Total No. of Questions: 3 *Total No. of Printed Pages:2*

Enrollment No.....

Faculty of Pharmacy
End Sem Examination May-2024
PY3EL02 Pharmaceutical Regulatory Science

Programme: B. Pharm. Branch/Specialisation: Pharmacy

Duration: 3 Hrs. **Maximum Marks: 75**

Note: All questions are compulsory. Internal choices, if any, are indicated. Assume suitable data if necessary. Notations and symbols have their usual meaning.

Q.1	i.	Enlist the stages of drug discovery.	**2**
	ii.	Define pre-clinical trials.	**2**
	iii.	Define NDA.	**2**
	iv.	Name the regulatory authority for pharmaceuticals of Australia.	**2**
	v.	Give the full form of CDSCO.	**2**
	vi.	Give the title for rule no 94 for export of drugs from India.	**2**
	vii.	What is the purpose of inform consent process?	**2**
	viii.	Define clinical trial protocol.	**2**
	ix.	Define federal register.	**2**
	x.	What is the use of orange book.	**2**
Q.2		Attempt any two:	
	i.	Define drug discovery and explain in detail about the drug discovery process.	**10**
	ii.	(a) Write a note on IND. (b) Explain in short about the USFDA.	**10**
	iii.	(a) Explain briefly about the concept of innovator & generic drugs. (b) Write about NDA.	**5** **5**
Q.3		Attempt any seven: Two questions from each section is compulsory.	
		Section - A	
	i.	Explain eCTD with its module.	**5**
	ii.	What is drug master formula record.	**5**
	iii.	Discuss ASEAN common technical document.	**5**

P.T.O.

Section - B

iv.	Explain the process to develop a clinical trial protocol.	**5**
v.	Give the constitution and working of IRB.	**5**
vi.	Explain how pharmacovigilance helps in monitoring clinical trial protocols.	**5**

Section - C

vii.	Write a note on code for federal regulations.	**5**
viii.	Write an exhaustive note on the concept of orange book.	**5**
ix.	Discuss importance of purple book.	**5**

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Marking Scheme

Pharmaceutical Regulatory Science (T) - PY3EL02 (T)

Q.1	i)	4 Stages	(0.5 Mark*4)	**2**
	ii)	Definition	2 Marks	**2**
	iii)	Definition	2 Marks	**2**
	iv)	for Short form for the full form (TGA)	1 Mark 1 Mark	**2**
	v)	Full form	2 Marks	**2**
	vi)	Name of the rule	2 Marks	**2**
	vii)	Purpose	2 Marks	**2**
	viii)	Definition	2 Marks	**2**
	ix)	Definition	2 Marks	**2**
	x)	Definition	2 Marks	**2**

Q.2 Attempt any two:

i.	Drug Discovery definition	1 Mark	**10**
	Drug Development definition	1 Mark	
	4 Stages of Drug Development	(2 Mark *4)	
ii.	a) An exhaustive note on IND	5 Marks	**10**
	b) About the USFDA	5 Marks	
iii.	Innovator & Generics	(2.5 Mark*2)	**5**
	Note	5 Marks	**5**

Q.3 Attempt any seven: Two questions from each section is compulsory.

Section – A

i.	Definition	1 Mark	**5**
	Comopnents	4 Marks	
ii.	Definition	1 Mark	**5**
	Comopnents	4 Marks	
iii.	Full Form ……..1 Mark Comopnents……...4 Mark		**5**

Section – B

iv.	Definition of Clinical Trial	1 Mark	**5**
	Phases	4 Marks	
v.	Full Form	1 Mark	**5**
	Comopnents	4 Marks	
vi.	Short note	5 Mark	**5**

Section - C

vii.	Short note	5 Marks	**5**
viii.	Short note	5 Marks	**5**
ix.	Short note	5 Marks	**5**

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