
Roll.No.

BP-702 T

ODD SEMESTER EXAMINATION,2022-23

COURSE NAME-B.Pharm

SEMESTER- VII

SUBJECT-Industrial Pharmacy II

TIME: 3 HOURS MAX MARKS:75

NOTE: Attempt all parts.

PART A (1X20)

1. Who gives license to medical store

a. State drugs standard control organization

b. Central drugs standard control organization

c. a and b

d. Drug inspector

2.How many phases occur in clinical trial

a. Three

b. Four

c. Two

d. One

3.CDSCO headquarter located in

a. New Delhi

b. Mumbai

c. Ghaziabad

d. Bangalore

4. SIDBI set up on

a. 3April 1990

b. 2 April 1990

c. 4 April 1992

d. 5 April 1993

5. Investigational New Drug Application for

a. Permission to start clinical trials

b. Permissions to start Non clinical trials

c. For drug discovery

d. For toxicology studies

6. COPP is recommended by

a. FDA

b. WHO

c. USFDA

d. GMP

7. Schedule Y is also called

a. preclinical trial

b. clinical trial

c. New drug trial

d. Post approval trial

8. Who publishes the Indian Pharmacopeia

a. FDA

b. USFDA

c. CDSCO

d. DCGI

9. Which technology transfer agency is for biotech product

a.SIDBI

b. TBSE

c. BCIL

d. NRDC

10.Which form to fill for approval of generic drugs

a. IND

b. ANDA

c. NDA

d. FDA

11. What is acceptance criteria in technology transfer

a. Under which test result will be considered acceptable

b. Under which test result will be considered unacceptable

c. Both a and b

d. Technology transferred in one area to another

12. Intercompany technology transfer occur between

a. Between sites of different companies

b. between sites of same company

c. Between sites of one company

d. Between sites of two company

13. What does SUPAC stand for

a. Scale- up pre approval changes

b. Scale -up post approval changes

c. Scale -up past approval changes

d. Scale -up pro approval changes

14. Phase 0 in clinical trial done for

a Micro dosing studies

b Therapeutic exploratory

c. Therapeutic confirmatory

d. Post marketing surveillance

15. ISO 14000 is related to

a. Promote effective environmental management system in organizations

b. Promote COPP

c. Issue license for production

d. For finished product

16. In pilot plant scale up techniques dry blending is done for

a. solid

b. Liquid

c. semisolid

d. syrup

17. 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

18. MoU stands for

a. Memorandum of Ubiquitous

b. Memorandum of understanding

c. Memorandum of Unpredictable

d. Memorandum of Unprofitable

19. The definition of quality Risk management has been mentioned in ICH guideline

a. Q7

b. Q8

c. Q9

d. Q10

20. Quality management system deals with

a. Quality for their product and services

b. Safety for their products and services

c. Quality and safety for their products

d. Quality and safety for their products and services

SEC-B (2X10)

ATTEMPT ANY TWO

21. Describe historical overview of regulatory affairs and role of regulatory affairs department.

22. Illustrate the function of technology transfer agencies in India.

23. Define and describe six sigma conceptNABL and GLP.

SEC-C (7X5)

ATTEMPT ANY SEVEN

24. Describe pilot plant scale up considerations for liquid

25. Discuss IND, NDA, ANDA and clinical research protocol.

26. Summarize regulatory authorities and responsibility of regulatory affairs professionals.
27. Define CDSCO and state licensing authority.
28. Conclude concept of quality and total quality management.
29. Interpret technology transfer protocol and transfer from R&D to production.
30. What are the regulatory requirements and approval procedures for new drugs.
31. Analyze COPP, NABL, and GLP.
32. Explain the following terms TIFAC,BCIL,NRDC and SIDBI.