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SVKM'S NMIMS

Shobhaben Pratapbhai Patel / School of Pharmacy & Technology Management

Programme: M. Pharm / M. Pharm + MBA (PQA) **Year:** I **Semester:** I
Academic Year: 2019-20 **Marks:** 75
Subject: Product Development and Technology Transfer **Time:** 02.00 pm to 5.00 pm
Duration: 3 hrs.
Date: 22 November 2019 **No. of Pages :** 01

FINAL EXAMINATION

Instructions: Candidates should read carefully the instructions printed on the question paper and on the cover of the Answer Book, which is provided for their use.

1. Question No. 1 is compulsory.
2. Out of remaining questions, attempt any 4 questions.
3. **In all 5 questions to be attempted.**
4. All questions carry equal marks.
5. **Answer to each new question to be started on a fresh page.**
6. **Figures in brackets on the right hand side indicate full marks.**
7. **Assume suitable data if necessary.**

Q.1	A.	Write the basic requirements of pharmaceutical packging	**15**
	B.	Enlist the tests for closures used in pharmaceutical packaging	
	C.	Enlist the types of closures	
	D.	Write the phases of technology transfer	
	E.	Justify the need for BACPAC guidelines	
Q.2	A.	Write a note on cosolvency as a technique for solubility enhancement	**5**
	B.	Justify the need of a proper design and layout of a plant with suitable examples for successful pilot activity	**5**
	C.	Write the criterias for selection of pharmaceutical packaging materials	**5**
Q.3	A.	Enlist the contents of new drug application	**5**
	B.	Discuss different strategies adopted to improve the solution state stability of a formulation	**5**
	C.	What are the basic challenges faced by the indian pharmaceutical drug discovery and development teams. Write a roadmap to overcome those challenges	**5**
Q.4	A.	What do you mean by ANDA. Write in brief about Hatch waxman act and its role in ANDA filing	**5**
	B.	Write the information for pre market notification of medical deveice packaging	**5**
	C.	What do mean by drug comapatability studies, write the importance and methodolgy for the same	**5**
Q.5	A.	Explain the need for new product development with an insight on the opportunity and challenges for the same	**5**
	B.	Discuss any one qualitative and one quantitative model for technology transfer in pharmaceutical industry	**10**
Q.6	A.	What are the basic points to be considered while developing a preformulation protocol	**05**
	B.	Elaborate the development and scale up of an immediate release tablet dosage form	**10**
Q.7	A.	Write a note on the problems in technology transfer	**05**
	B.	What are the stages in pharamceutical product development? Explain the informational content to be added in Investigational New Drug Application (INDA)	**10**

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