Question Paper

Exam Date & Time: 29-Dec-2021 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Industrial Pharmacy [PCE-BP702T]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Which of the following is not true with respect to scale-up of dry blending? (1)

- Geometric similarity of equipment between scales should not be maintained
- Low-dose API is preferably added to the blender before addition of excipients
- Mixing efficiency is highest below 10% fill level of the blender
- All the above

2) The responsibility for pilot plant studies belongs to ___. (1)

- only R&D scientists
- only Production team
- Separate pilot plant team
- Any of the above

3) Which of these is applicable to scale-up of fluid bed granulation operation? (1)

- Roller pressure
- Spray rate
- Impeller diameter
- Roller speed

4) If the data shows that the process performs consistently at critical step to produce a product that falls within release specification, then that process is said to be _____ (1)

- Qualified
- Calibrated
- Validated
- Installed

5) Which of these is not a part of the GMP checklist with respect to scale-up of a new product or process? (1)

- Equipment qualification
- Availability of SOPs
- Training of personnel
- Modification of product specification

6) An Indian pharmaceutical manufacturer has to seek permission from which of the following agencies for import of new drug? (1)

- ICMR
- CDSCO

DST

DBT

7) Which of the following is used for permission to manufacture/ import a new drug in India? ____ (1)

Form 49

Form 471

Form 44

Form 50

8) 'ANVISA' is the drug regulatory agency of which geography? (1)

USA

Australia

UK

Brazil

9) Which of the following can be a sponsor for a clinical trial? (1)

Government agency

Scientific institution

Drug manufacturer

All the above

10) Investigational New Drug application is not required for which of the following? (1)

New Chemical Entity

Generic drug

New dosage level

Previously unapproved combination of two drugs

11) According to Six Sigma Concept, the accuracy of process and products manufactured are statistically expected to be free of defects with..... (1)

3.4 defects in million

4.3 defects in million

3.3 defects in million

4.4 defects in million

12) The definition of Quality Risk Management (QRM) has been mentioned in ICH guideline ..... (1)

Q7

Q8

Q9

Q10

13) Installation Qualification (IQ) is ..... (1)

A documented verification of the proposed design of the facilities, systems and equipments.

An evidence of all key aspects of the process equipment and ancillary system installation.

Objective evidence process for the control limits and action levels in product of all predetermined requirements.

Verifying a process, under anticipated condition, consistently produces a product which meets all predetermined requirements

14) Out of Specification deals with..... (1)

If the analytical result(s) or batch or material is/are falling within the established specification ranges

If the analytical result(s) or batch or material is/are falling outside the established specification ranges

Both of these

None of these

15) Which one of the following law was passed in 1945 by the Indian Government? (1)

The poisons Act

Drug Enquiring committee

The Drugs and Cosmetics Rules

The Narcotic Drugs and Psychotropic Substances Act

16) Important component of technology transfer involves all of the following except (1)

Proper Research & paper work

Pricing & publicity

Partnership & People's Acceptance

FDA's sanction

17) ..... Is/ are the guidelines for defining to handle the OOS products/materials/batches (1)

MHRA guidelines

CDER guidelines

PIC/S guidelines

All of the above

18) Give the full form of TIFAC (1)

Technology in Forecasting and Assessment of Council

Technology Information for Formulation and Assessment Council

Technology Information of Forecasting and Assessment in Council

Technology Information, Forecasting and Assessment Council

19) Identify which of the below is ISO 14000 related to? (1)

To help companies sell drug at lower cost

To help companies reduce industrial waste and environmental damage

To help company develop automatic technology transfer process

To help company procure and sell API

20) Which one of the following place is not having zonal office of CDSCO (1)

Ahmedabad

Mumbai

Bangalore

Chennai

II Long Answers

Answer all the questions.

1) Describe the scale-up considerations in the manufacture of tablet dosage form. (10)

2) Discuss in detail about Central Drug Standard Control Organization (CDSCO) (10)

III Short Answers

Answer all the questions.

1)	Describe Investigators' brochure and Investigational New Drug Application	(5)
2)	Write a note on drug discovery project-team and the disciplines associated with this team	(5)
3)	Describe the chemical and pharmaceutical information to be submitted to the regulatory agency for manufacture of a new drug in India	(5)
4)	Write a note on the drug discovery project-team and the disciplines associated with this team	(5)
5)	Discuss and Elaborate practical aspects and problems in commercialization	(5)
6)	Explain Out of Specification (OOS) concept	(5)
7)	What is technology transfer? Write in details WHO guidelines for technology transfer	(5)

-----End-----