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

Enrollment No.....

Faculty of Pharmacy

End Sem (Odd) Examination Dec-2022

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.

Q.1	i.	Define pilot plant. What are the space requirements in pilot plant scale up?	**2**
	ii.	What is the full form of SUPAC? Explain its significance.	**2**
	iii.	Define technology transfer. What do you understand from CCP?	**2**
	iv.	Define drug master file. What is its significance?	**2**
	v.	Define regulatory affairs. Name different regulatory authorities in world.	**2**
	vi.	Define acute toxicity and chronic toxicity.	**2**
	vii.	Define QMS. Give its significance.	**2**
	viii.	Define quality guideline. ICH Q9 provide the guidance for _____.	**2**
	ix.	What is the full form of DCGI? Give examples of central drug testing laboratories?	**2**
	x.	What are the requirements for import and registration?	**2**
Q.2		Attempt any two:	
	i.	Explain the procedure for pilot plant scale up technique for solid dosage form?	**10**
	ii.	Define quality risk management? Describe the principle & process along with flow diagram?	**10**
	iii.	(a) Explain SUPAC guidelines?	**5**
		(b) Write a note on analytical method transfer? What are the basic responsibilities of sender unit & receiving unit?	**5**

P.T.O.

Q.3		Attempt any seven: Two questions from each section is compulsory.	
		Section - A	
	i.	What are the elements of clinical trial? Describe systematically the protocol of a clinical trial.	**5**
	ii.	Write a note on investigator brochure.	**5**
	iii.	Explain the concept of Investigational New Drug Application (INDA).	**5**
		Section - B	
	iv.	Write a short note on ICH guidelines.	**5**
	v.	Define OOS? Explain with flow chart and example.	**5**
	vi.	What do you understand with NABL and GLP? Describe in brief.	**5**
		Section - C	
	vii.	What do you understand from COPP? Explain in brief.	**5**
	viii.	Define CDSCO. Explain in brief the functions, roles and responsibilities of CDSCO.	**5**
	ix.	Write a note on central drug testing laboratories in India.	**5**

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Marking Scheme
PY3CO30 Industrial Pharmacy -II

Q.1	i)	Definition 1 mark. + 1 mark any two space requirement	**2**
	ii)	1 mark full form+ 1 mark significance	**2**
	iii)	Definition 1 mark. + 1 mark CCP	**2**
	iv)	Definition 1 mark. + 1 mark significance	**2**
	v)	Definition 1 mark. + 1 mark names of any two authorities	**2**
	vi)	Definition 1 mark. + 1 mark definition	**2**
	vii)	Definition 1 mark. + 1 mark significance	**2**
	viii)	Definition 1 mark. + 1 mark fill in the blanks	**2**
	ix)	Full form 1 mark. + 1 mark any one example	**2**
	x)	Import requirement 1 mark. + 1 mark registration requirement	**2**
Q.2			
	i.	2 marks for Definition, 3 marks for general considerations + 2.5 marks for manufacturing procedure for tablet 2.5 mark for manufacturing process of capsules.	**10**
	ii.	Definition - 1 mark Principle – 2 marks Process – 4 marks Flow diagram - 5 marks	**10**
	iii.	a) 1.5 marks Definition, components + 3.5 marks levels of changes	**5**
		b) 2.5 marks note + 2.5 marks 3 responsibilities each of sender unit & receiving unit	**5**
Q.3		Section - A	
	i.	2.5 marks for definition, phases of clinical trials + 2.5 marks protocol	**5**
	ii.	1 mark definition + 4 marks note	**5**
	iii.	1 mark definition + 4 marks complete concept of INDA	**5**
		Section - B	
	iv.	1 mark definition + 4 marks different types, short note	**5**
	v.	1 mark definition + 4 marks flow chart, responsibilities, 1 example	**5**
	vi.	Definition of NABL 1 mark Definition of GLP 1 mark Description of NABL 1.5 marks Description of GLP – 1.5 marks	**5**
	vii.	Definition 1 mark + 4 marks short note	**5**
	viii.	Definition 1 mark + 4 marks function, role, responsibilities	**5**
	ix.	2 marks for names of central drug testing labs in India + 3 marks for descripiton	**5**

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