Exam Date & Time: 03-Dec-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Industrial Pharmacy II [PCE-BP702T - S3]

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

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Which of these is not applicable to scale-up of fluid bed granulation operation?

1)	Atomization air pressure		2)	Spray rate		3)	Air volume		4)	Roller speed	

(1)

2) ASMF refers to:

1)	Active Specification Manufacturing Formula		2)	Active Substance Master File		3)	Active Substance Manufacturing Formula		4)	Active Specification Manufacturing File	

(1)

3) Which of these is the goal of an NDA?

1)	To approve the marketing strategy of a new drug		2)	To approve the marketing strategy of a generic drug		3)	To determine the safety and effectiveness of a new drug for its proposed use		4)	To determine the safety and effectiveness of a generic drug for its proposed use	

(1)

4) In the context of drug regulatory affairs, MAA refers to ___.

1)	Marketing Approval Application		2)	Marketing Authorisation Application		3)	Marketing Approval Authorisation		4)	Marketing Authorisation and Approval	

(1)

5) A process is said to be validated when the product ____

1)	Falls within release specification		2)	Falls outside release specification		3)	Falls within release specification 50% of the times		4)	Falls within release specification 60% of the times	

(1)

6) The vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S is:

(1)

1)	NDA		2)	INDA		3)	ANDA		4)	IB	

7) DMF is prepared by ____.

1)	API manufacturer		2)	API customer		3)	Regulatory agency		4)	Regulatory reviewer	

(1)

8) Changes to approved NDA can occur due to:

1)	Revised market forecast		2)	Qualification of new API source		3)	Optimization of manufacturing process		4)	All the above		(1)

9) Medicines Control Council is the regulatory agency for: (1)

1)	India		2)	Canada		3)	Brazil		4)	South Africa	

10) CEP - certificate that proves that a substance qualifies to the relevant monographs of the ___

1)	European Pharmacopoeia		2)	Japan Pharmacopoeia		3)	US Pharmacopoeia		4)	Australia Pharmacopoeia		(1)

11) Generally, reporting head for scale-up studies

1)	R&D head or Formulator who developed product		2)	QC department		3)	Management		4)	None of the above		(1)

12) CDSCO is related to

1)	Technology Transfer		2)	Production		3)	Regulatory requirements		4)	Quality-by-design		(1)

13) Pharmacovigilance is a part of .....

1)	ICH E1 guidelines		2)	ICH E3 guidelines		3)	ICH E2 guidelines		4)	ICH E2 (A-F) guidelines		(1)

14) The basic principle of ISO 9000 is .....

1)	Customer focus and Engagement of people		2)	Relationship management and Leadership		3)	Evidence based decision making and Continuous improvement		4)	All of these		(1)

15) Data used for filing process in technology transfer is of

1)	Scale up batch		2)	Exhibit batch		3)	R&D batch		4)	None of the above		(1)

16) The transfer of technology between sites of different companies is called as .....

1)	Inter-company transfer		2)	Intra-company transfer		3)	Technology transfer		4)	Technology transfer protocol		(1)

17) Six sigma concept includes .....

1)	Define, Measure, Analyze, Improve and Control		2)	Design, Measure, Analyze, Improve and Control		3)	Define, Manage, Analyze, Improve and Control		4)	All of these		(1)

18) Quality management system deals with ..... (1)

1)	Quality for their products and services		2)	Safety for their products and services		3)	Quality and safety for their products		4)	Quality and safety for their products and services	

19) Sir Bill smith is "Father of....."

1)	Technology Transfer		2)	Total Quality Management Systems		3)	Six Sigma		4)	Quality-by-Design	

(1)

20) Which of the following is not a scale-up process?

1)	Laboratory to pilot-scale		2)	Pilot-scale to industrial-scale		3)	Industrial to pilot-scale		4)	Laboratory to industrial-scale	

(1)

II Long Answers

Answer all the questions.

1) What is drug regulatory affairs? Describe the drug development teams. (10)

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

III Short Answers

Answer all the questions.

1) What are the components of Form 44? Describe the data to be submitted in the application for grant of permission to import or manufacture a new drug in India. (5)

2) Describe Investigational New Drug Application and Investigator's Brochure. (5)

3) Describe SUPAC level 1 changes for manufacturing (5)

4) Discuss in brief about ISO 14000 Standard (5)

5) Explain the concept of Total Quality Management (5)

6) Explain technology transfer process for premises and equipments (5)

7) Explain various technology transfer agencies in India (5)

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