Total No. of Questions: 6 *Total No. of Printed Pages:2*

Enrollment No.....

Faculty of Pharmacy

End Sem (Even) Examination May-2022

PY3CO28 Pharmaceutical Quality Assurance

Programme: B. Pharma Branch/Specialisation: Pharmacy

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

Note: All questions are compulsory. Internal choices, if any, are indicated.

Q.1 i. Total Quality management system focuses on: **2**
(a) Employees (b) Customers
(c) Both (a) and (b) (d) None of these

ii. The guidelines that explain about stability testing of drug substances and drug products are: **2**
(a) ICH Q2 (b) ICH Q1 (c) ICH Q8 (d) ICH Q9

iii. Clean rooms are classified according to the: **2**
(a) Quality of air
(b) Material Selection
(c) The number and size of particles permitted per volume of air
(d) All of these

iv. The term HEPA filter refers to- **2**
(a) High Efficiency Permeation filter
(b) High Efficiency Particulate filter
(c) High Efficiency Portion filter
(d) High Efficiency Pollution filter

v. The packaging that comes in direct contact with the formulation is termed as: **2**
(a) Primary Package (b) Secondary Package
(c) Tertiary Package (d) None of these

vi. Water attack test is done for which type of packaging material: **2**
(a) Plastic (b) Glass (c) Aluminium (d) Metals

vii. In which type of complaint product recall is immediately required. **2**
(a) Critical Complaint (b) Major complaint
(c) Minor Complaint (d) None of these

viii. The first step involved in handling of complaints is: **2**
(a) Receiving of complaints (b) Investigation of complaints
(c) Finding corrections (d) None of these

P.T.O.

ix. For performing validation number of batches required are: **2**
(a) 1 (b) 2 (c) 3 (d) 4

x. Regulations regarding the process validation are available in: **2**
(a) IP (b) USP (c) BP (d) FDA

Q.2 Attempt any two:

i. (a) Explain the term ICH guidelines along with its significance in pharmaceutical industry. **10**
(b) Describe the guidelines of ICH, associated with the stability of pharmaceutical formulations.

ii. What importance does a Design, construction and plant layout have in pharmaceutical industry setup? **10**

iii. (a) What is TQM? Write in detail about the elements and philosophies of TQM. **5**
(b) Write about maintenance of stores in industry in relation with raw materials raw materials. **5**

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

Section – A

i. Give details of quality control tests for containers and closures. **5**

ii. Discuss types of packaging materials in details in reference to glass and plastics. **5**

iii. Explain good laboratory practices in context to organization and personnel. **5**

Section - B

iv. Enlist the differences between the batch formula record and master formula record. **5**

v. Explain the terms handling and evaluation of complaints. **5**

vi. What is meant by SOP and what is its importance in pharmaceutical industry. **5**

Section - C

vii. Define validation. Describe different types of validation. **5**

viii. Write a note on good warehousing practice and material management. **5**

ix. Define calibration. Explain the principles of calibration. **5**

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Marking Scheme
PY3CO28 Pharmaceutical Quality Assurance

Q.1	i.	Total Quality management system focuses on: (c) Both (a) and (b)		**2**
	ii.	The guidelines that explain about stability testing of drug substances and drug products are: (b) ICH Q1		**2**
	iii.	Clean rooms are classified according to the: (c) The number and size of particles permitted per volume of air		**2**
	iv.	The term HEPA filter refers to- (b) High Efficiency Particulate filter		**2**
	v.	The packaging that comes in direct contact with the formulation is termed as: (a) Primary Package		**2**
	vi.	Water attack test is done for which type of packaging material: (b) Glass		**2**
	vii.	In which type of complaint product recall is immediately required. (a) Critical Complaint		**2**
	viii.	The first step involved in handling of complaints is: (a) Receiving of complaints		**2**
	ix.	For performing validation number of batches required are: (c) 3		**2**
	x.	Regulations regarding the process validation are available in: (d) FDA		**2**

Q.2		Attempt any two:		
	i.	(a) ICH guidelines along with its significance	3 marks	**10**
		(b) Guidelines of ICH, associated with the stability of pharmaceutical formulations.	7 marks	
	ii.	Design and construction	5 marks	**10**
		Plant layout	5 marks	
	iii.	(a) TQM	1 mark	**5**
		Elements	2 marks	
		Philosophies of TQM	2 marks	
		(b) Write about maintenance of stores in industry in relation with raw materials. As per explanation		**5**

Q.3		Attempt any seven: Two questions from each section is compulsory.		
		Section – A		
	i.	Any 5 quality control tests	(1 mark * 5)	**5**
	ii.	Types of packaging materials	1 mark	**5**
		Glass	2 marks	
		Plastic	2 marks	
	iii.	Good laboratory practices	1 mark	**5**
		Organization	2 marks	
		Personnel	2 marks	
		Section - B		
	iv.	Any 5 differences	(1 mark * 5)	**5**
	v.	Handling	2 marks	**5**
		Evaluation of complaints	3 marks	
	vi.	SOP	1 mark	**5**
		Its importance in pharmaceutical industry	4 marks	
		Section – C		
	vii.	Validation	1 mark	**5**
		Types of validation	4 marks	
	viii.	Good warehousing practice	2 marks	**5**
		Material management	3 marks	
	ix.	Calibration	1 mark	**5**
		Principles of calibration	4 marks	

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