Question Paper

Exam Date & Time: 12-Jul-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 -S1]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Class I recall causes (1)

- Serious adverse health consequences or death
- Temporary adverse health consequences
- Not likely to cause any adverse health consequences
- Minor adverse health consequences

2) Medical complaint investigations shall be carried out within --- days of receipt of complaint (1)

- 5
- 3
- 2
- 10

3) GWP stands for (1)

- Good Warehousing Practices
- Good Wholesale Practices
- Good Warehousing Products
- Good Working Protocols

4) Which type of process validation we perform periodic and after change (1)

- Prospective validation
- Retrospective validation
- Concurrent validation
- Re-validation

5) For the calibration of pH meter which of the following standard solution is likely to be used (1)

- pH 6.0 buffer solution
- pH 2.45 buffer solution
- pH 4.0 buffer solution
- pH 11.6 buffer solution

6) UV-Visible spectroscopy is concerned with ultraviolet and visible regions which range from (1)

- 240-480 nm
- 200-780 nm
- 200-880 nm
- 220-780 nm

7) ----------department can be taken the purchasing decisions in the pharmaceutical industry (1)

- QA
- QC
- Purchase
- Production

8) ISO stands for (1)

- Indian standard for organization
- Internal organization for standard
- International Organization for Standardization
- Indian society for organ

9) The guidelines that describe the Analytical Method Validation (Text & Methodology) (1)

- ICH Q3
- ICH Q2
- ICH Q7
- ICH Q8

10) 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%

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

- Climatic zone I
- Climatic zone II
- Climatic zone III
- Climatic zone IV

12) _____ is not covered under Deming's 14 points (1)

- On job training
- Leadership
- Management
- Quality circle

13) The main objective of ISO 9000 is _____ (1)

- Profit making
- Customer Satisfaction

Skill enhancement
To avoid Environmental issues

14) The founder members of ICH is (1)

Japan, India & Europe
Japan, India & China
Japan, USA & Europe
Japan, India & Brazil

15) Personnel qualified in material management will be in (1)

Stores
Production
QC
QA

16) Water attack test is done for glass containers to check the leaching of (1)

Arsenic from surface
Reducing substance from surface
Alkali from surface
Acid from surface

17) pH of the paper and board surface is measured using (1)

pH meter
pH solution
Litmus paper
pH Paper

18) In hydrolytic resistance test for glass containers, if the normal capacity of the container is up to 3 ml.....number of containers are to be used. (1)

At least 20
20
More than 20
50

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

1972
1973
1975
1978

20) Good Laboratory Practices mainly focus on the following except _____ (1)

Sponsors
Resources
Rules
QA unit

II Long Answers

Answer all the questions.

1) a. Explain the need of personal training in pharmaceutical industry (5 Marks) (10)
b. Comment on the training calendar (5 Marks)

2)	a. How does calibration differ from validation explain using a tabular column? (5 Marks) b. Explain the process involved in the Calibration of a digital pH meter (5 Marks)	(10)

III Short Answers

Answer all the questions.

1)	Design a template for Standard Operating Procedure	(5)
2)	Discuss about Pharmaceutical distribution records	(5)
3)	Discuss in detail about the Total Quality Management concept	(5)
4)	Describe the process of NABL accreditation with the help of flow chart	(5)
5)	Analyse the critical points to be considered for sanitation in a pharmaceutical industry	(5)
6)	Explain the purpose, principle, procedure and limit for arsenic test for glass container	(5)
7)	Discuss the role of standard operating procedure in GLP	(5)

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