2024/05

SET A

B. PHARM.
EIGHTH SEMESTER
PHARMACEUTICAL REGULATORY SCIENCE
BP804ET

[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. List of approved drugs and their associated IPR is available in_____
   a. Pink book b. Orange book
   c. Red book d. Indian pharmacopoeia
2. Identify the relevant regulatory body in USFDA for approval of drugs
   a. BLA b. IND
   c. CBER d. CDER
3. Rule 96 means-
   a. Manner of packaging b. Manner of importing
   c. Manner of labelling d. Manner of distributing
4. How many types of DMF are there-
   a. 5 b. 3
   c. 2 d. 4
5. Placebo means-
   a. New medicine b. Medically effectual treatment
   c. Medically ineffectual treatment d. Clinical study
6. Drug regulatory body of Brazil is-
   a. TGA b. SFDA
   c. MHLW d. ANVISA
7. Which regulatory body reviews and updates the Indian pharmacopoeia.
   a. WHO b. CDSCO
   c. IPC d. DTAB
8. The Clinical trial legislative requirements are guided under-
   a. Schedule Y b. Schedule T
   c. Schedule C d. Schedule X
9. On _____, the CTD became the mandatory format for NDA in the EU and Japan.
   a. June 2003 b. January 2003
   c. July 2003 d. July 2013
10. Comparative trial is also known as-
    a. Three arm head-to-head study b. Placebo
    c. Two arm head-to-head study. d. Phase I clinical study

11. IRB means
    a. Institutional review board
    b. Independent review board
    c. Indian review board
    d. International review board

12. Type I DMF deals with -
    a. Packaging materials
    b. Manufacturing site
    c. Drug substance
    d. Excipients

13. Who reviews,evaluates and approves the scientific and ethical aspects of a clinical trial
    a. ICH
    b. CPCSEA
    c. IPC
    d. IRB/IEC

14. The CFR is divided into -
    a. 40 titles
    b. 25 titles
    c. 50 titles
    d. 10 titles

15. Narcotic and psychotropic substances Act and rules was established in-
    a. 1985
    b. 1986
    c. 1954
    d. 1956

16. Informed consent form is also known as-
    a. Informed consent document
    b. Patient consent form
    c. Both (a) and (b)
    d. None of the above

17. The standard format of submitting the regulatory information to health authority is -
    a. CTD
    b. eCTD
    c. DMF
    d. ACTD

18. Which schedule specifies the general requirements for factory premises and materials-
    a. Schedule Y
    b. Schedule G
    c. Schedule T
    d. Schedule M

19. MHLW is a regulatory body of -
    a. India
    b. Europe
    c. Japan
    d. China

20. NPPA means-
    a. National pharmaceutical pricing authority
    b. National pharmacy product act
    c. New pharmacy product advertisement
    d. National public protection act

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PART-B :Descriptive

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

[Answer any seven (7) questions]

1. Explain in details about the phases of clinical trials. **5**

2. What is a purple book. Mention the purposes of a purple book. **1+4=5**

3. Explain NDA and classify the drugs in NDA. **1+4=5**

4. What a short note on CTD. What are the various modules of CTD. **2+3=5**

5. Write about IRB/IEC mentioning its composition and procedures. **2+3=5**

6. Write short notes on: **2.5+2.5 =5**
   a. CDSCO
   b. DTAB

7. Explain about "Concept of generics". **5**

8. Write about **a)** Narcotic and psychotropic Act. **b)** Consumer Protection act. **2.5+2.5 =5**

9. Write about the rules related to export of drugs from India. **5**

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PART-C: Long type questions

[Answer any two (2) questions]

1. Write and explain in details about the stages of drug discovery. **10**

2. Write short notes on: **5+5=10**
   a. Innovator drugs
   b. Orange book

3. Explain in details about the steps involved in developing clinical trial protocols. **10**

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