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

Enrollment No.....

Faculty of Pharmacy
End Sem Examination May-2024
PY3EL11 Good Manufacturing Practices

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.	What do you mean by GMP?	**2**
	ii.	Write about the parts of schedule M.	**2**
	iii.	Describe investigational new drug (IND) application	**2**
	iv.	Define NDA and ANDA.	**2**
	v.	Write the importance of 21 CFR.	**2**
	vi.	Give the significance of pharmaceutical cGMP.	**2**
	vii.	Write four reasons for pharmaceutical product recall.	**2**
	viii.	Define product reprocessing.	**2**
	ix.	Write about operating characteristics curves for sampling.	**2**
	x.	What do you mean by sampling plan and sampling tools?	**2**
Q.2		Attempt any two:	
	i.	Discuss good manufacturing practices and good laboratory practices.	**10**
	ii.	Discuss the documentation process for investigational new drug (IND) and new drug application (NDA)	**10**
	iii.	(a) Explain Standard operating procedures (SOP)	**5**
		(b) Discuss the documentation & protocols for the maintenance of record in pharmaceutical industries.	**5**
Q.3		Attempt any seven: Two questions from each section is compulsory.	
		Section - A	
	i.	Differentiate GMP and c-GMP.	**5**

	ii.	Discuss cGMP guidelines according to United States Food and Drug Administration (USFDA).	**5**
	iii.	Explain the parts of code of federal regulation.	**5**
		Section - B	
	iv.	Classify pharmaceutical product recall and give strategy for effective recall.	**5**
	v.	Discuss about the FDA requested recall and firm-initiated recall procedures.	**5**
	vi.	Discuss about finished product reprocessing and salvaging.	**5**
		Section - C	
	vii.	Write the WHO guidelines for sampling plans and techniques.	**5**
	viii.	Discuss the maintenance of sampling records of finished product.	**5**
	ix.	Write about the maintenance of sampling records of packaging material.	**5**

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Marking Scheme
Good Manufacturing Practices (T) - PY3EL11 (T)

Q.1	i)	Explanation	2 Marks	**2**
	ii)	Name of Part MQ	1 Mark	**2**
		Importance	1 Mark	
	iii)	Explanation of investigational new drug (IND) – 2 Marks		**2**
	iv)	Define NDA	1 Mark	**2**
		Define ANDA	1 Mark	
	v)	One importance of 21 CFR	(1 Mark*2)	**2**
	vi)	One significance of pharmaceutical cGMP	(1 Mark*2)	**2**
	vii)	One reasons for pharmaceutical product recall	(0.5 Mark*4)	**2**
	viii)	Definition	2 Mark	**2**
	ix)	Operating characteristics curves for sampling	2 Mark	**2**
	x)	Sampling Requirements	1 Mark	**2**
		Tools	1 Mark	
Q.2	Attempt any two:			
	i.	Good Manufacturing Practices	5 Marks	**10**
		Good Laboratory Practices	5 Marks	
	ii.	Investigational new drug (IND)	5 Marks	**10**
		New drug application (NDA)	5 Marks	
	iii.	(a) Explanation	5 Marks	**5**
		(b) Documentation	2.5 Marks	**5**
		(b) Protocols	2.5 Marks	
Q.3	Attempt any seven: Two questions from each section is compulsory.			
	i.	One Difference	(1 Mark*5)	**5**
	ii.	Importance	3 Marks	**5**
		Explanation	2 Marks	
	iii.	Importance	2 Mark	**5**
		Explanation	3 Marks	
	iv.	Classification	2.5 Marks	**5**
		Strategy	2.5 Marks	
	v.	FDA requested recall	2.5 Marks	**5**
		firm-initiated recall procedures	2.5 Marks	
	vi.	finished product reprocessing	3 Marks	**5**
		Salvaging	2 Marks	
		Section – C		
	vii.	WHO guidelines for sampling plans	2.5 Marks	**5**
		WHO guidelines for sampling techniques	2.5 Marks	
	viii.	Maintenace	2 Marks	**5**
		Discussion	3 Marks	
	ix.	Maintenace	2 Marks	**5**
		Discussion	3 Marks	

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