REV-01
[BP] 03/31/36

2023.12

**SET C**

# B. PHARM.
## SEVENTH SEMESTER
## INDUSTRIAL PHARMACY II
## BP702T
[USE OMR SHEET FOR OBJECTIVE PART]

Duration : 3 hrs. **Full Marks : 75**

## [ PART-A: Objective ]

Time : 30 min. **Marks : 20**

***Choose the correct answer from the following:*** ***1×20=20***

1. ICH Q7 for
   a. Impurity
   b. GMP
   c. Stability
   d. Pharmacopoeia
2. Definition of Quality risk management has been mentioned in ICH guideline
   a. Q7
   b. Q8
   c. Q9
   d. Q3
3. National regulatory authority of United states?
   a. USFDA
   b. CDSCO
   c. MHLW
   d. MHRA
4. National regulatory authority of INDIA?
   a. USFDA
   b. CDSCO
   c. MHLW
   d. MHRA
5. Which department responsible for auditing pilot plant?
   a. QA
   b. QC
   c. R&D
   d. Production
6. Rule 122A for
   a. Clinical trials
   b. Permission to import new drugs
   c. Permission to manufacture new drugs
   d. Issue of import license
7. Head of central drug testing laboratory-
   a. Drug controller of India
   b. Director general of health services
   c. DCGI
   d. None of the above
8. ICH Q8 for
   a. Impurity
   b. Pharmaceutical Development
   c. Stability
   d. Genotoxicity study
9. Form 10/ 10A for
   a. Clinical trials
   b. Permission to import new drugs
   c. Permission to manufacture new drugs
   d. Issue of import license

10. ICH guidelines involve _____
    a. Quality, Safety
    b. Quality, Safety and efficiency
    c. Quality control and multidisciplinary guidelines
    d. Quality, Safety, efficiency and multidisciplinary guidelines

11. _____ acts as an interface between the pharmaceutical industry and drug regulatory authorities across the world.
    a. QA
    b. R&D
    c. RA
    d. QC

12. Which one is a focus of TQM?
    a. Cost of product
    b. Timeline
    c. Customer focus
    d. None of the above

13. Full form of SUPAC?
    a. Scale up and post approval changes
    b. Scale down and post approval changes
    c. Syrup and parental approval changes
    d. None of the above

14. Scale-up process performed by?
    a. R&D
    b. Technology transfer
    c. Production
    d. All of the above

15. Assay comes under _____
    a. QTPP
    b. CQA
    c. QA
    d. CQP

16. Two or more drug products that contain the same labelled active ingredient and in same amount, is called
    a. Chemical equivalence
    b. Pharmaceutical equivalence
    c. Bioequivalence
    d. Therapeutic equivalence

17. MFC is prepared by?
    a. Production
    b. R&D
    c. QA
    d. QC

18. What is a synonym/description for the phase 4 trials?
    a. Post marketing surveillance
    b. Pre market surveillance
    c. Pre FDA approval
    d. Post FDA approval

19. What is purpose of NDA?
    a. Sale and marketing
    b. Clinical trial
    c. Market survey
    d. None of the above

20. ISO 14000 for
    a. Environment responsibility
    b. Accreditation body
    c. Customer need
    d. Both b and c

## PART-B : Descriptive

Time : 2 hrs. 30 min. Marks : 35

*[ Answer any seven (7) questions ]*

1. What is IND application? Explain different IND applications 5
2. Write a note on responsibility of Regulatory Affair Professional. 5
3. Define TQM. Explain six sigma process. 5
4. Define OOS, Change control and ISO. Write functions of CDSCO. 5
5. Write a note on Investigator Brochure 5
6. Discuss principle of QRM and Process. 5
7. What is SUPAC guideline? Write general requirements for pilot plant scale up. 5
8. Define validation. Mention steps followed in technology transfer protocol. 5
9. Define Regulatory affair. Mention layout chart for IND application. 5

## PART-C: Long type questions

*[ Answer any two (2) questions ]*

1. What do you mean by pilot plant scale -up? What is its significance of pilot plant scale up with routine production procedure? Explain the critical aspects of solid and semi solid dosage form. 10

2. Define QbD. Explain objectives of QbD and elements of QbD. 10

3. What is NDA? Write its aim. Explain NDA contents and NDA review process. 10

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