

**GUJARAT TECHNOLOGICAL UNIVERSITY****B.PHARM - SEMESTER- VIII • EXAMINATION – SUMMER-2016****Subject Code:2280008****Date: 10/05/2016****Subject Name: Bioavailability and Therapeutic Drug Monitoring****Time: 10:30 AM to 1:30 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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|-------------|-----|---|-----------|
| <b>Q.1</b>  | (a) | Explain following terms:  | <b>06</b> |
|             |     | 1. Relative Bioavailability   |           |
|             |     | 2. Absolute Bioavailability   |           |
|             |     | 3. First pass clearance   |           |
|             | (b) | Define TDM. Explain objective of TDM.   | <b>05</b> |
|             | (c) | What is the role of clinical pharmacist in TDM?   | <b>05</b> |
| <b>Q.2</b>  | (a) | Explain Invivo – Invitro correlation studies.   | <b>06</b> |
|             | (b) | Explain techniques of bioavailability enhancement through drug solubility.                    | <b>05</b> |
|             | (c) | Explain methods and parameters of assessing bioavailability.                                  | <b>05</b> |
| <b>Q.3</b>  | (a) | Enumerate bioequivalence study design. Explain any one in detail.                             | <b>06</b> |
|             | (b) | Enumerate elements of bioequivalence study protocol. Explain subject selection in detail.     | <b>05</b> |
|             | (c) | Explain factors affecting bioavailability.  | <b>05</b> |
| <b>Q.4</b>  | (a) | Explain collection and storage of body fluids samples.  | <b>06</b> |
|             | (b) | Explain problems of interference in biological matrix.  | <b>05</b> |
|             | (c) | Explain factor affecting in serum drug concentration.   | <b>05</b> |
| <b>Q.5</b>  | (a) | Enumerate physical methods used in TDM. Explain any one in detail.                            | <b>06</b> |
|             | (b) | Enumerate Immunoassay methods used in TDM. Explain ELISA in details.                          | <b>05</b> |
|             | (c) | Explain Physiochemical parameter of drug for TDM.   | <b>05</b> |
| <b>Q. 6</b> | (a) | Write clinical monitoring and dosing parameter techniques for Digoxin.                        | <b>06</b> |
|             | (b) | Explain algorithm for the interpretation of TDM result for drug used as prophylactic therapy. | <b>05</b> |
|             | (c) | Write adverse drug reaction and drug interaction of Phenobarbitone.                           | <b>05</b> |
| <b>Q.7</b>  | (a) | Explain in detail the conditions when TDM should perform.                                     | <b>06</b> |
|             | (b) | Explain NIIA detection technique with respect to application for TDM.                         | <b>05</b> |
|             | (c) | Write techniques used for estimation of addictive drugs.                                      | <b>05</b> |

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