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

Note:-All questions are compulsory

Figures to the right indicate marks

Please check whether you have got the right question paper.

Q I **Multiple Choice Questions** (20)

1 In clinical studies for new chemical entity, safety evaluation is done in
- 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

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

20 Drug regulatory Authority of Australia 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	Discuss the application and approval process for NDA	5
	B	Explain the key features of Hatch and Waxman Act	5
III	A	Write a note on ASEAN CTD	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.	Explain the concept of SUPAC guidelines with reference to immediate release dosage forms	5
6.	Differentiate between IND and ANDA	5
7.	Explain GCP obligations of investigators, sponsors and monitors	5
8.	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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