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

Enrollment No.....

Faculty of Pharmacy
End Sem Examination Dec-2023
PY3CO30 Industrial Pharmacy -II

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.	Define pilot plant with its uses.	**2**
	ii.	Write the full form of SUPAC with its significance.	**2**
	iii.	Give the full form of APCTD and TIFAC.	**2**
	iv.	What is the full form of TBSE? Also explain its features.	**2**
	v.	Name the pharmaceutical regulatory authority of Australia and USA.	**2**
	vi.	Write the full form of IB and define it.	**2**
	vii.	Differentiate between ISO 9000 and ISO 14000.	**2**
	viii.	Explain the concept of QbD.	**2**
	ix.	Enlist any four functions of Central Drug Testing Laboratory.	**2**
	x.	Write the full form and significance of DCGI.	**2**
Q.2		Attempt any two:	
	i.	Discuss the significance and procedure of pilot plant scale up considerations for solid dosage form.	**10**
	ii.	Define technology transfer and describe the features of WHO guidelines for technology transfer.	**10**
	iii.	(a) Write a detailed note on SUPAC guidelines.	**5**
		(b) Explain the principle and process of quality risk management.	**5**
Q.3		Attempt any seven: Two questions from each section is compulsory.	
		Section - A	
	i.	Discuss the roles and responsibilities of regulatory affairs department.	**5**

P.T.O.

	ii.	Explain the aim and review process of New Drug Application (NDA).	**5**
	iii.	Describe the protocol of clinical research.	**5**
		Section – B	
	iv.	Explain in brief the concept of total quality management (TQM).	**5**
	v.	Discuss good laboratory practices.	**5**
	vi.	Write a note on Six Sigma concept.	**5**
		Section – C	
	vii.	Explain the requirements for import and approval procedure of new drugs in India.	**5**
	viii.	Describe the documentation procedure of COPP.	**5**
	ix.	Discuss the organizational structure and responsibilities of central licensing authority of India.	**5**

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Marking Scheme
PY3CO30 - Industrial Pharmacy -II

Q.1	i)	- Definition of pilot plant	1 Mark	**2**
		- Any two uses	1 Mark	
	ii)	- Full form of SUPAC	1 Mark	**2**
		- Significance	1 Mark	
	iii)	- Full form of APCTD	1 Mark	**2**
		- Full form of TIFAC	1 Mark	
	iv)	- Full form of TBSE	1 Mark	**2**
		- Features	1 Mark	
	v)	- Regulatory authority of Australia	1 Mark	**2**
		- Regulatory authority of USA	1 Mark	
	vi)	- Full form of IB	1 Mark	**2**
		- Definition	1 Mark	
	vii)	Give title of ISO9000	1 Mark	**2**
		ISO14000	1 Mark	
	viii)	- Concept of six sigma QbD	2 Marks	**2**
	ix)	- Any two functions	2 Marks	**2**
	x)	- Full form of DCGI	1 Mark	**2**
		- Significance	1 Mark	

Q.2 Attempt any two:

i.	- Definition of pilot plant	1 Mark	**10**
	- Significance	2 Marks	
	- Procedure of Pilot plant scale up	7 Marks	
ii.	- Definition of Technology Transfer	1 Mark	**10**
	- Goals	2 Marks	
	- Features of WH O guidelines for technology transfer form	7 Marks	
iii.	a. - Definition	1 Mark	**5**
	- Explanation about SUPAC guidelines	4 Marks	
	b. - Principle	2 Marks	**5**
	- Process of QRM	3 Marks	

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

Section – A

i.	- Roles	2 Marks	**5**
	- Responsibility of RA department	3 Marks	
ii.	- Aim	2 Marks	**5**

P.T.O.

	- Review Process of NDA	3 Marks	
iii.	- Definition/ Significance	1 Mark	**5**
	- Clinical research protocol	4 Marks	

Section – B

iv.	- Define	1 Mark	**5**
	- Concept of TQM	4 Marks	
v.	- Definition of GLP	1 Mark	**5**
	- Description	4 Marks	
vi.	- Concept	4 Marks	**5**
	- Significance	1 Mark	

Section – C

vii.	- Requirements for import	2 Marks	**5**
	- Approval procedure for new drug	3 Marks	
viii.	- Full form and define	1 Mark	**5**
	- Procedure	4 Marks	
ix.	- Name of authority	1 Mark	**5**
	- Organizational structure	2 Marks	
	- Responsibilities	2 Marks	

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