BRAINWARE UNIVERSITY

Term End Examination 2024-2025

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

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 full form of GMP.

a) Good Laboratory Practice b) Good Manufacturing Practice
c) Good Manufacturing Process d) None of these

(ii) Identify the correct option regarding the full form of cGMP.

a) Correct Good Manufacturing Practice b) Current Good Manufacturing Practice
c) Control Good Manufacturing Practice d) Collect Good manufacturing Practice

(iii) Identify the correct option regarding the full form of FDA-

a) Food and Drug Assembly b) Food and Drug Administration
c) Food and Drug Authority d) None of these

(iv) Select the correct option regarding periodic eye examinations.

a) Cleaning b) Personal Hygine
c) Sanitation d) None of these

(v) Select the education the production personnel should go through.

a) Aeronautical Engineering b) Chemical Engineering
c) Genetic Engineering d) None of these

(vi) Select the full form of BPR-

a) Batch Process Record b) Batch Packing Record
c) Batch Planning Record d) None of these

(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
b) In Process Quality
c) In Production Control
d) In Process Control

(x) Select the full form of DQ.

a) Data Quality
b) Design Quality
c) Design Qualification
d) Development Quality

(xi) Select the full form of IQ.

a) Operational Qualification
b) Investing Qualification
c) In Process Qualification
d) Installation Qualification

(xii) Select the full form of OQ.

a) Operational Qualification
b) Outstanding Qualification
c) In Process Qualification
d) other qualification

(xiii) Identify the full form of PQ-

a) Process Qualification
b) Premises Qualification
c) Performance Qualification
d) None of these

(xiv) Write the full form of GMP?

a) Good Laboratory Practice
b) Good Manufacturing Practice
c) Good Manufacturing Process
d) None of these

(xv) Write the full form of QC.

a) Quantitative control
b) Quality control
c) Quality concern
d) Quality care

(xvi) Write the components of qualification-

a) IQ
b) OQ & PQ
c) DQ
d) all of these

(xvii) Write the correct answer: Pharmacy act is established in-

a) 1940
b) 1948
c) 1954
d) 1919

(xviii) Write the correct answer: SMF stands for-

a) store manufacturing file
b) stability material file
c) store material file
d) site master file

(xix) Write the correct answer: Patent Act is established in-

a) 1970
b) 1971
c) 1980
d) 1985

(xx) Write the correct answer: AHU stands for-

a) artificial holding unit
b) air handling unit
c) air holdup unit
d) artificial handling unit

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Demonstrate airlock. (5)
3. Describe personnel qualification required as per GMP. (5)
4. Define the purpose of ICH guidelines. (5)
5. Contrast the benefits of ISO certification. (5)
6. Write about SOP. (5)
7. Differentiate between calibration and validation. (5)

OR

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

8. Explain the types of validation in pharmaceutical industry. (5)

OR

Explain about ISO and advantages of ISO 9000 and ISO 14000. (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Write about the contents of reports and documents. (10)
10. Explain Validation Master Plan. (10)

OR

Explain good warehousing practice. (10)

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