Exam Date & Time: 16-Feb-2022 (10:00 AM - 01:00 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) Using which of the following, does a sponsor formally propose that the USFDA approve a new pharmaceutical for sale? (1)

1)	NDA		2)	ANDA		3)	INDA		4)	Any of the above	

2) DMF is prepared by ____.

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

3) In the context of drug regulatory affairs, MAA refers to ___. (1)

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

4) A process is said to be validated when the product ____ (1)

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	

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

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

6) Along with the application for permission to import a new drug, data has to be submitted by applicant (1) as per ____

1)	Schedule A		2)	Schedule Y		3)	Schedule B		4)	Schedule Z	

7) CDSCO regulates pharmaceutical products in which of the following geographies?

1)	Australia		2)	New Zealand		3)	India		4)	Argentina	

(1)

8) The disintegrant level in a tablet formulation was changed by 0.1% w/w during scale-up. Which of the following levels applies to this change, under SUPAC?

(1)

1)	Level 3		2)	Level 2		3)	Level 1		4)	Outside the ranges of SUPAC	

9) Which of the following is true with respect to scale-up of dry blending?

1)	It is preferable to maintain geometric similarity of equipment between scales		2)	Low-dose API is preferably added to the blender before addition of excipients		3)	Mixing efficiency is highest below 10% fill level of the blender		4)	Blender rpm should never be same between two scales	

(1)

10) 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		2)	Availability of SOPs		3)	Training of personnel		4)	Modification of product specification	

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)

12) Quality management system deals with .....

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	

(1)

13) ISO 14000 relies on .....

(1)

1)	DMAIC model		2)	PDCA model		3)	Six-sigma concept		4)	All of these	

14) The basic requirement of Technology Transfer is ..... (1)

1)	Sending Unit (SU)		2)	Receiving Unit (RU)		3)	Both (a) and (b)	4)	None of these

15) Technology Transfer documentation involves

1)	Master Formula Card		2)	Master packaging Card		3)	Master Formula	4)	All of the above	(1)

16) Which one of the following place is not having sub-zonal office of CDSCO (1)

1)	Chandigarh		2)	Jammu		3)	Bangalore	4)	Mumbai

16) Which one is not types of COPP?

1)	WHO 1975 type COPP		2)	WHO 1978 type COPP		3)	WHO 1988 type COPP	4)	WHO 1992 type COPP	(1)

18) For which of the following drugs COPP may be issued? (1)

1)	Approved drug products		2)	Unapproved drug products		3)	Active pharmaceutical ingredients (APIs)	4)	All of the above

19) DCGI stands for.....

1)	Drug Controller General of India		2)	Director Controller General of India		3)	Drug Controller Governor of India	4)	Director Controller Governor of India	(1)

20) CDSCO is related to

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

II Long Answers

Answer all the questions.

21) Define drug regulatory affairs. Describe any two drug-development teams in detail.

22) Elaborate the aspects of approval of new drug in India

III Short Answers

Answer all the questions.

23) What is SUPAC? 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)

24) Describe the scale-up considerations for fluid bed granulation.

25) Describe any five elements of a clinical trial protocol checklist.

26) Discuss in brief about ISO 14000 Standard

27) Explain Transfer of packaging materials in detail.

28) Write a note on APCTD

29) Explain the concept of Total Quality Management

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