BRAINWARE UNIVERSITY

Term End Examination 2023
Programme – B.Pharm-2020
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) Write the correct answer: Pharmacy act is established in
   a) 1940 b) 1948
   c) 1954 d) 1919

(ii) Write the correct answer: Patent Act is established in
   a) 1970 b) 1971
   c) 1980 d) 1985

(iii) Write the correct answer: Poisonous Act is established in
   a) 1942 b) 1957
   c) 1989 d) 1919

(iv) Select the full form of ANDA
   a) Application for New Drug Approval b) Abbreviated New Drug Application
   c) Application for New Drug Agency d) Approval for New Drug Agency

(v) Choose the correct answer: FTA belongs from
   a) risk assessment b) QMS
   c) quality assesments d) analytical tools

(vi) Select the correct option: Capping is due to which of the following reasons
   a) Air entrapment b) Too high compression force
   c) Too rapid expansion d) All of these

(vii) Choose the correct answer: SOP means
   a) standard operation protocol b) standard optimum price
   c) standard operating procedure d) standard observation process

(viii) Select the correct option: Guidelines on stability testing of drugs are given in
   a) ICH b) USFDA
   c) Both d) None

(ix) Choose the correct answer: Deviation is a part of

a) risk assessment b) production
c) quality analysis d) QMS

(x) Select the appropriate option: Gelatine is used as a/an

a) Encapsulating agent b) Antimicrobial agent
c) Viscosity agent d) Tablet glidant

(xi) Select the appropriate option: Disposable Syringe are made of

a) Polypropylene b) Transparent polystyrene
c) Glass d) PTFE

(xii) Identify the option which has minimum permissible solid content

a) Distilled Water b) WFI
c) SWFI d) None of the Above

(xiii) Select the full form of IQ

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

(xiv) Tell the full form of GMP

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

(xv) Memorise the full form of TQM

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

(xvi) Select the second step of PDSA cycle

a) Study the data collected b) Implementation of the plan
c) Act depending on the result d) Planning

(xvii) Select the fourth step of PDSA cycle

a) Planning b) Implementation of the plan
c) Act d) Study the data collected

(xviii) Identify the purpose of Guideline Q1

a) Impurities b) Analytical validation
c) Stability related quality d) Specifications

(xix) Identify the purpose of Guideline Q3

a) Stability b) Analytical validation
c) Impurities related to quality d) Specifications

(xx) State the full from of ICH

a) Indian conference of Harmonization b) International council of Harmonization
c) International conference of Harmonization d) Indian council of Harmonization

Group-B

(Short Answer Type Questions) 5 x 7=35

Answer the questions.

2. State about the advantages and disadvantages of TQM. (5)
3. Describe Personnel Qualification is required as per GMP? (5)
4. Contrast the benefits of ISO certification. (5)
5. Describe Standard Operating Procedure (5)
6. Write in detail about C-GMP (5)
7. Explain Recalled Product (5)

OR

Illustrate the term Reference Standard (5)

8. write in detail about disqualification of testing facilities (5)

OR

write in detail about types of complaints (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

Answer the questions.

9. Summarize in detail about ISO 9000 (10)
10. Explain Hydrolytic Resistance Test for Glass Containers (10)

OR

Explain Quality Control test for Closures (10)

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