Paper / Subject Code: 14224 / Pharmaceutical Regulatory Science T.Y.

Sem-VIII final year B.Pharm 29/04/25

Time: 3 hours **Total Marks: 75**

Please check whether you have got the right question paper.

1. All questions are compulsory
2. Figures to the right indicate marks

Q I Multiple Choice Questions (20)

1 In clinical studies post marketing surveillance is a part of .....
- a Phase I
- b Phase II
- c Phase III
- d Phase IV

2 New drug application is filed under following section of Federal FD&C act
- a 505 b1
- b 505 b2
- c 505 j
- d 505 a

3 Type IV DMF is applicable for
- a Drug substance
- b Excipient
- c Manufacturing site
- d Packaging material

4 Orange book data base is published by regulatory agency of following country
- a USA
- b Europe
- c India
- d Japan

5 Medicines and Health Care Products Regulatory Agency (MHRA) is regulatory body of
- a USA
- b UK
- c Canada
- d South Africa

6 IND is referred to as
- a Investigational New Drug
- b Investigational Novel Drug
- c Investigational Novel Dosage
- d Investigational New Dosage

7 Following body in USFDA for approval of drugs
- a BLA
- b IND
- c NDA
- d CDER

8 CMC stands for
- a Chemistry, Manufacturing, and Controls
- b Chemical and Medicinal Control
- c Chemical and Manufacturing Control
- d Chemical and Managerial Control

9 The application that contains information to show that the proposed product is identical to previously approved reference listed drug (RLD) is known as
- a ANDA
- b NDA
- c IND
- d ADA

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10 Module 4 of CTD deals with
   a Clinical study reports
   b Non clinical study report
   c Quality reports
   d Administrative reports

11 Committee for Medicinal Products for Human Use (CHMP) comes under
   a FDA
   b EMEA
   c TGA
   d MHRA

12 Generic companies that are first to file ANDA are get marketing exclusivity for ------ days
   a 120 days
   b 90 days
   c 180 days
   d 45 days

13 SUPAC means
   a Scale up post approval changes
   b Scale up pre approval changes
   c Scale up pre agreement changes
   d Scale up post agreement change

14 Para II filing for ANDA certification indicates that
   a No relevant patent is listed in the Orange Book
   b The listed patent has expired
   c The listed patent, plus any other exclusivity, will expire before the requested approval
   d The listed patent is invalid or will not be infringed by the commercialization of the generic drug

15 Marketing Authorization Application (MAA) is submitted to regulatory agency of
   a USA
   b Europe
   c India
   d Japan

16 Institutional review board monitors
   a biomedical research involving animals
   b biomedical research involving cell lines
   c biomedical research involving human subjects
   d biomedical research involving pathogens

17 Following ICH guideline applies to Good Clinical Practice(GCP)
   a E5
   b E6
   c E7
   d E8

18 Following member ensures safety of subjects participating in clinical trial
   a Investigator
   b Sponsor
   c Patient
   d Reviewer

19 How many drugs can be imported under single Form 11 license
   a 20
   b 5
   c 10
   d 15

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20 Drug regulatory Authority of Japan is

a TGA

b SFDA

c MHLW

d ANVISA

Q. II Attempt any two questions out of three **(20)**

I. A. Enlist the various stages of drug discovery & development of new medicine and discuss in clinical studies. 5

B. Explain the concept of marketing exclusivity and mention different types 5

II. A Write a note on NDA 5

B Explain the key features of Hatch and Waxman Act 5

III A What is ASEAN CTD? Explain in detail. 5

B Explain the organization and functions of European Union regulatory agency 5

Q. III Attempt any seven questions out of nine **(35)**

1. Explain the composition and role and responsibilities of Institutional Review Board 5
2. Write a note on Orange book database and mention its coding system 5
3. What is DMF? Explain different types of DMF 5
4. Discuss the contents of clinical trial protocols 5
5. Differentiate between innovator and generic drug product 5
6. Differentiate between IND and ANDA 5
7. Explain GCP obligations of investigators, sponsors and monitors 5
8. Enlist different filing systems for EU drug approval. Write a note on Decentralized procedure for approval of drug in EU 5
9. Explain the different modules of CTD in detail 5

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