

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**M. Pharm. – SEMESTER – II • EXAMINATION – WINTER 2013**

**Subject Code: 2920104****Date: 28-11-2013****Subject Name: Modern Pharmaceutical Analysis****Time: 10.30 am - 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.**

- |             |     |   |           |
|-------------|-----|---|-----------|
| <b>Q.1</b>  | (a) | Enlist analytical methods for biotechnological products. Discuss isoelectric focusing.  | <b>06</b> |
|             | (b) | Give a brief account on “tryptic mapping”.  | <b>05</b> |
|             | (c) | What is Automated analysis? State its advantages and briefly explain the concept.   | <b>05</b> |
| <b>Q.2</b>  | (a) | Explain the importance of pre-formulation studies . Describe the analytical techniques for pre-formulation studies.                                 | <b>08</b> |
|             | (b) | Describe the US-FDA guidelines in pharmaceutical analysis.  | <b>08</b> |
| <b>Q.3</b>  | (a) | State the importance of solid-state analysis. Explain in detail about the properties associated with particulate level.                             | <b>06</b> |
|             | (b) | Write a note on Drug substance degradation study.   | <b>05</b> |
|             | (c) | Elaborate upon compendial testing for API and its formulated products.  | <b>05</b> |
| <b>Q.4</b>  | (a) | Describe sampling of medicinal plant materials. State the importance of macroscopic and microscopic examination.                                    | <b>08</b> |
|             | (b) | Explain how the following parameters would be determined in medicinal plant materials-(1) Pesticide residue (2) Bitterness value (3) Swelling index | <b>08</b> |
| <b>Q.5</b>  | (a) | Describe methods of analysis of ANY ONE of the cosmetic formulations.   | <b>06</b> |
|             | (b) | Define the term ‘Cosmetic’. Give a brief account on ingredients used in manufacturing cosmetic formulations.  | <b>05</b> |
|             | (c) | Explain the concept of automation with respect to solid dosage form analysis.   | <b>05</b> |
| <b>Q. 6</b> | (a) | How the parenteral dosage forms are evaluated for sterility testing?  | <b>08</b> |
|             | (b) | Describe in detail Bacterial endotoxin testing in parenteral products.  | <b>08</b> |
| <b>Q.7</b>  | (a) | What do you mean by radiopharmaceuticals? Give a brief account on QC tests for radiopharmaceuticals.  | <b>08</b> |
|             | (b) | Describe regulatory guidelines for radiopharmaceuticals.  | <b>08</b> |

\*\*\*\*\*