

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm – SEMESTER I • EXAMINATION – WINTER 2016****Subject Code:910102****Date: 02/01/2017****Subject Name: Pharmaceutical Formulation Development & Biopharmaceutics****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) | State and explain with reasons about physicochemical and pharmaceuticals factors to be considered while formulating Cefadroxil pediatric dry syrup. | 06 |
| | (b) | How crystallinity affects dosage forms? | 05 |
| | (c) | Write short notes on organic volatile impurities. | 05 |
| Q.2 | (a) | Differentiate solid solution and solid dispersion. Explain in detail mechanism of solid dispersion in solubility improvement of poorly soluble drug with appropriate examples. | 06 |
| | (b) | What are the various factors affecting solubility? Explain. | 05 |
| | (c) | Explain Super Critical Fluid technology as a tool for micronization. | 05 |
| Q.3 | (a) | Enumerate patient related factors influencing drug absorption. | 06 |
| | (b) | How will you measure Bioavailability and Bioequivalence? | 05 |
| | (c) | What is CACO ₂ cell? Enlist the advantages, limitations of the same. | 05 |
| Q.4 | (a) | Define various pharmacokinetic terms. Explain different routes of clearance. | 06 |
| | (b) | Describe the methods of determining protein binding. | 05 |
| | (c) | How analysis of blood data can be done to get bioavailability of drug? | 05 |
| Q.5 | (a) | State the importance and applications of various pharmacokinetic models. | 06 |
| | (b) | Explain one compartment open model_ IV bolus with the equations. | 05 |
| | (c) | Detail out the Wagner- Nelson method of estimating K _a . | 05 |
| Q. 6 | (a) | Describe in brief the applications of IVIVC. | 06 |
| | (b) | Write short notes on herbal shampoo and its evaluation methods. | 05 |
| | (c) | Explain the utilization of micro calorimetry in stability study. | 05 |
| Q.7 | (a) | Explain the processing factors affecting stability study of solid dosage form with suitable examples. | 06 |
| | (b) | How to determine the shelf life of a product by Free and Blythe theory method? | 05 |
| | (c) | State and explain the guidelines for carrying out the stability study of Sparfloxacin containing dosage forms. | 05 |
