

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

CLASS: M.PHARM
BRANCH: PHARMACY

SEMESTER: 1ST
SESSION: MO 2025

SUBJECT: MQA104T PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

TIME: 3.00 Hours

FULL MARK: 75

INSTRUCTIONS:

1. The missing data, if any, may be assumed suitably.
2. Before attempting the question paper, be sure that you have got the correct question paper.
3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
5. Answer any five questions.

- 1a. Discuss the hatch Waxman act in detail. [7]
1b. Discuss the investigational new drug application in detail. [8]
- 2a. Discuss the various aspects of aseptic packaging in detail. [7]
2b. Discuss the various aspects of formulae & equipment evaluation and also salient features of physical and personnel requirement for pilot plant scale up operation. [8]
- 3a. Discuss the granulation aspects in detail for pilot plant scale up operation for solid dosage form. [7]
3b. Discuss the drying aspects for pilot plant scale up operation for solid dosage form with suitable diagrammatic representation. [8]
- 4a. Discuss the various salient features for liquid products during pilot plant scale up operation. [7]
4b. Discuss the various aspects of capsule generally taken care off during pilot plant scale up operation. [8]
- 5a. Derive the equation of solubility weakly acidic drug in relation with hydrogen ion concentration. [7]
5b. Derive the equation of solubility weakly basic drug in relation with hydrogen ion concentration. [8]
- 6a. Derive an equation for complexation of drug with protein. [7]
6b. Discuss the various factors affecting dissolution rate. [8]
- 7a. Discuss the role of optimization in technology transfer. [7]
7b. Discuss the quality control test for container in detail. [8]

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