

BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI  
(END SEMESTER EXAMINATION)

CLASS: M.PHARM  
BRANCH: PHARMACY

SEMESTER : I  
SESSION : MO/19

SUBJECT: MQA104T PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

TIME:3:00 HOURS

FULL MARKS: 75

**INSTRUCTIONS:**

1. The question paper contains 7 questions each of 15 marks and total 105 marks.
  2. Candidates may attempt any 5 questions maximum of 75 marks.
  3. The missing data, if any, may be assumed suitably.
  4. Before attempting the question paper, be sure that you have got the correct question paper.
  5. Tables/Data handbook/Graph paper etc. to be supplied to the candidates in the examination hall.
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- Q.1(a) Describe in detail about drug discovery and development with suitable example. [7]  
Q.1(b) What do you mean by NDA? Write about significant parameters of NDA submission. [8]
- Q.2(a) Justify the role of IND in drug development process. [7]  
Q.2(b) Explain the role of USFDA in drug regulation. [8]
- Q.3(a) Discuss the role of pKa and pH in drug absorption of new chemical entities during pre-formulation studies. [7]  
Q.3(b) Discuss the importance of Noyes-Whitney equation in enhancing the intrinsic dissolution of drugs while performing pre-formulation studies of new drug. [8]
- Q.4(a) During intrinsic dissolution studies of new chemical entity, how surface area is held constant. Explain its importance. [7]  
Q.4(b) Explain two-factor simplex optimization to enhance the solubility of new drug while performing pre-formulation studies. [8]
- Q.5(a) Define technology transfer and discuss its importance. [7]  
Q.5(b) What do you mean by horizontal and vertical technology transfer? Distinguish between quantitative and qualitative technology transfer models. [8]
- Q.6(a) What is meant by packaging? What are ideal characteristics of packaging? Explain different types of packaging? [7]  
Q.6(b) Explain the different packaging requirements of solid dosage forms. [8]
- Q.7(a) Explain QTTP and CQA with reference to scale up? [7]  
Q.7(b) Explain the scale up process of a solid dosage form with an example of scale up operation? [8]

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