

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – VII • EXAMINATION – WINTER – 2015

Subject Code: 2270001

Date: 04/12/2015

Subject Name: Dosage Form Design - I

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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|-------------|-----|---|-----------|
| Q.1 | (a) | What do you understand by first pass metabolism? How would you avoid it? | 06 |
| | (b) | Explain LADME. What is the importance of loading dose? | 05 |
| | (c) | Explain AUC. What is its significance? How will you measure it? | 05 |
| Q.2 | (a) | Define i) Bioavailability ii) C_{max} iii) t_{max} | 06 |
| | (b) | Why “Bioequivalence is covered under regulatory requirements?” | 05 |
| | (c) | Write a short note on “Plasma Protein Binding”. | 05 |
| Q.3 | (a) | What is BCS classification? How does it affect development of dosage form? | 06 |
| | (b) | What is the importance of $t_{1/2}$ in design and development of a dosage form? | 05 |
| | (c) | Explain a dissolution apparatus. How does it give an idea of dissolution of various dosage form? | 05 |
| Q.4 | (a) | What do you understand by adjuvants? How are they utilized in designing innovative dosage forms? | 06 |
| | (b) | Write a note on ‘Biodegradable Polymers’. | 05 |
| | (c) | Briefly outline the parameters to consider as per ICH guidelines. | 05 |
| Q.5 | (a) | What do you understand by prodrug? How do they help in designing a better dosage form? | 06 |
| | (b) | Enumerate properties of API to be considered before designing its dosage form. | 05 |
| | (c) | Discuss Matrixing and Bracketing Techniques: Purpose and objective. | 05 |
| Q. 6 | (a) | What are the ideal properties of preservatives? | 06 |
| | (b) | Discuss the effect of containers and closures on stability of pharmaceuticals. | 05 |
| | (c) | ‘Lactose is an ideal diluent’ Comment. | 05 |
| Q.7 | (a) | Effect of pKa and pH on absorption parameter. | 06 |
| | (b) | “Hydrophyllicity and lipophyllicity property of a drug decide its absorption” Comment with justification. | 05 |
| | (c) | Explain shelf life and overages briefly. Why are they important for a dosage form? | 05 |
