

Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem.-1)
DOCUMENTATION & REGULATORY WRITING

Subject Code : MRA 102T

M.Code : 79181

Date of Examination : 23-01-23

Time : 3 Hrs.

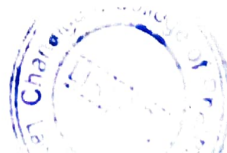
Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

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

1. Discuss in detail about Product Development Report (PDR)
2. Discuss the compilation and review of dossier in detail.
3. Discuss in detail about Print pack specifications.
4. Discuss about overview and various modules of CTD.
5. Discuss GMP compliance audit in detail.
6. Discuss in detail about FDA inspection and enforcement.

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Roll No.

Total No. of Pages : 01

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M.Pharmacy (Regulatory Affairs) (Sem.-1)
CLINICAL RESEARCH REGULATIONS

Subject Code : MRA-103T

M.Code : 79182

Date of Examination : 25-01-23

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 about different types of Clinical studies. Describe about various phases of clinical trials in detail.
2. Discuss the historical perspective of Nuremberg code, thalidomide study, Nazis trials and Tuskegee syphilis study. Discuss about Belmont Report and Declaration of Helsinki.
3. Discuss the regulations to conduct drug studies as per USFDA. Discuss about NDA 505(b) (1) and NDA 505(b)(2) applications.
4. Describe the composition, roles, responsibilities and ethical review procedure of Institutional Ethics Committee.
5. Discuss about Good Clinical Practice Guidelines (ICH GCP E6)
6. Discuss about guidelines for Good Pharmacovigilance Practices and Pharmacoepidemiological Assessment.

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Roll No.

Total No. of Pages : 02

Total No. of Questions : 06

M. Pharmacy (Pharmacology) (2017 & Onwards) (Sem.-1)
CELLULAR & MOLECULAR PHARMACOLOGY

Subject Code : MPL-104T

Time : 3 Hrs.

M. Code : 74678

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

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

1. Write notes on following (Any THREE)

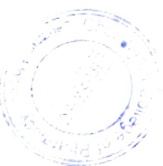
- a) Nutrigenomics 5
- b) Microarray techniques 5
- c) Second messengers 5
- d) ELISA 5

2. Describe the following :

- a) Autophagy 5
- b) Intrinsic and extrinsic pathways of apoptosis 10
3. a) What are the types of immunotherapeutics? Discuss their clinical status. 6, 5
- b) Describe briefly about genomics. 4

4. Answer the following :

- a) How cells are isolated and characterised in cell culture techniques? 6
- b) Define cryopreservation. Why it is used? 3
- c) Discuss the various types of cell culture. 6
5. a) Explain in detail JAK/STAT signalling pathway and its roles. 8
- b) Discuss about GPCR's. 7



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6. Discuss the following (Any TWO)

a) siRNA

7.5

b) Gene mapping and its applications

7.5

c) Micro RNA

7.5

d) Cell cycle and its regulation

7.5



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M.Pharmacy(Pharmacology) (2017 & Onwards) (Sem.-1)
**PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
METHODS-I**

Subject Code : MPL-103T

M.Code : 74677

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

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

- Q1. Write notes on following :
- a) Immunoassay of digoxin 5
 - b) GLP 5
 - c) Immunomodulators 5
- Q2. Explain in detail preclinical screening of :
- a) Antidepressant agents 7.5
 - b) Antipyretic agents 7.5
- Q3. Discuss briefly :
- a) Elevated plus maze 5
 - b) One animal model for evaluation of analgesic effect 5
 - c) Morris water maze 5
- Q4. a) What are hepatoprotective agents? Discuss the screening methods for hepatoprotective agents. 10
- b) Aphrodisiacs agents 5
- Q5. Write notes on following :
- a) Transgenic animals 7.5
 - b) Bioassay 7.5
- Q6. What are the limitations of animal experiments? Discuss the various alternatives to animal experiments. 15

