

**R07**

**Code No: R7701**

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY, HYDERABAD**

**B. Pharmacy IV Year II Semester Examinations, April/May-2012**

**NOVEL DRUG DELIVERY SYSTEMS AND REGULATORY AFFAIRS**

**Time: 3 hours**

**Max. Marks: 80**

**Answer any five questions**

**All questions carry equal marks**

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- 1.a) Explain different approaches for dissolution controlled oral drug delivery systems.
- b) Write different types of osmotic pumps. Explain the functioning of elementary osmotic pump. [8+8]
2. Write different types of transdermal drug delivery systems. Explain different methods evaluation of TDDS. [16]
3. Explain different approaches for preparation of resealed erythrocytes. [16]
- 4.a) Explain different mechanisms of bioadhesion.
- b) Describe different mucoadhesive materials used for formulation of mucoadhesive based systems. [10+6]
5. Explain the procedure of NDA filing to USFDA. [16]
6. Explain the quality assurance activities pertaining to manufacturing and packaging. [16]
7. Describe general good manufacturing practices as per 21 CFR Part 210 of USFDA. [16]
8. Explain the concept of analytical method validation with applicable general procedures. [16]

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