

GUJARAT TECHNOLOGICAL UNIVERSITY**BE - SEMESTER-VIII(NEW) EXAMINATION – SUMMER 2019****Subject Code:2183601****Date:09/05/2019****Subject Name:Drug Delivery, Biotechnology & Validation Requirement****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.

| | | MARKS |
|------------|---|-----------|
| Q.1 | (a) Write a note on “Liposome” | 03 |
| | (b) Discuss about Pre-formulation & the steps involved in the pre-formulation of sustained release drug delivery system. | 04 |
| | (c) Discuss about the role of agitators in Fermentation and list out the different types of agitators used in fermentation. Describe any two in detail. | 07 |
| Q.2 | (a) Write a note on radiopharmaceuticals | 03 |
| | (b) What are the roles of restriction enzyme in recombinant DNA technology. Write a brief note on it. | 04 |
| | (c) Explain genetic engineering and the process involved in it. | 07 |
| | OR | |
| | (c) Describe the components of aerosol system with a neat-labeled diagram | 07 |
| Q.3 | (a) Discuss about New Drug Application and the types of data involved | 03 |
| | (b) Write in detail about Schedule-M guidelines for Process validation | 04 |
| | (c) Differentiate between solid state fermentation (SSF) & submerged liquid fermentation (SLF). | 07 |
| | OR | |
| Q.3 | (a) Write a note on “Drug Master File” | 03 |
| | (b) Discuss Transmucosal drug delivery system in detail. | 04 |
| | (c) What are the major components of Fermentation process? Discuss about them. | 07 |
| Q.4 | (a) Define aerosols and explain its evaluation tests in detail | 03 |
| | (b) Describe the classifications & the components of the transdermal drug delivery system (TDDS). | 04 |
| | (c) Explain in detail “Ophthalmic drug delivery system” | 07 |
| | OR | |
| Q.4 | (a) What are emulsions? Explain the role of emulsifying agent | 03 |
| | (b) Write a note on cosmetic products | 04 |
| | (c) Discuss sustained and controlled release dosage forms. Describe in detail about the material used for the sustained release drug delivery. | 07 |
| Q.5 | (a) Write a note on how sterilization is effected in fermenter. | 03 |
| | (b) What is “DPCO”. Write a detailed note on it. | 04 |
| | (c) Describe Immobilized enzyme in detail. | 07 |
| | OR | |
| Q.5 | (a) Draw the basic design of fermenter. Label it properly. | 03 |
| | (b) Write notes on (1). Informed consent, (2). Ethics committee. | 04 |
| | (c) Describe NDA & ANDA in detail. | 07 |
