Exam Date & Time: 08-Jun-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-S1]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Batch formula record is derived from

1)	Validation record		2)	Master formula record		3)	Batch packaging record		4)	Site master file		(1)

2) The level 3 in the quality documentation system is

1)	Records		2)	Quality policy		3)	Quality procedures		4)	Work instructions		(1)

3) Which type of process validation do we perform periodically and after any change

1)	Prospective validation		2)	Retrospective validation		3)	Concurrent validation		4)	Re-validation		(1)

4) If the purchaser has specified that the equipment is going to run in a range of 50-100 RPM and will draw a specific amount of power, how they will verify that the equipment is achieving those operational requirements?

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

5) Who is the responsible person for executing the function of the stores

1)	QA manager		2)	QC manager		3)	Store manager		4)	Production manager		(1)

6) After each single measurement, the pH meter probe is rinsed with ---------- to remove any trace of the solution being measured

1)	Ionized water		2)	Acetic acid		3)	Deionized water		4)	Methanol		(1)

7) Regulatory basis of process validation is available in

1)	FDA		2)	USP		3)	IP		4)	BP		(1)

8) VMP Stands For (1)

1)	Validation Material Plan		2)	Validation Master Plan		3)	Verification Master Procedure		4)	Validation Machine Plan	

9) For the calibration of pH meter which of the following standard solution is likely to be used

1)	pH 5.0 buffer solution		2)	pH 7.0 buffer solution		3)	pH 1.68 buffer solution		4)	pH 12.3 buffer solution	

(1)

10) _____ is not covered under Deming's 14 points

1)	On job training		2)	Leadership		3)	Management		4)	Quality circle	

(1)

11) Long term stability studies conditions for Drug substance intended for storage in a freezer_____

1)	- 25 °C ± 5°C		2)	- 20 °C ± 3°C		3)	- 20 °C ± 5°C		4)	- 80 °C ± 5°C	

(1)

12) The over all aspects that governs the quality of a product is

1)	Quality Control		2)	Good Laboratory Practices		3)	Quality Assurance		4)	Inspection	

(1)

13) One of the following cannot be categorized as QbD elements

1)	Quality Target Product Profile (QTPP).		2)	Critical Quality Attributes (CQA).		3)	Standard operating procedure		4)	Design Space.	

(1)

14) _____ is Analytical method validation guideline

1)	Q1A		2)	Q1B		3)	Q3		4)	Q2R1	

(1)

15) Personnel should be qualified in.....for store management

1)	Material management		2)	Machine management		3)	Animal management		4)	Microbial management	

(1)

16) Internal bursting pressure test is done for

1)	Paper		2)	Rubber		3)	Glass		4)	Plastic	

(1)

17) The most suitable glass for most acidic and neutral, aqueous preparation of parenteral and non- parenteral use is

1)	Type-I		2)	Type-II		3)	Type-III		4)	Type-IV	

(1)

18) Concentration of Arsenic standard solution used in arsenic test for glass containers is .....ppm

1)	10		2)	100		3)	1		4)	20	

(1)

19) A Weight printout taken during weighing activity is called as _____ (1)

1)	Record		2)	Data		3)	Document		4)	MFR	

20) Deviations from current SOP related to the study should be documented and must be approved by _____ (1)

1)	Analyst		2)	Team leader		3)	Sponsorer		4)	Study director	

II Long Answers

Answer all the questions.

1) Explain the factors to be considered while choosing a location for Pharmaceutical plant. (10)

2) a. Explain in detail about the various phases involved in the quality audit process (7 Marks)
b. Write the importance of the Annual Product Quality Review (APQR) (3 Marks) (10)

III Short Answers

Answer all the questions.

1) What is instrument calibration? Explain the procedure for calibration of the pH meter (5)

2) What are the requirements to maintain a Good Warehouse in the pharmaceutical industry? (5)

3) Discuss in detail about the Total Quality Management concept (5)

4) List and explain the advantages and challenges of QbD implementation in the pharmaceutical sector (5)

5) Explain the measures to reduce/prevent the cross contamination. (5)

6) Explain the principle, procedure and limit for Fragmentation test for rubber closures. (5)

7) Define the term GLP, write a note on disqualification of testing facilities (5)

-----End-----