Question Paper

Exam Date & Time: 13-Jan-2021 (01:30 PM - 04:30 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Industrial Pharmacy [PCE-BP702T - S2]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Therapeutic confirmatory trials are part of which phase of a clinical trial? (1)
a) Phase IV
b) Phase III
c) Phase II
d) Phase I

a
b
c
d

2) 'Therapeutic Goods Administration' is the drug regulatory agency of which geography? (1)
a) USA
b) Australia
c) UK
d) Brazil

a
b
c
d

3) Which of the following can be a sponsor for a clinical trial? (1)
a) Government agency
b) Scientific institution
c) Drug manufacturer
d) All the above

a
b
c
d

4) An Investigational New Drug Application is not required for which of the following? (1)
a) New Chemical Entity
b) New dosage level
c) Generic drug
d) Previously unapproved combination of two drugs

a
b
c
d

5) Which of these statements is not correct? (1)
a) A DMF cannot be used to support an NDA
b) DMF is reviewed upon receipt letter of authorization from the API manufacturer
c) Certificate of suitability is recognized by USFDA
d) Part of a DMF may be submitted to API customer

a
b
c
d

6) Which of the following is not part of an INDA? (1)
a) Animal pharmacology studies
b) Manufacturing information
c) Clinical protocols and investigator information
d) Results of clinical trial

a
b
c
d

7) An Indian pharmaceutical company has to seek permission from which of the following agencies for import of new drug?___ (1)
a) Indian Council of Medical Research
b) Central Drugs Standard Control Organization
c) Department of Science and Technology
d) Department of Biotechnology

a
b
c
d

8) Which of the following is used for permission to manufacture/ import a new drug in India? ____ (1)
a) Form 45
b) Form 48
c) Form 44
d) Form 43

a
b
c
d

9) Which of these is a part of Schedule Y? (1)
a) Animal pharmacology data
b) Chemical and pharmaceutical information
c) Animal toxicology data
d) All of the above

a
b
c
d

10) CTD format is used for which of the following? (1)
a) Application for permission to import new drug
b) Conduct of clinical trial
c) Conduct of paediatric toxicology studies
d) Permission to conduct local clinical trials

a
b
c
d

11) What is full form of NRDC? (1)
a) National research development corporation
b) National research on drug consumption
c) National regulatory and drug community
d) National regulation and drug corporation

a

b
c
d

12) ISO 14000 is related --------- (1)
a) to help companies reduce industrial waste and environmental damage
b) to help companies sell drug at lower cost
c) to help company develop automatic technology transfer process
d) to help company procure and sell API

a
b
c
d

13) Full form of APCTD is ---------- (1)
a) The Asian and Pacific Centre for Transfer of Technology
b) The Asian and Pacific centre for technology Transfer
c) The Asian and Pacific Corporation for Transfer of Technology
d) The Asian and Pacific Corporation for Technology Transfer

a
b
c
d

14) WHO guideline is for technology transfer of (1)
a) API
b) Excipients
c) Documents
d) All of the above

a
b
c
d

15) What is full form of TIFAC? (1)
a) Technology Information, Forecasting and Assessment Council
b) Technology Information for Formulation and Assessment Council
c) Technology in Forecasting and Assessment of Council
d) Technology Information of Forecasting and Assessment in Council

a
b
c
d

16) Technology transfer is related to ------- (1)
a) Packaging and cleaning
b) API and Excipients
c) Materials and method transfer
d) All of the above

a
b
c
d

17) Full form of WHO is ---------- (1)
a) World Health Organization
b) World for Health Organization
c) World of Health Organization
d) World in Health Organization

a
b
c

d

18) SIDBI stands for ---------- (1)
a) Small Industrial Development Bank of India
b) Small Industrial Drug Bank of India
c) Scale up of Industrial Development Batch of India
d) Scale up for Industrial Dosage Batch in India

a
b
c
d

19) COPP stand for (1)
a) Certificate of Pharmaceutical Product
b) Certificate of Pharmacy Product
c) Certificate in Pharmacy and Production
d) Certificate for Pharmaceutical Production

a
b
c
d

20) CDSCO is related to --------- (1)
a) Technology Transfer
b) Production
c) Regulatory requirements
d) QbD

a
b
c
d

II Long Answers

Answer all the questions.

1) Define drug regulatory affairs. Describe any two drug-development teams in detail. (10)

2) Explain the concept of TQM. (10)

III Short Answers

Answer all the questions.

1) Describe the scale-up considerations for fluid bed granulation. (5)

2) Write the importance of pilot plant batch in the manufacture of pharmaceuticals. Describe any two considerations in pilot plant scale-up. (5)

3) What chemical and pharmaceutical information is required to be submitted to the regulatory agency for manufacture of a new drug in India? (5)

4) What are Scale-up and post-approval changes? Give reasons for changes to an approved ANDA. Give the criteria for a batch size change to be classified under SUPAC Levels 1 and 2. (5)

5) Write a short note on COPP (5)

6) Add a note on TIFAC (5)

7) Explain Transfer of Packaging Materials in detail. (5)

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