2023/08

SET A

B. PHARM.
SEVENTH SEMESTER
INDUSTRIAL PHARMACY II- THEORY
BP702T |SPECIAL 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. BMR is prepared by?
   a. Production b. R&D
   c. QA d. QC

2. Self life of a drug is determined by
   a. Stability study b. Chemical analysis
   c. Assay d. Pharmacovigilance

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

4. GMP stands for?
   a. Good manufacturing practices b. Good material purchase
   c. Goods material procurement d. None of the above

5. Key components of TQM?
   a. Consumer/Customer focus b. Continuous improvement
   c. Involvement of employee d. All of the above

6. 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

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

8. COPP is recommended by
   a. WHO b. CDSCO
   c. State d. None of the above

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

10. Basic principle of ISO 9000-
    a. Customer focus and engagement of people
    b. Relationship management and leadership
    c. Evidence based decision making and continuous improvement
    d. All of the avove

11. Six sigma concept includes
    a. Define, Measure, Analyse, Improve and control
    b. Design, Measure, Analyse, Improve and control
    c. Define, manage, Analyse, Improve and control
    d. All of the above

12. Phase I clinical trial gives idea about
    a. Safety and tolerability
    b. Side effects
    c. Toxicity
    d. Post market survey

13. Phase II clinical trial gives idea about
    a. Safety and tolerability
    b. Side effects
    c. Toxicity
    d. Post market survey

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

15. The transfer of technology between sites of different companies is called as
    a. Inter-company transfer
    b. Intra- company transfer
    c. Technology transfer
    d. Technology transfer protocol

16. ICH Q3 guideline for
    a. Stability
    b. Impurity
    c. Validation
    d. QRM

17. Quality control is defined as _____?
    a. Sampling and documentation
    b. Sampling, Specification and documentation
    c. Sampling, specification, testing, documentation and release procedures
    d. None of the above

18. ICH involves ?
    a. Quality, safety
    b. Quality, safety and efficacy
    c. Quality control and multidisciplinary guidelines
    d. Quality, safety, efficacy and multidisciplinary guidelines

19. 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

20. Which of the following is not a scale-up process?
    a. Laboratory to pilot Scale
    b. Pilot scale to industrial scale
    c. Industrial to Pilot Scale
    d. Laboratory to Industrial Scale

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PART-B :Descriptive

Time : 2 hrs. 30 min. **Marks : 35**

[Answer any seven (7) questions]

1. Write a note on documents required for applying for granting or revalidation of COPPs. 5
2. Write critical aspects of semisolid manufacturing 5
3. Write five objectives of TQM and QBD 5
4. Define terms- API, Excipients, DQ, IQ, PQ 5
5. Mention technology transfer protocol. 5
6. Write a note on IND application 5
7. Mention functions of GMP and its advantages and disadvantages. 5
8. Write functions of CDSCO. 5
9. Write a note on documents required for applying for granting or revalidation of COPPs. 5

PART-C: Long type questions

[Answer any two (2) questions]

1. Write the principles of technology transfer. Write a note on technical documents required for NDA 10

2. What do you mean by Out of specification? Write a note on Six sigma process. Write two advantages of NABL. 10

3. Write the names of different central drug testing laboratories. State the functions of state licensing authorities. Mention parts of clinical research protocol. 10

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