

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-2 EXAMINATION – SUMMER-2019

Subject Code: 2920104**Date: 29/05/2019****Subject Name: Modern Pharmaceutical Analysis****Time: 10:30 AM TO 01:30 PM****Total Marks: 80****Instructions:**

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

- Q.1** (a) What is solid state analysis of drug substances? Discuss properties associated with particulate level. **06**
(b) Enlist and discuss in brief ICH quality guidelines in Pharmaceutical analysis. **05**
(c) Discuss role of Near Infrared Analysis in solid dosage form analysis. **05**
- Q.2** (a) Write a note on US-FDA guidelines in pharmaceutical analysis. **06**
(b) What is tryptic mapping? Discuss its uses and limitations. **05**
(c) Discuss Amino acid sequence analysis. **05**
- Q.3** (a) Explain effect of impurities on drug stability and its therapeutic action. **06**
(b) Discuss format of pre-formulation report. **05**
(c) Write in brief spectrophotometric methods of pKa determination. **05**
- Q.4** (a) Write analytical methods used in preformulation studies. Give methods for separation of drug substances. **06**
(b) Discuss compendial testing of solid oral dosage form. **05**
(c) Enlist various physicochemical characterization methods for solid oral dosage form analysis. Discuss any one in detail. **05**
- Q.5** (a) What is sterility testing? Discuss Significance in parenteral formulations. Give methods to check sterility of samples. **06**
(b) Write in brief about standardization of crude drugs and herbal formulations. **05**
(c) How quality control testing of radiopharmaceuticals is performed? **05**
- Q. 6** (a) Give a brief account on isolation and identification of impurities. **06**
(b) Write a note on degradation studies of drug substances. **05**
(c) Write a note on evaluation of cosmetic formulations. **05**
- Q.7** (a) What are the advantages and disadvantages of automated analysis? Write applications of automated analysis. **06**
(b) Write a note on Ion exchange amino acid analysis. **05**
(c) Write a detailed note on Isoelectric focusing. **05**