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(S31)-452

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Roll No. _____

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Total No. of Questions : 06

M. Pharmacy (Pharmacology) (2017 & Onwards) (Sem.-1)

ADVANCED PHARMACOLOGY-I

Subject Code : MPL-102T

M.Code : 74676

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 G-protein coupled receptors. 8
- b) Add a note on cholinomimetics and their therapeutic implications. 7
2. Write notes on following :
 - a) ACE inhibitors. 5
 - b) Clopidogrel. 5
 - c) Streptokinase. 5
3. a) Write a note on drug therapy of Parkinsonism. 8
- b) Discuss pathophysiology and drug therapy of mania. 7
4. Discuss pathophysiology and drug therapy of psychosis. 15
5. Discuss critically about anti-ischemic drugs. 15
6. Write notes on following :
 - a) 2nd Generation anti-histamines 8
 - b) Opioids 7



2020

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M. Pharmacy (Pharmacology) (2017 & Onwards) (Sem.-1)

ADVANCED PHARMACOLOGY-I

Subject Code : MPL-102T

M.Code : 74676

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 G-protein coupled receptors. | 8 |
| b) Add a note on cholinomimetics and their therapeutic implications. | 7 |
| 2. Write notes on following : | |
| a) ACE inhibitors. | 5 |
| b) Clopidogrel. | 5 |
| c) Streptokinase. | 5 |
| 3. a) Write a note on drug therapy of Parkinsonism. | 8 |
| b) Discuss pathophysiology and drug therapy of mania. | 7 |
| 4. Discuss pathophysiology and drug therapy of psychosis. | 15 |
| 5. Discuss critically about anti-ischemic drugs. | 15 |
| 6. Write notes on following : | |
| a) 2 nd Generation anti-histamines | 8 |
| b) Opioids | 7 |

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105
Total No. of Pages : 01

Roll No.

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M. Pharmacy (Pharmacology) (2017 & Onwards) (Sem.-1)

ADVANCED PHARMACOLOGY-I

Subject Code : MPL-102T

M.Code : 74676

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) | Write a note on G-protein coupled receptors. | 8 |
| | b) | Add a note on cholinomimetics and their therapeutic implications. | 7 |
| 2. | | Write notes on following : | 5 |
| | a) | ACE inhibitors. | 5 |
| | b) | Clopidogrel. | 5 |
| | c) | Streptokinase. | 8 |
| 3. | a) | Write a note on drug therapy of Parkinsonism. | 7 |
| | b) | Discuss pathophysiology and drug therapy of mania. | 15 |
| 4. | | Discuss pathophysiology and drug therapy of psychosis. | 15 |
| 5. | | Discuss critically about anti-ischemic drugs. | |
| 6. | | Write notes on following : | 8 |
| | a) | 2 nd Generation anti-histamines | 7 |
| | b) | Opioids | |



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(S31) 292



6. Discuss the following (Any TWO)
- a) siRNA 7.5
 - b) Gene mapping and its applications 7.5
 - c) Micro RNA 7.5
 - d) Cell cycle and its regulation



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M.Pharmacy(Pharmacology) (2017 & Onwards) (Sem.-1)

**PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
METHODS-I**

Subject Code : MPL-103T

M.Code : 74677

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

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

- Q1. Write notes on following : 5
- a) Immunoassay of digoxin 5
- b) GLP 5
- c) Immunomodulators
- Q2. Explain in detail preclinical screening of : 7.5
- a) Antidepressant agents 7.5
- b) Antipyretic agents
- Q3. Discuss briefly : 5
- a) Elevated plus maze 5
- b) One animal model for evaluation of analgesic effect 5
- c) Morris water maze
- Q4. a) What are hepatoprotective agents? Discuss the screening methods for hepatoprotective agents. 10
- b) Aphrodisiacs agents 5
- Q5. Write notes on following : 7.5
- a) Transgenic animals 7.5
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