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Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmaceutical Quality Assurance) (Sem.-1)

**PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER**

Subject Code : MQA-104T

M.Code : 74702

Time : 3 Hrs.

Max. Marks: 75

**INSTRUCTIONS TO CANDIDATES :**

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

**1. Write briefly :**

- A. New drug application
- B. SUPAC
- C. Partition coefficient
- D. Importance of hygroscopicity in pre-formulation parameters
- E. Slugging in tablet manufacturing process
- F. Enlist various Technology Transfer Models
- G. Types of glass used for pharmaceutical packaging

2. Explain pilot plant design in detail. How is it crucial in designing scale up studies for a pharmaceutical product?
3. Write in detail about polymorphism, solubility, partition coefficient and  $pK_a$  of drug molecule in reference to preformulation profiling.
4. Discuss NDA chemical post approval changes in reference to guidance to industry document, USFDA.
5. Discuss in detail various quality control tests for containers (Glass and plastic).
6. Explain various steps involved in the technology transfer from R & D to the production phase of drug development.

**NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.**

