Total No. of printed pages = 4

Bina Chowdhury Central Library
Girijananda Chowdhury University
Hatkhowapara, Azara, Ghy-17

**BP 606T**

Roll No. of candidate | | | | | | | | | | |

**2023**

**B.Pharm. 6th Semester (Regular)End-Term Examination**

**PHARMACEUTICAL QUALITY ASSURANCE – THEORY**

**New Regulation (w.e.f. 2017-2018)**

Full Marks – 75 Time – Three hours

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The figures in the margin indicate full marks for the questions.

1. Answer the following questions : (20 × 1 = 20)

(i) Which of the following department holds responsibilities for quality monitoring or Audit

(a) QC

(b) QA

(c) Production

(d) all

(ii) TQM aims at long term success through

(a) Customer satisfaction

(b) owner satisfaction

(c) Management satisfaction

(d) All

(iii) Which of the following is said to be the binding mortar in elements of TQM

(a) Training

(b) Team work

(c) Communication

(d) Ethics

(iv) ISO 9001 provides for

(a) Definition of the terms and fundamental quality management principles

(b) Guidance to an organization on ways to frame their QMS

(c) Information necessary to implement a QMS in an organization

(d) None of the above

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(v) The main elements of Quality Management System is/are

(a) Quality planning

(b) Quality Assurance

(c) Both (a) and (b)

(d) Only (b)

(vi) Select the correct statement:

According to the TQM requirements for Pharma Industry,

(a) Environmental conditions should be recorded at regular intervals

(b) All API materials should be stored together separately in a well defined storage area

(c) Storage conditions only needs to be tested against temperature and pressure

(d) All the above

(vii) Which of the following is important during purchase of raw materials?

(a) Quality

(b) Purity

(c) Identity

(d) All of the above

(viii) Water attack test is used for ———— glass containers

(a) Type I

(b) Type II

(c) Type III

(D) Type IV

(ix) One of the following is not a parameter of analytical method validation

(a) Specificity

(b) Linearity

(c) Robustness

(d) Prospective validation

(x) ICH Q5 outlines the guidelines for which of the following product

(a) Biotechnological

(b) Potent drug

(c) New products development

(d) None of the above

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(xi) Full form of ICH is ————————

(xii) ISO 9000 has been revised———— times till now.

(xiii) A quality product has four products likely ———————— and purity.

(xiv) ICH has three parties namely———— Japan and ————

(xv) Light sensitive material should be stored in———— container

(xvi) Full form of SOP is ————————

(xvii) Validation involves the systematic study of ————————

(xviii) ———————— is known as the Father of Quality Control.

(xix) NABL is registered under————————Act.

(xx) ———————— department is responsible for evaluation of Batch records.

2. Answer any seven from the following: $(7 \times 5 = 35)$

(a) What are the objectives and benefits of ISO 9000?

(b) Discuss the Maintenance and calibration of Equipment.

(c) Explain Master Formula record.

(d) Explain the elements of TQM

(e) Write a note on purchase and maintenance of stores for raw materials.

(f) Define complaints and add a note on evaluation of complaints?

(g) Elaborate Quality Control tests for containers and closures.

(h) Discuss in detail the concept of GMP.

(i) Define Intellectual Property rights and patent.

3. Answer any two out of three: (2 × 10 = 20)

(a) (i) Describe the process for NABL licensing and accreditation for Pharmaceutical Drug Industry. (5)

(ii) Write a note on GLP. (5)

(b) (i) Discuss in detail about ICH with special emphasis on its constitution, function and role. (6)

(ii) Explain Quality by design. (4)

(c) (i) Explain analytical method validation with its importance. (5)

(ii) Differentiate between Quality Control and Quality Assurance (5)