Total No. of printed pages = 4

BP 606 T

2025

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

PHARMACEUTICAL QUALITY ASSURANCE

Full Marks – 75 Time – Three hours

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

1. Answer the following (MCQ) : 1×20

(i) ISO 9000 deals with the fundamentals of ————————

(a) Risk Assessment

(b) Optimization

(c) Quality management system

(d) None of these

(ii) ISO 14000 is the set of standards addressing

(a) Quality Management System requirements

(b) Environmental Management System requirements

(c) Both (a) and (b)

(d) None of the above

(iii) The layout and design of the equipment must aim to

(a) Minimize risk of errors

(b) Permit effective cleaning

(c) Labeled as defective if instrument not working

(d) All of the above

(iv) Basic principles and methodology sequence of ISO 14000 series are

(a) Plan, Do, Act, Check

(b) Plan, Do, Check, Act

(c) Do, Act, Check, Plan

(d) None

[Turn over

(v) To approve or reject the starting materials, packaging materials, and intermediate, bulk, and finished products is the responsibility of which department?

(a) QC (b) QA

(c) Production (d) All

(vi) ———— provides guidance so that responsible firms may conduct an effective recall.

(a) 21 CFR 7 (b) 22 CFR 3

(c) 23 CFR 5 (d) None

(vii) URS stands for?

(a) User Requirement Specification

(b) User Resource Specification

(c) User Retrospective Specification

(d) User Reference Specification

(viii) SOP denotes

(a) Standard Operating Procedures

(b) Standard Operating Principles

(c) Standard of Processes

(d) Standard Operation Procedure

(ix) Powdered glass test is performed to determine the ————

(a) Surface alkali

(b) Alkali content

(c) Transparency

(d) Quantity of boron

(x) In internal bursting pressure test, the test bottle is filled with ————

(a) Water (b) HCL

(c) HNO3 (d) None of these

(xi) Removal of product from market which may be of specific batches of product or all the batches of product is known as

(a) Product complaint

(b) Product recall

(c) Handling of return goods

(d) Destruction of product

(xii) The guidelines that describe the Analytical Method Validation-Text & Methodology are ————————

(a) ICH Q2

(b) ICH Q1

(c) ICH Q8

(d) ICH Q9

(xiii) NABL provides ———————— services to laboratories that are performing tests/calibration in accordance with NABL

(a) Utility support

(b) Emergency

(c) Laboratory Accreditation

(d) None

(xiv) The type of process validation which is based on information generated during actual implementation of the process is known as ————————

(a) Prospective validation

(b) Retrospective validation

(c) Concurrent validation

(d) Analytical validation

(xv) ———————— product recall involves a potentially hazardous situation, but not a life-threatening condition.

(a) Class I

(b) Class II

(c) Class III

(d) None of these

(xvi) Good documentation is an essential part of

(a) Quality control

(b) Quality assurance

(c) Production

(d) All of the above

(xvii) The key element of TQM is

(a) Focus on the customer

(b) Continuous improvement

(c) Employee involvement

(d) All of the above

(xviii) The ———— of an analytical procedure expresses the closeness of agreement between the value which is accepted either as a conventional true value or an accepted reference value and the value found.

(a) Accuracy (b) Precision

(c) Specificity (d) Reproducibility

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

(a) Quality (b) Purity

(c) Identity (d) All of the above

(xx) ISO standards ensure _____ of products and services to customers and other users.

(a) Consistency and quality (b) Continuous improvement

(c) Global recognition (d) All of these

2. Answer any *seven* questions : 7×5

(a) What is SOP? Write the general contents of an SOP. 1 + 4

(b) What is mean by recall? Explain the recall process of pharmaceutical products. 1 + 4

(c) What is QSEM? Write a short note on Q guidelines. 1 + 4

(d) Explain in detail, the purpose, production and contents of master formula record.

(e) Explain the GLP protocol for the conduct of a nonclinical laboratory study.

(f) Write in details about Purchase specifications and maintenance of stores for raw materials.

(g) Write briefly about Quality control test for containers.

(h) Write short note on: 2.5 + 2.5

(i) Good Laboratory Practices,

(ii) Quality Audit

(i) Write a brief about NABL accreditation.

3. Answer any *two* questions : 2×10

(a) Give a brief idea about ISO 9000 certification and explain the steps of ISO 9000 registration process. 5 + 5

(b) Describe the concept of TQM? Explain elements of QbD program. 5 + 5

(c) What is the difference between calibration, qualification and validation? Write briefly about importance, scope of validation and types of validation. 3 + 7