Question Paper

Exam Date & Time: 29-Nov-2023 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
PQA - MQA 104T: PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Product Development and Technology Transfer [PQA-MQA104T - S3]

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

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1)		Explain the levels of manufacturing process changes with required documentation for regulatory approval for an approved drug product.	(10)
2)		"Particle size greatly affects a number of quality parameters like dissolution rate, solubility, bioavailability, content uniformity, and lack of grittiness". Explain the given statement with suitable examples.	(5)
	a.)		
	b.)	Discuss the application of particle size study during preformulation stage.	(5)
3)		Enlist the contents of NDA as per 21CFR part 314.	(5)
	a.)		
	b.)	Analyse the objectives of NDA review process of FDA using a flow chart.	(5)
4)		Write the differences between a biologic and a small molecule drug.	(5)
	a.)		
	b.)	Discuss the specification for biologics and biotechnology derived medicinal products.	(5)
5)		Explain the method transfer process flow.	(8)
	a.)		
	b.)	List the contents of analytical transfer package.	(2)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6)	Analyse the objectives of Phase 1 study as a part of drug development. Write a design for dose escalation study.	(5)
7)	Discuss the types of IND amendments with suitable examples.	(5)
8)	Write the key steps involved in data analytics.	(5)
9)	Explain the drug-excipient compatibility studies performed during preformulation studies.	(5)
10)	MedSigna has planned to market a solid dosage form in hot-dry zone country. Before initiating the regulatory submission, data for stability study should be ready. Based on this case, answer the following, a. Write the condition for the stability studies to be performed. (2 marks)	(5)

b. Explain the stability study detail for this drug product. (3 marks)

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