BRAINWARE UNIVERSITY

Term End Examination 2023-2024
Programme – B.Pharm-2020/B.Pharm-2021
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) Identify the full form of IPC-

a) In Process Check b) In Process Quality
c) In Production Control d) In Process Control

(ii) Select the full form of DQ.

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

(iii) Write the full form of GMP?

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

(iv) Memorise the full form of TQM-

a) Total Quantity Maintenance b) Total Quality Mixup
c) Total Quantity Management d) Total Quality marking

(v) Select the building bricks of TQM-

a) Training b) Team Work
c) Leadership d) All of these

(vi) State the full form of CPPs-

a) Critical Process Parameters b) Control Process Parameters
c) Commercial Process Parameters d) None of these

(vii) Identify the section which conducts the first level of training.

a) Functional area b) One-on-one training
c) Both a & b d) HR

(viii) Select the temperature for autoclaving-

a) 190 ºC b) 200 ºC
c) 90 ºC d) 121 ºC

(ix) Identify the area required for manufacturing of parenteral dosage form.

a) 50 m^2 b) 60 m^2
c) 80 m^2 d) 100 m^2

(x) Identify the option: which dye is used for the leak test?

a) Orange Red b) Methylene Blue
c) Methylene Red d) None of these

(xi) Select the correct option: very soluble-

a) 1-10 parts b) less than 1 parts
c) 30-100 parts d) 100-1000 parts

(xii) Identify the regulatory authority of TGA.

a) Japan b) America
c) Australia d) China

(xiii) Select the correct option: Pharmaceutical Quality System guideline comes under-

a) Q8 b) Q7
c) Q10 d) Q9

(xiv) Identify the stainless steel used in pharmaceutical industry for direct product contact.

a) 316 b) 310
c) 308 d) 306

(xv) Choose the correct answer: Drug price control order act is established in-

a) 1991 b) 1920
c) 1995 d) 1993

(xvi) Choose the correct answer: Narcotic and psychotropic substance act is established in-

a) 1985 b) 1989
c) 1925 d) 1930

(xvii) Choose the correct answer: The All India Council for Technical Education Act is established in-

a) 1992 b) 1957
c) 1994 d) 1958

(xviii) Choose the correct answer: Fish bone is tools of-

a) QMS b) analysis
c) production d) route cause identifications in risk assesments

(xix) Choose the correct answer: Standard for GMP comes under-

a) Sch Q b) Sch P
c) Sch W d) Sch M

(xx) Choose the correct answer: disintegration time for Coated tablet.

a) NMT 15 min b) NMT 30 min
c) NMT 45 min d) NMT 60 min

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Describe personnel qualification required as per GMP. (5)
3. Report the handling of return goods. (5)
4. Explain the basic requirements of quality control in the pharmaceutical industry. (5)
5. Write the steps of raw materials purchasing. (5)
6. Describe the purpose of disqualification of testing facilities. (5)
7. Differentiate between calibration and validation. (5)

OR

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

8. Discuss a short note on validation master plan. (5)

OR

Write the calibration method of pH meter. (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Discuss about ISO 14000. (10)
10. Briefly explain the different parameters of analytical method validation. (10)

OR

Explain the job responsibilities of production head. (10)

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