Jan 2024
MPH MPH 104 T
Semester I

Time: 3hr **Marks: 75**

Q.1 Attempt all multiple –choice questions (MCQ) **20M**

Sr.No./Options Questions

1 The nonclinical study reports should be presented in CTD is described in Guideline
a M4S
b M4Q
c M4E
d M4R

2 Fixed-dose combination means
a A particular combination of actives irrespective of the formulation or brand
b A finished pharmaceutical product that contains two or more actives
c A product consisting of two or more separate pharmaceutical combination products in their final dosage form
d Actives that have not previously been authorized for marketing as a drug for use in humans

3 ICH Q1 C guideline is applicable for
a Stability testing for new dosage form
b Impurities in drug product
c Product Development
d Quality Risk Management

4 The content and format of following CTD module is specific to individual Regulatory Authorities
a Module 1
b Module 2
c Module 3
d Module 4

5 Drug Regulatory agency of Australia is
a TGA
b CDSCO
c MHRA
d ANVISA

6 The term of patent is valid for the period of 20 years from the
a Date of approval
b Date of examination
c Date of publication

d Date of filing of application

7 The CFR is divided into ---------titles that represent broad area subject to federal regulation

a 40
b 45
c 50
d 55

8 ASMF stands for

a Assessment of substance master file
b Active substance master formula
c Assessment of substance main formula
d Active substance master file

9 21 CFR include --------- chapter

a 1
b 3
c 2
d 4

10 Master formula record is used for the preparation of

a Batch manufacturing record
b SOP
c Drug master file
d Validation record

11 List of approved drugs and their associated IPR is available in _____

a Pink book
b Orange book
c Red book
d Black book

12 _____product does not require a BLA

a Serum
b Blood, blood component or derivative
c Glucagon
d Vaccine

13 The "Certificate of Suitability" as per EU guidelines is valid for..... years from the date when the original certificate was granted.

a 5
b 10
c 15
d 20

14 Marketing Authorization Application (MAA) is an application to the relevant authority to market a drug or medicine in

a US market
b Europe market
c Canadian market
d All countries

15 The therapeutic biological products include all except

a Monoclonal antibodies for in-vivo use
b Cytokines, growth factors, enzymes, immunomodulatory; and thrombolytic
c Other non-vaccine therapeutic immunotherapy
d Synthetic API

16 Whose responsibility is to prepare essential documents like informed consent form, protocol, IB in clinical trials

a Investigator
b Ethics committee
c Scientist
d Sponsor

17 Requirement of IMPs (investigational medical products) to be tested in clinical studies Except phase

a Phase I
b Phase II
c Phase III
d Phase IV

18 21 CFR 320 apply to ANDA stands for

a New drugs
b Bioavailability and Bioequivalence requirements
c Application for FDA approval to market new drug
d Rejected drug applications

19 What is PHI

a Protected Hospital Information

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b Protected Harmful Information
c Protected Health Information
d None of These

20 CDSCO stands for
a Central Drugs Standard Control Organization
b Central Drugs Safety Control Office
c Central Directory For Safety And Control Of Organization
d Central Drugs Safety Control Office

Q. 2. Attempt any two questions **20 M**

1. Explain in detail the application and approval process for ANDA
2. Explain in detail the procedure of product approval process of biological
3. Define and compare common technical document (CTD) and electronic common technical document (eCTD). Explain different modules in CTD and eCTD.

Q. 3. Attempt any seven questions **35 M**

I. Elaborate on need of bioequivalence studies
II. Regulatory requirement for API approval
III. What are the objectives of the International conference on harmonization (ICH)? Enlist quality guidelines
IV. Briefly describe the global submission of ANDA (Abbreviated New Drug Application)
V. What is IMPD and IB
VI. Explain the global submission of IND (Investigational New Drug)
VII. Discuss the composition and function of IRB/IEC (Institutional Review Board/ Independent Ethics Committee)
VIII. What is HIPAA new? Highlight contents of it.
IX. Write note on framework for Pharmacovigilance during clinical trials

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