Exam Date & Time: 29-Jul-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences, MAHE, Manipal
B. Pharm VI Semester End Semester Examination June-2022
Sub code: PQA-BP606T
Sub title: Pharmaceutical Quality Assurance

Pharmaceutical Quality Assurance [PQA-BP606T]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) MFR is prepared by

1)	Production Supervisor		2)	Research & development team		3)	Regulatory affairs team		4)	Company chairman		(1)

2) All the Product Quality Complaints shall be investigated jointly with QA, F&D and Manufacturing within ---------- days of the receipt of the complaint. (1)

1)	7	2)	3	3)	5	4)	10		

3) An audit performed by an organization on itself is

1)	External audit		2)	A third-party audit		3)	Internal audit		4)	A second party audit		(1)

4) Documented verification of a proposed design ability to meet the requirements it needs to fulfil is called as

1)	Design qualification		2)	Installation qualification		3)	Operational qualification		4)	Performance qualification		(1)

5) The closeness of agreement between the value that are accepted either as conventional true values or an accepted reference value and the value found is called (1)

1)	Specificity		2)	Range		3)	Accuracy		4)	Precision		

6) What is the importance of validation?

1)	Increase the product cost		2)	Reduce the product quality		3)	Reduction in batch rejections		4)	Increase the batch failures		(1)

7) Store the pH bulb/electrode in saturated solution of (1)

1)	KCl		2)	NaCl		3)	H_2SO_4		4)	NH_4Cl		

8) URS stands for

1)	Union Requirement Specification		2)	User Requirement Specification		3)	User Regional Specifications		4)	Utility Requirement Specification		(1)

9) Prospective validation is performed on at least ---- successive production-size (1)

1)	Five	2)	Three	3)	Two	4)	Six

10) ISO stands for _____ (1)

1)	Indian standard for organization	2)	Internal organization for standard	3)	International organization for standard	4)	Indian society for organ

11) Northern Europe, Canada, Russia comes under_____ (1)

1)	Climatic zone I	2)	Climatic zone II	3)	Climatic zone III	4)	Climatic zone IV

12) Recommended storage condition for ZONE IV A countries is _____ (1)

1)	30^0C/65 % R.H	2)	30^0C/75 % R.H	3)	30^0C/45 % R.H	4)	20^0C/75 % R.H

13) The main objective of ISO 9000 is_____ (1)

1)	Profit making	2)	Customer Satisfaction	3)	Skill enhancement	4)	To avoid Environmental issues

14) Accelerated stability studies conditions for Drug substance intended for storage in a refrigerator _____ (1)

1)	35°C ± 2°C/60% ± 5%	2)	25°C ± 2°C/65% ± 5%	3)	45°C ± 2°C/60% ± 5%	4)	25°C ± 2°C/60% ± 5%

15) Role and responsibilities of a Qualified personnel is defined in (1)

1)	GMP Chapter-2	2)	GMP Chapter-1	3)	GMP Chapter-12	4)	GMP Chapter-5

16) One of following test is used to differentiate four types of glasses (1)

1)	Water attack test	2)	Hydrolytic resistant test	3)	Powdered glass test	4)	Autoclaving

17) In Powdered glass test, volume of 0.02N sulphuric acid consumed should not be more than.....ml for Type-III Glass (1)

1)	1.5	2)	15	3)	0.5	4)	8.5

18) In the self-sealability test for rubber, Pierce cap .....times with hypodermic needle at different sites. (1)

1)	10	2)	15	3)	5	4)	12

19) All precision instruments should be_____ before used for routine analysis (1)

1)	Checked	2)	Maintained	3)	Calibrated	4)	Authenticated

20) A valid standard operating procedure should be identified by _____ (1)

1)	Documentation number	2)	Signature	3)	Title of the document	4)	Scope of the document

II Long Answers

Answer all the questions.

1)	Comment on the factors influencing air change rate in pharmaceutical industry.	(10)
2)	a. Enlist and explain the various characteristics that should be considered during Analytical Method Validation (7 Marks) b. Write the scope of performance qualification (3 Marks)	(10)

III Short Answers

Answer all the questions.

1)	Draw and explain a quality documentation pyramid	(5)
2)	What contents should be included in Master Formula Record explain with details?	(5)
3)	Discuss in detail about ISO 14000 certification process.	(5)
4)	List and explain the advantages and challenges of QbD implementation in the pharmaceutical sector	(5)
5)	List the points to be considered while purchasing equipments	(5)
6)	Explain the principle, procedure and limit for reducing substance test for rubber closures.	(5)
7)	Explain the functional elements of non-clinical laboratory study protocol	(5)

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