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. No.

I Choose the appropriate option for following multiple choice based questions. (write the correct option and the correct answer) (20 Marks)

1 If a new drug is indicated in hypertension, phase 1 studies on the drug are conducted in

(a) Hypertensive subjects
(b) Healthy subjects
(c) Mix of healthy subjects and hypertensive subjects
(d) Diabetic subjects

2 Generic drug is

(a) the drug launched without regulatory approval
(b) the drug for which original patent is expired
(c) the drug for which patent is infringed
(d) synonym for innovator drug

3 Prior to a subject's participation in the trial, the written informed consent form should be signed by

(a) any physician
(b)the subject or by the subject's legally acceptable representative
(c)the subject only
(d)the subject's legally acceptable representative only

4 Screening tests are done to
(a)indicate presence or absence of a particular pharmacodynamic activity
(b)find out pharmacokinetic activity
(c)infer on efficacy
(d)conclude on adverse effects

5 Which is the Drug regulatory agency of country UK?
(a) TGA
(b) SAHPRA
(c) MHRA
(d)ANVISA

6 CTD is a joint effort of
(a)DCGI and EMEA
(b)EMEA and US FDA
(c)MHLW and US FDA
(d)EMEA, US FDA and MHLW

7 DMF Holder sends how many copies of DMF to US (United States) FDA
(a)5
(b)2
(c)1
(d)3

8 Adverse event means
(a)any medical occurrence associated with the use of a drug in humans, considered drug related
(b) any untoward medical occurrence associated with the use of a drug in humans, considered drug related
(c) any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related
(d) only severe allergic reaction

9 IEC should contain at least..
(a)5 members
(b)7 members
(c)3 members
(d)2 members

10 As per documentation rules
(a)entries can be made only with pencil
(b) entries should be made with inedible medium
(c)overwriting without signature is appropriate
(d)correction made in the document need not be signed

11 Part 2 of ACTD should contain
(a)clinical document
(b)quality document
(c)non clinical document
(d) manufacturing document

12 In India, shipment bill is to be obtained from customs department by
(a)An exporter after exporting his pharma products
(b)An importer before importing his pharma products
(c) an exporter before getting his pharma products ready to ship from India
(d)An importer after importing his pharma products

13 The CFR is divided into _____titles that represent broad areas subject to federal regulation
(a)40
(b)50
(c)45
(d)55

14 Which type of ANDA filing is used when the patent for the drug has already been expired?
(a)Para I
(b)Para II
(c)Para III
(d)Para IV

15 _____provides instructions how changes to an approved NDA should be reported to US FDA
(a) 21 CFR 314.70
(b) 21 CFR PART 14
(c) 21 CFR 211
(d) 21 CFR 820

16 In silico studies means_____
(a)studies using living organisms
(b)studies performed on computer
(c) studies done in controlled environment outside living organism
(d) studies done using silicon crucible

17 The ANDA for generic drug approval should comprise of
(a)bioequivalence to the brand name product
(b)only animal toxicity studies
(c)only clinical studies
(d)animal toxicity studies and clinical studies

18 _____is the centre within US FDA that regulates biological product for human under applicable federal laws
(a)CBER
(b)PHS
(c)CDER
(d) Bureau of Biologic

19 ANDA form includes
(a)356h
(b)354i
(c)353g
(d)356i

20 INDA requires completion of following forms.
(a)1575 and 3224
(b)1574 and 3574
(c)1571, 1572 and 3674
(d) 1570, 1574 and 3672

2 Answer any 2 questions (20 marks)

1 Explain drug approval process in Europe

2 Explain steps in drug development process.

3 What is ICH Guideline? What are the objectives? Write in detail CTD and its modules

3 Answer any 7 questions (35 marks)

1 Give an overview of orange book and purple book

2 Write constitution of IRB and enlist its four functions.

3 Write role of DMF and enlist its components

4 Differentiate between innovator and generics drug product

5 Enlist four GCP obligations of sponsor towards clinical trials and explain any two

6 Explain the post approval changes for USFDA

7 Write a note on drug regulatory authorities of Australia

8 Differentiate between CTD and eCTD

9 Write the drug regulatory body for India, Canada, Japan, EU and Australia

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