SET A

B. PHARM.
SEVENTH SEMESTER
INDUSTRIAL PHARMACY II
BP702T [REPEAT]
[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. ______ acts as an interface between the pharmaceutical industry and drug regulatory authorities across the world.
   a. QA b. R&D
   c. RA d. QC

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

3. 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

4. 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

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

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

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

8. ICH Q7 for
   a. Impurity b. GMP
   c. Stability d. Pharmacopoeia

9. 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

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

11. Definition of Quality risk management has been mentioned in ICH guideline
    a. Q7
    b. Q8
    c. Q9
    d. Q3

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

13. Which department responsible for auditing, pilot plant?
    a. QA
    b. QC
    c. R&D
    d. Production

14. Head of central drug testing laboratory-
    a. Drug controller of India
    b. Director general of health services
    c. DCGI
    d. None of the above

15. Form 10/10A for
    a. Clinical trials
    b. Permission to import new drugs
    c. Permission to manufacture new drugs
    d. Issue of import license

16. Rule 122A for
    a. Clinical trials
    b. Permission to import new drugs
    c. Permission to manufacture new drugs
    d. Issue of import license

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

18. ICH Q8 for
    a. Impurity
    b. Pharmaceutical Development
    c. Stability
    d. Genotoxicity study

19. National regulatory authority of INDIA?
    a. USFDA
    b. CDSCO
    c. MHLW
    d. MHRA

20. National regulatory authority of United states?
    a. USFDA
    b. CDSCO
    c. MHLW
    d. MHRA

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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