SET B

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. For long term toxicity study, how many groups of animals are taken?
   a. 1 b. 2
   c. 3 d. 4

2. IND application is submitted to FDA for:
   a. Marketing a new drug b. Approval of Clinical trials
   c. Bioequivalence study d. All of these

3. CMC of a drug contains details about:
   a. Manufacturing details b. Composition of drug
   c. Stability data d. All of these

4. Pre-clinical study involves:
   a. In-vitro study b. In-vivo study
   c. Both (a) & (b) d. None of these

5. NDA is submitted to FDA for:
   a. Approval of new drug b. Marketing a new drug
   c. Approval of clinical trial d. None of these

6. Regulatory authority in US is:
   a. CDSCO b. EMA
   c. FDA d. None of these

7. The full form of NRDC is:
   a. National research development corporation b. National research development centre
   c. National research design corporation d. None of these

8. Technology transfer report consists of :
   a. Procedures b. Conclusions
   c. Both (a) & (b) d. None of these

9. TIFAC's thematic areas include:
   a. Education b. Water
   c. Both (a) & (b) d. None of these

10. Issue of import license is in form
    a. 10 b. 10A
    c. Both (a) & (b) d. None of these

11. The CDSCO works with the WHO to promote:
    a. Health
    b. GMP
    c. DCGI
    d. All of these

12. The DCGI is advised by the:
    a. DTAB
    b. DCC
    c. Both (a) & (b)
    d. None of these

13. The CDSCO is headed by the:
    a. DTAB
    b. DCGI
    c. DCC
    d. None of these

14. The main regulatory body for regulation of pharmaceuticals, medical devices and clinical trials in India is:
    a. CDSCO
    b. DCGI
    c. Both (a) & (b)
    d. None of these

15. Over loading in blender causes:
    a. Reduces the efficiency
    b. Causes content un-uniformity
    c. Both (a) & (b)
    d. None of these

16. The physical form of a drug product that is pourable displays:
    a. Non-newtonian flow
    b. Newtonian flow
    c. Both (a) & (b)
    d. None of these

17. Which of the following is a problem arising due to compression defects in tablets?
    a. Cracking
    b. Weight variation
    c. Peeling
    d. None of these

18. Equipment used in the scale up of liquid dosage formulations include?
    a. Mixer
    b. Homogenizer
    c. Filtration assembly
    d. All of these

19. The reporting responsibility of pilot plant and scale up is of:
    a. R&D group
    b. QA group
    c. QC group
    d. None of these

20. Pilot plant is the bridge between?
    a. R&D & QA
    b. R&D & Production
    c. R&D & QC
    d. None of these

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PART-B :Descriptive

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

[Answer any seven (7) questions]

1. Explain the different steps involved in the process of scale up. What are the main uses of scale up? 5

2. Discuss the different steps and critical aspects of liquid oral dosage form manufacturing. 5

3. Write a brief note on Quality Risk Management. 5

4. Write the definition, organization and functions of CDSCO. 5

5. Explain the importance of COPP. 5

6. Describe the role of regulatory affairs department in the drug development process. 5

7. Briefly describe the toxicological approaches to drug discovery. 5

8. Write a brief note on GLP guidelines. 5

9. Describe the concept of Total Quality Management. 5

PART-C: Long type questions

[Answer any two (2) questions]

1. Write a detailed note on the general requirements for pilot plant and scale up. **10**

2. Write a detailed note on the procedure for approval of new drugs in India. **10**

3. Explain the general considerations of New Drug Application. **10**

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