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

Enrollment No.....

Faculty of Pharmacy
End Sem Examination Dec 2024
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.

			Marks	BL	PO	CO	PSO
Q.1	i.	What is SUPAC?	**2**	2	1, 3, 7, 8	1	
	ii.	Define pilot & scale up plant.	**2**	2	1, 3, 7, 8	1	
	iii.	Define DMF.	**2**	3	1, 7, 8	3	
	iv.	Enlist components of TTR.	**2**	2	1, 3, 7, 8	2	
	v.	What is clinical trial?	**2**	3	1, 7, 8	3	
	vi.	What is CTD?	**2**	3	1, 7, 8	3	
	vii.	What is GLP?	**2**	3	1, 7, 8	4	
	viii.	Enlist the series of ISO 9000.	**2**	3	1, 7, 8	4	
	ix.	Enlist different central drug testing laboratories.	**2**	4	1, 7, 8	5	
	x.	Enlist functions of DCGI.	**2**	4	1, 7, 8	5	
Q.2		Attempt any two:					
	i.	Discuss the general factors to be considered in pilot plant scale up technology for solid dosage forms.	**10**	2	1, 3, 7, 8	1	
	ii.	Discuss about documentation, premises, equipments and technology transfer sample protocol for TT as per WHO guidelines.	**10**	2	1, 3, 7, 8	2	
	iii.	(a) Discuss the platform technology.	**5**	2	1, 3, 7, 8	2	
		(b) Discuss granularity of TT process (API, excipients, finished products, packaging materials) as per WHO guidelines.	**5**	2	1, 3, 7, 8	2	

			Marks	BL	PO	CO	PSO
Q.3		Attempt any seven: Two questions from each section is compulsory.					
		Section - A					
	i.	Discuss different regulatory authorities and role of regulatory affairs department.	**5**	3	1, 7, 8	3	
	ii.	Write note on clinical research protocol.	**5**	3	1, 7, 8	3	
	iii.	Differentiate between NDA and ANDA.	**5**	3	1, 7, 8	3	
		Section - B					
	iv.	Explain in brief concept of quality by design (Qbd).	**5**	4	1, 7, 8	5	
	v.	Write note on total quality management (TQM).	**5**	4	1, 7, 8	5	
	vi.	Write a note on change control & out of specification (OOS).	**5**	4	1, 7, 8	5	
		Section - C					
	vii.	Write a note on CDSCO.	**5**	4	1, 7, 8	5	
	viii.	Discuss general requirements for submission of application of new COPP.	**5**	4	1, 7, 8	5	
	ix.	Write note on state licensing authority.	**5**	4	1, 7, 8	5	

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			Marks	BL	PO	CO	PSO
Q.1	i.	What is SUPAC?	**2**	2	1, 3, 7, 8	1	
	ii.	Define pilot & scale up plant.	**2**	2	1, 3, 7, 8	1	
	iii.	Define DMF.	**2**	3	1, 7, 8	3	
	iv.	Enlist components of TTR.	**2**	2	1, 3, 7, 8	2	
	v.	What is clinical trial?	**2**	3	1, 7, 8	3	
	vi.	What is CTD?	**2**	3	1, 7, 8	3	
	vii.	What is GLP?	**2**	3	1, 7, 8	4	
	viii.	Enlist the series of ISO 9000.	**2**	3	1, 7, 8	4	
	ix.	Enlist different central drug testing laboratories.	**2**	4	1, 7, 8	5	
	x.	Enlist functions of DCGI.	**2**	4	1, 7, 8	5	
Q.2		Attempt any two:					
	i.	Discuss the general factors to be considered in pilot plant scale up technology for solid dosage forms.	**10**	2	1, 3, 7, 8	1	
	ii.	Discuss about documentation, premises, equipments and technology transfer sample protocol for TT as per WHO guidelines.	**10**	2	1, 3, 7, 8	2	
	iii.	(c) Discuss the platform technology.	**5**	2	1, 3, 7, 8	2	
		(d) Discuss granularity of TT process (API, excipients, finished products, packaging materials) as per WHO guidelines.	**5**	2	1, 3, 7, 8	2	

Q.3		Attempt any seven: Two questions from each section is compulsory.					
		Section - A					
	i.	Discuss different regulatory authorities and role of regulatory affairs department.	**5**	3	1, 7, 8	3	
	ii.	Write note on clinical research protocol.	**5**	3	1, 7, 8	3	
	iii.	Differentiate between NDA and ANDA.	**5**	3	1, 7, 8	3	
		Section - B					
	iv.	Explain in brief concept of quality by design (Qbd).	**5**	4	1, 7, 8	5	
	v.	Write note on total quality management (TQM).	**5**	4	1, 7, 8	5	
	vi.	Write a note on change control & out of specification (OOS).	**5**	4	1, 7, 8	5	
		Section - C					
	vii.	Write a note on CDSCO.	**5**	4	1, 7, 8	5	
	viii.	Discuss general requirements for submission of application of new COPP.	**5**	4	1, 7, 8	5	
	ix.	Write note on state licensing authority.	**5**	4	1, 7, 8	5	

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Marking Scheme

PY3CO30 (T) Industrial Pharmacy -II (T)

Q.1	i)	Scale-up and Post Approval Changes, refers to guidelines that govern changes made during the post-approval phase of drug manufacturing.	-2 marks	**2**
	ii)	Scale-up/ Pilot -Definition	-2 mark	**2**
	iii)	Definition Component	-1 marks -2 marks	**2**
	iv)	Components- Procedures, acceptance criteria, result, conclusion, deviations if any tech transfer report	-2 marks	**2**
	v)	Clinical trial, phases and explanation	-2 marks	**2**
	vi)	Common technical document, use	-2 marks	**2**
	vii)	Good laboratory practices, importance	-2 marks	**2**
	viii)	Series of ISO 9000	**-** Each 0.5 marks	**2**
	ix)	central drug testing laboratories , locations headquarters **-** Each 0.5 marks		**2**
	x)	Drug controller general of India (DCGI)	**-** Each 1 mark	**2**

Q.2	Attempt any two:			
	i.	Material handling, blending, granulation, drying dry compaction, direct compression, slugging	**-** Each 2M	**10**
	ii.	documentation, premises, equipment's and technology transfer sample protocol	**-** Each 2M	**10**
	iii.	(a)Any 5- Nanotechnology, Microsphere technology, Liposomal technology, hot melt extrusion, sustained release formulation technology, orally disintegrating formulation technology, inhalation technology, sprinklers	**-**Each 1M	**5**
		(b) Introduction, API, excipients, finished products, packaging materials	**-** Each 2M	**5**

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

Section – A

i.	different regulatory authorities role of regulatory affairs department	-2.5 marks -2.5 marks	**5**
ii.	Clinical research protocol		**5**
iii.	New drug application Abbreviated new drug application	-2.5 marks -2.5 marks	**5**

Section – B

iv.	Qbd definition , Qbd system Elements of Qbd	-2.5 marks -2.5 marks	**5**
v.	Total quality management definition, principle Elements of TQM	-2.5 marks -2.5 marks	**5**
vi.	change control & out of specification (OOS)	-2.5 marks -2.5 marks	**5**

Section - C

vii.	Central Drugs standard and control organization (CDSCO) Organizational details/chart Functions of CDSCO	-2.5 marks -2.5 marks	**5**
viii.	general requirements Process	-2.5 marks -2.5 marks	**5**
ix.	state licensing authority introduction responsibilities/functions	-2.5 marks -2.5 marks	**5**

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