

GUJARAT TECHNOLOGICAL UNIVERSITY**BE - SEMESTER-VIII EXAMINATION – SUMMER 2016****Subject Code:183601****Date:16/05/2016****Subject Name:Drug Delivery, Biotechnology &Validation Requirement (Department Elective-IX)****Time:10:30 AM to 01:00 PM****Total Marks: 70****Instructions:**

1. Attempt all questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) Write down main contents of 'Validation Master Plan' (VMP) **07**
- (b) What are the functions of 'Head of Quality Control' **07**
- Q.2** (a) Define Radiopharmaceuticals. Give examples of radioactive isotopes? Mention advantages and disadvantages of Radiopharmaceuticals **07**
- (b) What is Genetic Engineering? What are basic steps in Genetic **07**
- OR**
- (b) What is Penicillin? What are the Penicillin drugs? List few Penicillin drugs. Is cross-contamination a concern with Penicillin drugs? **07**
- Q.3** (a) What is meant by cloning of animals? Explain development of Animal Cloning in the Lab. **07**
- (b) What are the Liposomes? Write the Mechanism of Liposome formation. **07**
- OR**
- Q.3** (a) What are basic requirements for GMP? **07**
- (b) Define: Qualification, Validation and Recall. What are reasons for recall? **07**
- Q.4** (a) How to assure that during manufacture of any targeted product, no contamination has taken place when the process is a pure culture one. **07**
- (b) How microbial product formation is different from plant and animal cell? **07**
- OR**
- Q.4** (a) Classify fermentation process. How solid state fermentation is different from submerged fermentation? **07**
- (b) Explain the different theories involved in the mucoadhesive drug delivery systems **07**
- Q.5** (a) Give a detailed description of encapsulation of Sustained Release Dosage forms? **07**
- (b) What are the physicochemical properties of sustained release dosage forms? Give an example of Marketed formulations of Sustained release dosage forms **07**
- OR**
- Q.5** (a) Define Biotechnology and explain its applications in Food, Pharmaceutical **07**
- (b) What are the basic differences between upstream and downstream processing? **07**