Total No. of Pages: 01

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# M.Pharmacy (Regulatory Affairs) (Sem.-1) GOOD REGULATORY PRACTICES

Subject Code: MRA 101T

M.Code: 79180

Date of Examination: 21-01-23

Time: 3 Hrs.

Max. Marks: 75

#### INSTRUCTIONS TO CANDIDATES:

- 1. Attempt any FIVE questions out of SIX.
- 2. Each question carries FIFTEEN marks.
- 1. a) Write a note on EC principles of GMP.
  - b) Write a note on US cGMP guidelines.
- 2. a) Give principles and requirements of GALP.
  - b) Explain software evaluation checklist in detail.
- 3. Discuss the USFDA GLP regulations.
- 4. What do you understand by GDP? Give principle and discuss the legal GDP requirements in detail.
- 5. a) Comment on concept of quality. Explain total quality management in quality management system.
  - b) Describe out of specifications concept of quality management system.
- 6. a) Give in detail ICH guidelines with respect to quality safety and efficacy of drug substances and products.
  - b) Give types of validation with special emphasis on cleaning validation.

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Total No. of Questions: 06

Total No. of Pages: 01

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 :

- 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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Total No. of Pages: 01

Total No. of Questions: 06

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.
- 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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Total No. of Pages: 01

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M.Pharmacy (Regulatory Affairs) (Sem.-1)

## REGULATIONS & LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICE, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA & INTELLECTUAL PROPERTY RIGHTS

Subject Code: MRA104T

M.Code: 79183

Date of Examination: 27-01-23

Time: 3 Hrs.

Max. Marks: 75

# INSTRUCTIONS TO CANDIDATES:

- 1.Attempt any FIVE questions out of SIX questions.
- 2.Each question carries FIFTEEN marks.
  - a) How the prices of biological and herbals are fixed or revised by Government under DPCO? 1.
    - b) Discuss all the provisions which NPPA notifies for medical devices as drugs under DPCO2013 for quality control & price monitoring.
  - a) Discuss the powers of Central Government to permit/control and regulate the sale of Narcotic and Psychotropic substances. 2.
    - b) Write the Education regulation prescribed in Pharmacy Act.
  - Discuss the requirements/steps for obtaining spirit from non-bonded laboratories.
  - Discuss the role of CDSCO in the regulatory requirements and approvals of food and 3. 4. neutraceuticals.
  - Discuss the contents of regulatory dossier filing.
  - a) What are BA and BE studies? Discuss the regulatory requirements of bioequivalence studies. 5. 6.
    - b) Discuss the ICMR guidelines for stem cell research.

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Total No. of Questions: 06 Roll No. Total No. of Pages: 02

M.Pharmacy (Pharmacology) (2017 & Onwards) CELLULAR & MOLECULAR PHARMACOLOGY Subject Code: MPL-104T (Sem.-1)

3 Hrs. M.Code: 74678

Max. Marks:

Time :

# INSTRUCTIONS TO CANDIDATES:

- Attempt any FIVE questions out of SIX questions.
- Each question carries FIFTEEN marks.
- Write notes on following (Any THREE)
- Nutrigenomics
- <u>b</u>) Microarray techniques

S

S S

**a**) ELISA Second messengers

0

- Describe the following:
- 2 Autophagy
- <u>b</u> Intrinsic and extrinsic pathways of apoptosis
- Ċ. What are the types of immunotherapeutics? Discuss their clinical status.

6,5

10

4. Answer the following:

9

Describe briefly about genomics

a

How cells are isolated and characterised in cell culture techniques?

6

- <u>b</u> Define cryopreservation. Why it is used?
- a Explain in detail JAK/STAT signalling pathway and its roles

 $\infty$ 

**C** 

Discuss the various types of cell culture

- S
- <u>b</u>) Discuss about GPCR's



# 6. Discuss the following (Any TWO)

1)	SIRNA	7.5
)	Gene mapping and its applications	7.5
c)	Micro RNA	7.5
d)	Cell cycle and its regulation	7.5



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Total No. of Questions: 06

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

5

5

7.5

7.5

5

5

5

5

7.5

7.5

# INSTRUCTIONS TO CANDIDATES :

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

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Total No. of Pages: 01

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) 2 <sup>nd</sup> Generation anti-histamines	8
	b) Opioids	7
	2 of 6	

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Total No. of Pages: 01

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) 2 <sup>nd</sup> Generation anti-histamines	8
b) Opioids	7

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Roll No.

Total No. of Questions: 06 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 :

- Attempt any FIVE questions out of SIX questions.
- Each question carries FIFTEEN marks.
- a) Write a note on G-protein coupled receptors. 7 b) Add a note on cholinomimetics and their therapeutic implications. 1.
- 5 Write notes on following:
  - 5 a) ACE inhibitors. 5
  - b) Clopidogrel. 8
  - c) Streptokinase.
- a) Write a note on drug therapy of Parkinsonism. 7 b) Discuss pathophysiology and drug therapy of mania. 3.
  - 15 Discuss pathophysiology and drug therapy of psychosis.
  - 15
- 4. Discuss critically about anti-ischemic drugs. 5.
- Write notes on following: 6. a) 2<sup>nd</sup> Generation anti-histamines
  - b) Opioids

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Total No. of Questions: 06

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

Subject Code: MPL-104T

M.Code: 74678

Time: 3 Hrs.

Max. Marks: 75

#### INSTRUCTIONS TO CANDIDATES:

- Attempt any FIVE questions out of SIX questions.
- Each question carries FIFTEEN marks. 2.
- Write notes on following (Any THREE) 1.

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

#### Answer the following: 4.

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

7

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(531)-600

6. Discuss the following (Any TWO) siRNA 7.5

**d**) Cell cycle and its regulation

c

Micro RNA

<u>b</u>

Gene mapping and its applications

7.5

7.5

7.5

a)

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Total No. of Pages: 01 Total No. of Questions: 06

#### 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.
- 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 <sup>nd</sup> Generation anti-histamines	8
	b) Opioids	7

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Total No. of Pages: 01

Total No. of Questions: 06

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

Subject Code: MPL-103T

M.Code: 74677

Max. Marks: 75 Time: 3 Hrs.

# INSTRUCTIONS TO CANDIDATES:

- Attempt any FIVE questions out of SIX questions.
- 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	otective
04	c) Morris water maze a) What are hepatoprotective agents? Discuss the screening methods for hepatopro	10
Q4.	agents.	5
	b) Aphrodisiacs agents	
	Try to an following:	75

- Q5. Write notes on following: 7.5
  - a) Transgenic animals 7.5
- Q6. What are the limitations of animal experiments? Discuss the various alternatives to animal

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