Roll No. ..... Total Printed Pages - 08

F - 1288

B. Pharma. (Sixth Semester)
EXAMINATION, MAY-JUNE, 2022
Paper Sixth
PHARMACEUTICAL QUALITY ASSURANCE

Time : Three Hours] *[Maximum Marks : 75*

Note : The question paper consists of three parts i.e. A, B and C. Part A consists of 20. MCQs of I mark each. All questions are compulsory. Part B consists of 3 questions out of which 2 questions should be attempted, 10 marks each. Part C consists of nine questions out of which attempt 7 questions. 5 maks each.

(Section-A)

(Objective/Multiple Choice Questions)

(20×1=20 marks)

1. Total Quality Management focuses on

   (A) Employee

   (B) Customer

   (C) Both (A) & (B)

   (D) None of the above

2. Which of the following is the Environment management

   (A) ISO 9000

   (B) ISO 14000

   (C) ISO 26000

   (D) ISO 31000

3. GMP ensure which of the following parameter

   (A) Quality

   (B) Safety

   (C) Efficacy

   (D) All

4. The purpose of IQ is to check the

   (A) Design

   (B) Installation

   (C) Performance

   (D) Operation

5. It is also called as premarket validation

   (A) Retrospective validation

   (B) Concurrent Validation

   (C) Prospective Validation

   (D) Revalidation

6. PDCA stands for

   (A) Proceed Do Correct Act

   (B) Proceed Do Check Act

   (C) Plan Do Correct

   (D) Plan Do Check Act

7. Which of the following is building block of TQM

   (A) Training

   (B) Teamwork

   (C) Leadership

   (D) All of the above

8. In process of NABL accreditation, Laboratories are required to submit _____ set of duly filled in application form for each field of testing or Calibration.

   (A) Seven

   (B) Three

   (C) Five

   (D) Nine

9. ICHQ2 guideline is for

   (A) Cleaning Validation

   (B) Calibration

   (C) Analytical Validation

   (D) None of these

10. The premises/building shall confirm to all the conditions laid down in :

    (A) Pharmacy Act

    (B) Factory Act

    (C) D & C Act

    (D) None of the above

11. In which year factories act came into existence

    (A) 1958

    (B) 1948

    (C) 1968

    (D) 1978

12. Annealing is a process of

    (A) Heating

    (B) Melting

    (C) Cooling

    (D) Titrating

13. Mater formula record for each drug product describes all aspect of it

    (A) Manufacture

    (B) Packaging

    (C) Control

    (D) All

14. An audit performed by an organization on itself is

(A) Internal Audit

(B) Second Party Audit

(C) Third Party Audit

(D) None of the above

15. Good Distribution Practice is a part of

(A) Quality Control

(B) Quality Assurance

(C) IPQC

(D) None of these

16. Element of SOP are

(A) Title page

(B) Table of content

(C) Procedure

(D) All of the above

17. Which of the following is comes under phase-II Audit

(A) Preparation

(B) The review meeting

(C) The follow up

(D) None of these

18. Complain about product is an indicator of the product

(A) Quality

(B) Efficacy

(C) Safety

(D) None of these

19. Validation is an example of

(A) QA

(B) QC

(C) Both (A) and (B)

(D) None of the above

20. ISO 9000 deals with fundamentals of

(A) Risk Assessment

(B) Quality Management System

(C) Optimization

(D) None of the above

(Section- B)

(Long Answer Type Questions)

(2×10 marks)

Note : Attempt any two questions. Write answer in 75 words.

1. What is QbD? Discuss the elements, tools and steps of QbD?
2. Describe the layout, construction and maintenance of premises in pharmaceutical industry as per GMP?
3. Discuss the ICH guidelines with an overview of QSEM and emphasis on Q-series for stability of products?

(Section - C)

(Short Answer Type Questions)

(7×5=35 marks)

Note : Attempt any seven questions. Write answer in 75 words.

1. Differentiate between validation and calibration.
2. Discuss the tools and philosophies of TQM.
3. Explain the steps for registration of ISO 9000.
4. Write exhaustive note on NABL Accreditation.

5. Discuss the quality control test for containers and closures.
6. Discuss Good Laboratory Practices.
7. Define complaints and recall? Describe the procedure for handling the complaints.
8. Write short note on analytical method validation.
9. Explain good warehousing practice.