**Seat No: _____** **Enrollment No: _____**

# PARUL UNIVERSITY

## FACULTY OF PHARMACY

### B.Pharm. Winter 2022 - 23 Examination

**Semester: 7** **Date: 12/10/2022**
**Subject Code: BP702T** **Time: 10:00am to 1:00pm**
**Subject Name: Industrial Pharmacy** **Total Marks: 75**

**Instructions:**
1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

**Q.1 Multiple Choice Questions (MCQs)** (1 Mark Each) **(20)**

1. Validation is a part of
   a) GUI b) GMP
   c) CPM d) All of the above
2. Systemic authorized written procedure for equipment operation is known as
   a) VMP b) SOP
   c) QA d) WAP
3. Routinely used physical testing equipment's are
   a) pH meter b) Weighing balance
   c) Viscometer d) All of the above
4. Gap analysis identify critical elements of
   a) Receiving unit b) Sending unit
   c) Building unit d) All of the above
5. Which one following is a critical quality attributes of tablet formulation?
   a)Spreadability b) Kneading time
   c) Dissolution d) Blending
6. Drug master file is a part of
   a) VMP b) SOP
   c) FPP d) Marketing authorization
7. Sterilization process is supposed to get
   a) Validated b) Qualified
   c) Calibrated d) None of the above
8. Levels of change mentioned in SUPAC guidelines are
   a) 2 b) 3
   c) 4 d) 5
9. Development of a reliable and practical method of manufacture which results in an effective and orderly transition from the laboratory to routine processing into a full-scale production facility is called
   a) Formulation and Development b) Research and Development
   c) Pilot plant d) None of the above
10. The physical properties of the dosage form depend upon various factors, including
    a) The size of the dispersed particles b) The interfacial tension between the phases
    c) Drug – Excipient Interaction d) All of the above
11. Difference between definition of QbD Quality by design & QbT Quality by testing
    a) Quality was improved after manufacturing b) Quality is preplanned & zero risk defect is achieved
    c) Unimproved quality d) All of the above
12. OOS in quality management systems stands for
    a) Out of stock b) Out of sense
    c) Out of specification d) None of the above
13. Food and Drug Administration Modernization Act (FDAMA) was initiated in
    a) 1996 b) 1997
    c) 1998 d) 1999

14. The major disadvantage of ISO certification is
    a) cost of certification
    b) it has to be maintained through the lifespan of the organization
    c) willingness of the employer
    d) all of the above
15. Which of the following is not an objective of pilot plant technique
    a) To closely examines the formula to determine the ability of the formula to withstand batch scale and process modification
    b) To review a range of processing equipment to determine its compatibility with the formula
    c) To review the requirements like training, and responsibilities of personnel
    d) To review, develop and formulate a new product with commercial application
16. DMAIC model of six sigma is used for projects aimed at
    a) improving an existing business process
    b) creating new product or process designs
    c) improving an existing business process and creating new product or process designs
    d) none of the above
17. Total Quality Management (TQM) focuses on
    a) Employee
    b) Customer
    c) Employee and customer
    d) Quality of product or process
18. Total Quality Management (TQM) focuses on
    a) Critical quality attribute
    b) Target product profile
    c) Critical process parameters
    d) Quality
19. The difference in ICH Q10 guideline
    a) addition of life cycle management
    b) GMP checklist
    c) Quality risk management
    d) product life cycle
20. Finished pharmaceutical product does not contain information of
    a) Production
    b) Packaging
    c) Marketing
    d) Pricing

**Q.2 Long Answers (any 2 out of 3)** (10 Mark Each) **(20)**

1. Give a detail account on regulatory requirements for drug approval
2. Discuss pilot plant scale up considerations for solids and semi-solids
3. Write an exhaustive note on technology transfer agencies in India

**Q.3 Short Answers (any 7 out of 9)** (5 Mark Each) **(35)**

1. Explain quality risk management?
2. Discuss the role of regulatory affairs department and responsibility of regulatory affair professionals
3. Explain Quality and Total Quality Management
4. Discuss the general considerations of IND
5. Write a short note on SUPAC guidelines
6. Explain Quality by Design (QbD)
7. Write a short note on Six Sigma concept
8. Enlist the different regulatory authorities and explain one of them in detail
9. Explain management of clinical studies