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Library
Pharmaceutical Technology
Brainware University
Baranagar, Kolkata-700125

BRAINWARE UNIVERSITY

Term End Examination 2025-2026

Programme – B.Pharm-2020/B.Pharm-2021/B.Pharm-2022/B.Pharm-2023

Course Name – Quality Assurance Theory

Course Code - BP606T

(Semester VI)

Full Marks : 75

Time : 3:0 Hours

[The figure in the margin indicates full marks. Candidates are required to give their answers in their own words as far as practicable.]

Group-A

(Multiple Choice Type Question)

1 x 20=20

1. Choose the correct alternative from the following :

- (i) Select the correct option regarding periodic eye examinations.
 - a) Cleaning
 - b) Personal Hygiene
 - c) Sanitation
 - d) None of these
- (ii) Select the education the production personnel should go through.
 - a) Aeronautical Engineering
 - b) Chemical Engineering
 - c) Genetic Engineering
 - d) None of these
- (iii) Select the full form of BPR-
 - a) Batch Process Record
 - b) Batch Packing Record
 - c) Batch Planning Record
 - d) None of these
- (iv) Select the full form of QC-
 - a) Quantitative Control
 - b) Quality Care
 - c) Quality Concern
 - d) Quality Control
- (v) Select the full form of QMT-
 - a) Quality Modification Term
 - b) Quality Mannual Topic
 - c) Quality Management Team
 - d) Quality Management Topic
- (vi) Select the full form of AHU-
 - a) Artificial Holding Unit
 - b) Air Handling Unit
 - c) Air Holdup Unit
 - d) Artificial Handling Unit
- (vii) State the full form of QMS-
 - a) Quantity Management System
 - b) Quality Management System
 - c) Quality Management Standard
 - d) None of these
- (viii) Identify the meaning of OOS investigation-
 - a) Out-Of-Specification
 - b) Out-Odd-Specification
 - c) Out-Of-Standard
 - d) None of these
- (ix) Identify the full form of IPC-

- a) In Process Check
c) In Production Control
- (x) Select the full form of OQ.
a) Operational Qualification
c) In Process Qualification
- (xi) Define the foundation of TQM.
a) Ethics
c) Trust
- (xii) Select the second step of PDSA cycle-
a) Study the data collected
c) Act depending on the result
- (xiii) State the full form of ICH-
a) Indian conference of Harmonization
c) International conference of Harmonization
- (xiv) According to ICH Q8 design space is defined as-
a) 1 dimensional
c) 2 dimensional
- (xv) Write the full form of QC.
a) Quantitative control
c) Quality concern
- (xvi) Write the components of qualification-
a) IQ
c) DQ
- (xvii) Write the correct answer: Pharmacy act is established in-
a) 1940
c) 1954
- (xviii) Choose the correct answer: The All India Council for Technical Education Act is established in-
a) 1992
c) 1994
- (xix) Choose the correct answer: Deviation is a part of-
a) risk assessment
c) quality analysis
- (xx) Choose the correct answer: disintegration time for Coated tablet.
a) NMT 15 min
c) NMT 45 min
- b) In Process Quality
d) In Process Control
- b) Outstanding Qualification
d) other qualification
- b) Integrity
d) All of These
- b) Implementation of the plan
d) Planning
- b) International council for Harmonization
d) Indian council of Harmonization
- b) 5 dimensional
d) Multidimensional
- b) Quality control
d) Quality care
- b) OQ & PQ
d) all of these
- b) 1948
d) 1919
- b) 1957
d) 1958
- b) production
d) QMS
- b) NMT 30 min
d) NMT 60 min

2. Explain determination of CAPA. (5)
3. State the quality control test for closures. (5)
4. Describe the quality control test for cartons. (5)
5. Explain the basic requirements of quality control in the pharmaceutical industry. (5)
6. Explain the methods of hydrolytic resistance test of glass containers. (5)
7. Explain the types of validation in pharmaceutical industry. (5)

OR

- Explain about ISO and advantages of ISO 9000 and ISO 14000. (5)
8. Differentiate between calibration and validation. (5)

OR

- Explain the scope and importance of validation in pharmaceutical industry. (5)

Group-C

(Long Answer Type Questions)

10 x 2=20

9. Describe about quality assurance of excipients. (10)
10. Explain about control of contamination. (10)

OR

List the individual responsibilities of quality control head. (10)

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