each. (15)
6. Write notes on (any three) : (5 × 3 = 15)
a) Pharmacoeconomics
b) Responsibilities of a CRO
c) Pharmacovigilance in hospitals
d) International classification of diseases



Dec - 19

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(S31)-2510

Roll No.

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (2017 Batch) (Sem.-2)
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Subject Code : MPH-202T

M.Code : 74962

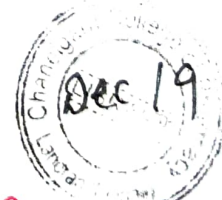
Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) Discuss the physico-chemical factors influencing drug dissolution from dosage forms. (7.5)
b) Give an account of Tight Junction Complex and its role in drug transport through the intestine. (7.5)
2. a) Explain pH-partition hypothesis for predicting drug absorption. (7.5)
b) Give an account of IVIVC methods and their utility. (7.5)
3. a) Distinguish one compartment from two compartment model. Derive a simple equation for predicting the plasma drug concentration for one compartment open model after IV bolus injection. (7.5)
b) Write a note on CyP 450 based interactions. (7.5)
4. a) What are biosimilars? Briefly explain biosimilars and their general compendial requirements. (7.5)
b) Give an account of the study designs used for bioequivalence assessment of drug products. (7.5)
5. a) What is non-linear pharmacokinetics? Mention the reasons for this behavior with suitable examples. (7.5)
b) Discuss briefly the methods used for assessing permeability of drug molecules in vitro. (7.5)
6. Write short notes on :
a) Generic substitution with examples (5)
b) Pharmacokinetics of peptides (5)
c) Immunotherapy and its modules (5)



Dec-19

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(S31)-964

Roll No.

Total No. of Questions: 06

Total No. of Pages: 01

M. Pharma (Pharmacology) (2013 & Onwards) (Sem. - 2)

PHARMACEUTICAL MEDICINE

M Code: 71341

Subject Code: PHCOL-132

Paper ID: [A2494]

Time: 3 Hrs.

Max. Marks: 80

INSTRUCTIONS TO CANDIDATES:

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries SIXTEEN marks.

1. Write notes on followings:
 - a) Lead identification and optimization
 - b) Acute toxicity studies
 - c) Special test for Mutagenicity6+6+4
2. Write short notes on following:
 - a) Blinding in clinical trials
 - b) Informed consent and its significance.
 - c) CRO
 - d) IND & NDA4+4+4+4
3.
 - a) Write a note on ICH guidelines for Good Clinical Practice
 - b) What is IPR? Explain mechanism for protection of intellectual property.8 + 8
4.
 - a) Write a note on in-vitro tests for neurochemical evaluations.
 - b) Add a note on nutraceuticals.8 + 8
5.
 - a) Write a note on Pharmacoepidemiology and its applications in health care.
 - b) What is pharmacovigilance how it is useful in health care.8 + 8
6. Write notes on following:
 - a) Clinical trial monitoring and report preparation.
 - b) Pharmacoeconomics8 + 8



Roll No.

Total No. of Questions: 06

Total No. of Pages: 01

M.Pharmacy (Pharmacology) (2017 Batch) (Sem. - 2)

ADVANCED PHARMACOLOGY -II

M Code: 74943

Subject Code: MPL-201T

Paper ID: [74943]

Time: 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES:

1. This paper consists of SIX questions. Attempt any FIVE questions.
2. Each question carries FIFTEEN marks.

1. How Insulin exerts its action at molecular level? Discuss various action of Insulin with specific emphasis on carbohydrate, lipid and protein metabolism. 15
2. Write notes on followings:
 - a) Oral contraceptive pills and their mechanism of contraceptive action. 8+7
 - b) Quinolones. 15
3. Discuss in detail about anti-tuberculostic drugs and also add a note on drug therapy multidrug resistance tuberculosis. 15
4. What is Chronopharmacology? Indicate various types of biological rhythms and discuss circadian variation of cardiovascular disorders. 15
5. a) Write a note on recent advances in drug therapy of Alzheimer's disease. 8+7
b) Discuss role of free radicals in etioathology of neurodegenerative disorders. 8+7
6. Write notes on following:
 - a) Anti-cancer drugs 7+8
 - b) Biochemical mediators of inflammations



Roll No.

