

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015

Subject Code: 2920104

Date: 14-05-2015

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.**

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|-------------|------------|--|-----------|
| Q.1 | (a) | Enlist analytical test for parenteral preparation. Describe sterility testing of antibiotics and thermo labile drug product. | 10 |
| | (b) | Discuss Bio-burden testing of parenteral products. | 06 |
| Q.2 | (a) | What are pre formulation studies? Describe analytical techniques used for the pre formulation studies. | 06 |
| | (b) | Explain various compendia parameters of standardization of herbal drugs and formulations. | 05 |
| | (c) | Outline validation procedure for assay method of API as per ICH guideline. | 05 |
| Q.3 | (a) | Explain physico- chemical characterization techniques for solid oral dosage forms. | 06 |
| | (b) | Outline IP method for validation of UV spectrophotometer. | 05 |
| | (c) | Define impurity. Explain effect of impurity in API? Write note on degradation study. | 05 |
| Q.4 | (a) | Enlist quality standard of Radio pharmaceutical. Explain Radio immune-assay of Insulin. | 10 |
| | (b) | Enlist molecular level physico chemical properties of new drug substance. Describe determination of any three of them. | 06 |
| Q.5 | (a) | Discuss evaluation of cosmetic products. | 10 |
| | (b) | What are classes of residual solvents in API? Describe method for determination of residual solvent in API. | 06 |
| Q. 6 | (a) | Write note on automated analysis. | 06 |
| | (b) | What are bacterial endotoxins? How is it determined? | 05 |
| | (c) | Discuss method for determination of amino acid sequence in peptide. | 05 |
| Q.7 | (a) | Describe isoelectric focusing method. | 06 |
| | (b) | Discuss a method of water determination in API. | 05 |
| | (c) | Write note on Regulatory aspects of radiochemical laboratory. | 05 |
