REV-01
BPH/40/20/25

2023/06

SET B

B. PHARM.
EIGHT 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. Form 41 of CDSCO is
   a. Registration certificate for drug
   b. Import License for drug
   c. Import of drug in small quantity for analysis
   d. Registration certificate for import of drug & cosmetic to India

2. Which of the following is an International regulatory authority for drug regulation
   a. WHO
   b. CDSCO
   c. EMA
   d. USFDA

3. Form 11 of CDSCO
   a. Import of drug in small quantity for analysis
   b. Registration certificate for import of cosmetic to India
   c. Registration certificate for drug
   d. Import License for drug

4. DHHS Stands for
   a. Department of Health and Human Service
   b. Department of Hard and Hearing Service
   c. Department of Health and Hygiene Service
   d. None of the above

5. CFR stands for
   a. Code of Federal Register
   b. Centre of Federal Regulator
   c. Centre of Federal Regulations
   d. Code of Federal Regulations

6. Part of 314 under 21 CFR is
   a. Guideline for Biological Product
   b. Guideline for GLP
   c. Guideline for OTC product
   d. Guideline for application of FDA approval to market a new drug

7. _____ is the report to the authorities for generic drug registration and marketing.
   a. IND
   b. ANDA
   c. Orange book
   d. NDA

8. _____ is responsible for approval of new drugs in India
   a. CDER
   b. RDTL
   c. ICMR
   d. CDSCO

9. Regulation (EC) no 726/2004 is of which agency
   a. USFDA
   b. CDSCO
   c. EMA
   d. CDSCO

10. How many laboratories are responsible for quality control of drug and cosmetic under CDSCO
    a. 5 b. 6
    c. 8 d. 7

11. FDA stands for
    a. Food and Drug Act b. Federal Drug Administration
    c. Food and Drug Authority d. Food and Drug Administration

12. 21CFR 314.70 provided for
    a. Post approval changes of NDA and ANDA drugs. b. Pre approval changes of IND
    c. Pre approval changes of NDA and ANDA drugs d. None of the above

13. Application to Therapeutic Goods Administration comes under section
    a. Section 23A b. Section 23B
    c. Section 24B d. Section 24A

14. East Zone office of CDSCO located in
    a. Mumbai b. Kolkata
    c. Guwahati d. Chennai

15. GCP stands for
    a. Good Clinical Practice b. Good Clinical Procedure
    c. Good Company Practice d. None of the above

16. Fill in the blanks
    Drug and Cosmetic Act (.....) and Rule (.....)
    a. 1940,1948 b. 1942,1948
    c. 1942,1945 d. 1940,1945

17. Who is the Current Drug Controller General of India
    a. Dr V G Somani b. Sri Jaisukh lal Hathi
    c. Dr Rajeev Singh Raghuvanshi d. Rajsekhar Mali

18. NDA application is reviewed by
    a. WHO b. CDER
    c. ICMR d. None of the above

19. DMF stands for
    a. Discovery of Medicine and Food b. Drug and Manufacturing Fault
    c. Drug Master File d. Dose Master File

20. ANDA stands for
    a. Appropriate New Drug Application b. Authorized New Drug Application
    c. Abbreviated New Drug Application d. None of the above

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PART-B :Descriptive

Time : 2 hrs. 30 min. Marks : 35

[Answer any seven (7) questions]

1. Write down the objective of ICH. 5
2. Describe the regulatory approval procedure for IND and ANDA. 5
3. Mention the formation and working procedure of IRB. 2+3=5
4. Write a note on Federal Register. 5
5. Which agency regulates the drug in United State? Write in details. 5
6. What are the different changes to an approved NDA and ANDA? 5
7. What is the Declaration of Helsinki? How an act is amended after establishing a law in a regulatory body? 2+3=5
8. What is GCP? Describe its principles. 1+4=5
9. Discuss about the stages of clinical trials. 5

PART-C: Long type questions

[Answer any two (2) questions]

1. What is Orange book? Mention the scientific rationale parts to develop a clinical trial protocol. **2+8=10**

2. Write down about the regulatory authorities involve in drug discovery of India. Describe the stages of drug discovery. **4+6=10**

3. What is Blinding Techniques in Clinical Trials? Draw the organizational flowchart of FDA. **4+6=10**

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