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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.