Question Paper

Exam Date & Time: 20-May-2024 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Pharmaceutical Regulatory Science [PRM-BP804ET -S1]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) What is the primary goal of preclinical testing? (1)

- Testing the drug in humans
- Assessing drug safety and efficacy
- Identifying potential drug targets
- Investigating drug metabolism and toxicity

2) Which of the following is NOT a primary step in drug discovery and development? (1)

- Target identification
- Preclinical testing
- Clinical trials
- Marketing

3) What is the term for the process of modifying a drug's chemical structure to optimize its properties? (1)

- Drug formulation
- Drug metabolism
- Drug synthesis
- Drug design

4) What is the primary advantage of generic drugs over branded drugs? (1)

- They have different active ingredients
- They are usually cheaper
- They have better efficacy
- They have fewer side effects

5) What is bioequivalence? (1)

- The chemical similarity between a generic drug and its branded counterpart
- The ability of a generic drug to be absorbed and distributed in the body at the same rate and extent as the branded drug
- The efficacy of a generic drug compared to its branded counterpart
- The safety profile of a generic drug compared to its branded counterpart

6) Which ministry oversees the functioning of CDSCO in India? (1)

- Ministry of Health and Family Welfare

Ministry of Science and Technology
Ministry of Commerce and Industry
Ministry of Chemicals and Fertilizers

7) What is the primary role of Health Canada? (1)

Ensuring food safety and Health
Regulating pharmaceuticals and medical devices
Conducting medical research
Providing healthcare services

8) Which phase of clinical trials typically follows the submission of an IND application? (1)

Phase I
Phase II
Phase III
Phase IV

9) What does NDA stand for in the pharmaceutical industry? (1)

New Drug Assessment
New Drug Application
Novel Drug Approval
National Drug Authorization

10) How does an ANDA differ from an NDA? (1)

ANDA is for generic drugs, while NDA is for new drugs
ANDA requires more extensive clinical data than NDA
ANDA is submitted before clinical trials, while NDA is submitted after
ANDA is only applicable for biologic drugs, while NDA is for small molecule drugs

11) Select the responsibility/s of RA personnel..... (1)

To analyze the content of the active ingredient in the formulation
Work with federal, state and local governing agencies to get the approval for drug
To undertake stability studies of the drug products
To supervise the production of the formulation

12) List of approved drugs and their associated IPR is available in _____ (1)

Pink book
Orange book
Red book
Black book

13) Identify the relevant regulatory body in USFDA for approval of drugs. (1)

BLA
IND
CBER
CDER

14) CTD is divided into .....modules (1)

3
4
5

6

15) In pharmacovigilance the term ADR stands for _____ (1)

Adverse Drug Reaction
Adverse Dose Reaction
Absolute Drug Reaction
Absolute Dose Reaction

16) Which of the following is regulatory authority of Australia? (1)

Pharmaceutical and Medical Devices Agency
Therapeutic Goods Administration
Medicines and Healthcare Products Regulatory Agency
Central Drug Standard Control Organization

17) Which of the following is an International regulatory authority for drug regulation? (1)

CDSCO
US-FDA
WHO
EMA

18) Marketing Authorization Application (MAA) is an application to the relevant authority to market a drug or medicine in... (1)

US market
Europe market
Canadian market
All countries

19) ASMF stands for..... (1)

Active substance master file
Assessment of substance master file
Active substance master formula
Assessment of substance main formula

20) The information of an ASMF is divided into.....parts. (1)

5
3
2
4

II Long Answers

Answer all the questions.

1) Describe the process of New Drug Discovery and Development, including the key stages, from initial research to market approval. Add a note on the role of preclinical studies in the process of New Drug Discovery and Development. (7+3=10marks) (10)

2) Write a note on Code of Federal Regulations and responsibilities of RA professionals. Discuss orange book and purple book. (6+4=10marks) (10)

III Short Answers

Answer all the questions.

1) Discuss in brief classification of generic drugs. What is the deference between bioequivalence, therapeutic equivalence, and pharmaceutical equivalence? (3+2=5marks) (5)

2)	What is INDA, NDA and ANDA for? Discuss key components of ANDA.	(5)
3)	What are the functions of European Medicines Agency? Discuss in brief the committees of EMA.	(5)
4)	What is institutional review board? Describe formation and working procedure.	(5)
5)	Write a note on ACTD.	(5)
6)	Differentiate between Bills, Ordinance, Act, Rules, Regulations, Section and Article.	(5)
7)	Discuss some unfortunate events that catalysed the development of medicines regulation. Enlist ICH SC members.	(5)

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