

Total No. of Questions: 3

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Enrollment No.....



Faculty of Pharmacy
End Sem Examination May-2024

PY3CO28 Pharmaceutical Quality Assurance

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
- Name any four elements of QBD. 2
 - Give the full form and scope of ICH. 2
 - What is vendor selection? Give its importance. 2
 - Write any four plant layout consideration as per GMP. 2
 - Define GLP and its objectives. 2
 - Give any one quality control test procedure of plastic containers. 2
 - Define critical complaint with examples. 2
 - Define quality audit and its types. 2
 - Give two differences between calibration and validation. 2
 - Write any four principles of material management. 2

- Q.2 Attempt any two:
- Discuss the concept of quality assurance and total quality management. 10
 - Discuss in detail about equipment and raw material considerations in pharmaceuticals as per GMP. 10
 - Write a short note on ISO 9000 and 14000. 5
 - Illustrate the concept of sanitation and control of contamination in sterile areas. 5

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

Section - A

- Discuss glass as packaging material and its quality control tests. 5

- Give types of packaging materials and container closures system for pharmaceutical products. 5
- Describe the role of GLP in drug development. 5

Section - B

- Write the short note on recalling and waste disposal. 5
- What are good documentation practices? Give do's and don'ts of GDP. 5
- Give the content and importance of BMR, MFR and SOP. 5

Section - C

- Define validation and discuss its types. 5
- Write the process of calibration of pH meter. 5
- Discuss the practices of good warehousing practices. 5

Marksing Scheme

Pharmaceutical Quality Assurance (T) - PY3CO28 (T)

Q.1	i)	Name four elements of QBD.		2
		Names of 4 elements of QBD -	0.5 each	
	ii)	Full form of ICH -	1 Marks	2
		scope of ICH -	1 Marks	
	iii)	What is vendor selection -	1 Marks	2
		Importance of vendor selection -	1 Marks	
	iv)	Write four plant layout considerations as per GMP.		2
		four plant layout considerations -	0.5 each	
	v)	Definition of GLP -	1 Marks	2
		Objectives -	1 Marks	
	vi)	Give any one Quality Control test procedure of plastic containers -		2
			2 Marks	
	vii)	Definition of critical complaint –	1 Marks	2
		Example –	1 Marks	
	viii)	Definition of Quality Audit –	1 Marks	2
		Types –	1 Marks	
	ix)	Give two differences between Calibration and Validation.		2
		Differences –	1 Marks each	
	x)	Write four principles of material management.		2
		Principles-	0.5 Marks each	
Q.2	Attempt any two:			
	i.	Concept of Quality Assurance –	5 Marks	10
		Total Quality Management –	5 Marks	
	ii.	Detail about Equipment –	5 Marks	10
		Raw materials –	5 Marks	
	iii.	a) a short note on ISO 9000 and 1400 –	2.5 Marks each	5
	b) concept of Sanitation and control of contamination in Sterile areas. –	2.5 Marks each	5	

Q.3	Attempt any seven: Two questions from each section is compulsory.		
	Section - A		
i.	Glass as packaging material –	2.5 Marks	5
	Quality Control tests-	2.5 Marks	
ii.	Types of packaging materials –	2.5 Marks	5
	Container closures system for pharmaceutical products –	2.5 Marks	
iii.	Roles of GLP in Drug development –	5 Marks	5

Section – B

iv.	Short note on Recalling –	2.5 Marks	5
	Short note on waste disposal –	2.5 Marks	
v.	Good Documentation Practices –	2.5 Marks	5
	Do's and Don'ts of GDP-	2.5 Marks	
vi.	Content of BMR, MFR and SOP –	2.5 Marks	5
	Importance of BMR, MFR and SOP –	2.5 Marks	

Section – C

vii.	Definition of Validation –	2.5 Marks	5
	Types –	2.5 Marks	
viii.	Process of calibration of pH meter –	5 Marks	5
ix.	Practices of Good Warehousing Practices –	5 Marks	5
