# Question Paper

Exam Date & Time: 24-May-2023 (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, May 2023
Sub code: PQA - BP606T
Sub title: Pharmaceutical Quality Assurance

**Pharmaceutical Quality Assurance (Theory) [PQA-BP606T -S2]**

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

**I Multiple Choice Questions (MCQs)**

**Answer all the questions.** Section Duration: 30 mins

1) Who is responsible for executing the function of the stores? (1)

- QA officer
- Store manager
- QC analyst
- Production head

2) Formula to calculate LOD (1)

- 5.3*SD of Intercept/Slope
- 3.3*SD of Intercept/Slope
- 10*SD of Intercept/Slope
- 15*SD of Intercept/Slope

3) BFR is primarily a replica of the --------- (1)

- JFR
- MFR
- PFR
- NFR

4) Which is the second step in handling of complaints (1)

- Investigation of the Complaint
- Receiving and Recording of a Complaint
- Reporting of Defects
- Quality Auditing

5) What is the effective time line for class III recall of the product from the market (1)

- Maximum of 45 days
- Maximum of 10 days
- Maximum of 30 days
- Maximum of 60 days

6) The level 1 in the quality documentation system is (1)

- Records
- Quality policy
- Quality procedures
- Work instructions

7) If the batch is found to be not complying with the regulatory specifications during the post-marketing stability study comes under---------- (1)

- Statutory recall
- Voluntary recall
- Patient recall
- Physician recall

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

- 5
- 3
- 2
- 6

9) Audit observations are made by regulatory bodies and deficiencies found are included in Form ------ (1)

- 481
- 482
- 483
- 484

10) The subcategory of ICH guidelines is (1)

- Quality, Safety, Efficacy and Multidisciplinary
- Quality, Authenticity, Efficacy and Multidisciplinary
- Quality, Safety, Efficacy and Multigenetic
- Quality, Safety, assurance and Multidisciplinary

11) Current SOP and obsolete SOP can be recognised by it's_____ (1)

- Document numbering system
- Signature
- Procedure
- Scope

12) Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products is _____ (1)

- Q1A
- Q1B
- Q1C
- Q1D

13) _____ is Analytical method validation guideline (1)

- Q1A
- Q1B
- Q3
- Q2R1

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

_____

35°C ± 2°C/60% ± 5%
25°C ± 2°C/65% ± 5%
45°C ± 2°C/60% ± 5%
25°C ± 2°C/60% ± 5%

15) Bubble air locks are found in (1)

Parenteral dosage form area
Semisolid dosage form area
Solid dosage form area
Liquid orals dosage form area

16) In arsenic test for glass containers, the intensity of the colour is measured in (1)

UV region
Visible region
IR region
Radiofrequency region

17) Penetrability test is done for (1)

Glass ampule
Glass vial
Rubber closure
Collapsible tube

18) Thickness of paper or paper board is measured using (1)

Measing scale
Measuring tape
Micrometre
Micropipette

19) Because of numerous cross-outs, a laboratory analyst copies his data onto a new worksheet and destroys the old worksheet. His data is no longer (1)

Attributable
Legible
Original
Accurate

20) GLP is a formal regulation that was created by the FDA (United states food and drug administration) in _____ (1)

1978
1987
1967
1977

**II Long Answers**

**Answer all the questions.**

| | | |
|---|---|---|
| 1) | a. Explain the factors to be considered while selecting the manufacturing site for pharmaceutical industry. (5 Marks)<br>b. Explain the measures to prevent or reduce the cross contamination. (5 Marks) | (10) |
| 2) | a. Why Analytical Method Validation is required in the Pharmaceutical industry? (4 Marks)<br>b. Explain the characteristics that should be considered during the validation of analytical methods. (6 Marks) | (10) |

**III Short Answers**

**Answer all the questions.**

| | | |
|---|---|---|
| 1) | Explain the complaint handling system in the pharmaceutical units | (5) |
| 2) | Discuss various Good Warehousing Practices parameters in the Pharmaceutical Industry | (5) |
| 3) | Discuss in detail about ISO 9000 certification process and its importance to pharmaceutical industries in the present scenario | (5) |
| 4) | List and explain the advantages and challenges of QbD implementation in the pharmaceutical sector | (5) |
| 5) | Why cleaning and sanitation is so important in pharmaceutical industry? | (5) |
| 6) | Explain the purpose, principle, procedure and limit for thermal shock test for glass bottle. | (5) |
| 7) | Discuss the consequences of noncompliance's for GLP facility | (5) |

-----End-----