

Roll No.

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

Paper ID : [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. a) What is an ANDA? Enumerate the details that have to be submitted in an ANDA. Mention the types of ANDA that can be filed and the advantages of filing them.
b) Briefly explain the CDSCO guidelines for pharmaceutical product registration.
2. a) How can surfactants be used for improving solubility of drugs? Give examples of dosage forms where they are employed for this purpose.
b) Write a note on polymorphic transformations of drugs during processing and its influence on dosage form stability and performance.
3. a) What is meant by product scale up? Outline the steps involved in this exercise and the critical considerations for a tablet dosage form.
b) Write a note on challenges in developing novel drug delivery systems.
4. a) Briefly discuss the quality control tests performed for assuring quality of containers for parenteral liquids.
b) Give an account of new packaging containers / designs for dosage forms and mention their advantages.
5. a) Outline the steps practiced for optimization of production.
b) Give a brief account of certification of food products in India.
6. Highlight the key features of technology transfer and the documentation involved in this process.