Total No. of Questions: 06

M-Pharm (Colony)

Principles of Drug Discovery

Total No. of Pages: 01

M. Pharma(Pharmacology) (2013 & Onwards) (Sem. - 2)

RECENT ADVANCES IN PHARMACOLOGY

M Code: 71343

Subject Code: PHCOL-136

Paper ID: [A2496]

Time: 3 Hrs.

Max. Marks: 80

INSTRUCTIONS TO CANDIDATES:

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries SIXTEEN marks.

1. a) Write a note on the role of cyclic nucleotides in cellular signaling.
b) Describe NMDA receptor ionophore complex and discuss its role in long term potentiation. (8+8)
2. a) Write a note on GABA_A receptor complex.
b) How do you define neurosteroids? Discuss therapeutic implications of neurosteroids. (8+8)
3. a) Write a note on "Phosphodiesterase inhibitors and their pharmacological applications".
b) Discuss role of neuropeptide-Y in the pathobiology of obesity. (8+8)
4. Write notes on followings:
a) PARP
b) PI3K
c) PPAR- γ
d) MDR proteins. (4+4+4+4)
5. What is apoptosis? What are components of death machinery? Discuss mitochondrial pathway of apoptotic cell death and give an account of anti-apoptotic drugs. (16)
6. a) Discuss circadian variation of cardiovascular disorders and add a note on chorotherapeutics.
b) Write a note on pharmacology of cytokines and chemokines. (8+8)



Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmacology) (2017 Batch) (Sem. - 2)

PRINCIPLES OF DRUG DISCOVERY

M Code: 74945

Subject Code: MPL-203T

Paper ID: [74945]

Time : 3 Hrs.

Max. : 75

INSTRUCTION TO CANDIDATES:

1. Attempt any FIVE questions from total SIX
2. All questions carry equal, FIFTEEN marks.

1. a) Comment on economics of drug discovery. 7.5
b) Describe the role of bioinformatics in drug discovery and development. 7.5
2. a) Explain the role of combinatorial chemistry in lead identification. 7.5
b) Describe the principle of homology modeling and give outline of its methodology. 7.5
3. a) What are the advantages of modern rational drug design over traditional approaches? 5
b) What is the concept of pharmacophore mapping? 5
c) How to screen the molecules for drug likeliness? 5
4. a) Describe docking based screening. 5
b) What is De novo drug designing? 5
c) Give the comparative analysis of SAR with QSAR. 5
5. a) What is regression analysis? Describe PLS analysis in detail along with the statistical parameters used to select the best QSAR model. 10
b) Explain the principle of CoMFA. 5
6. a) Describe the ideal properties of pro-moiety used in prodrug designing. 5
b) Explain the rationale behind prodrug designing. 5
c) Comment on practical considerations of prodrug designing. 5



Roll No.

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Total No. of Pages : 01

M.Pharmacy(Pharmacology) (2017 Batch) (Sem. - 2)
CLINICAL RESEARCH & PHARMACOVIGILANCE

M Code: 74946

Subject Code: MPL-204T

Paper ID: [74946]

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES:

1. Attempt any FIVE questions out of total SIX.
2. Each question carries FIFTEEN marks.

1. a) Define GCP. Discuss the principles of GCP. 08
b) Discuss structure and content of an informed consent process. 07
2. a) Discuss about plant layout of sterile and aseptic area. 08
b) Discuss about types and designs of clinical trials. 07
3. a) Describe about roles and responsibilities of sponsor and investigator in clinical trial. 08
b) Discuss about format and contents of clinical trial protocol. 07
4. a) Define Adverse drug reactions. Discuss about detection and reporting methods. 08
b) Discuss about industry and national programmes related to pharmacovigilance. 07
5. a) Discuss about Argus and Aris G. 08
b) Discuss about targeted clinical investigations and vaccine safety surveillance. 07
6. a) Discuss about role and application of pharmacoconomics in medication therapy. 08
b) Discuss about Pharmacoepidemiologic assessment. 07

April 2018