

Code: 9R01801

B.Pharm IV Year II Semester (R09) Supplementary Examinations April 2018

**NOVEL DRUG DELIVERY SYSTEMS & REGULATORY AFFAIRS**

Time: 3 hours

Max. Marks: 70

Answer any FIVE questions  
All questions carry equal marks

\*\*\*\*\*

- 1 (a) Explain mechanism, preparation and evaluation of osmotic oral drug delivery system.  
(b) Write a note on dissolution controlled drug delivery system.
- 2 (a) Write note on materials used in the preparation of transdermal patches.  
(b) Explain various evaluation tests of TDDS.
- 3 Classify materials used for preparation of mucoadhesive drug delivery system and add a note on their physical and chemical properties.
- 4 (a) Write a detailed note on resealed erythrocytes.  
(b) What are nano particles? Write their applications in targeted drug delivery systems.
- 5 (a) Write the salient features of drug regulations as per USFDA.  
(b) Write a note on Canadian HPFBI.
- 6 Write the steps involved in quality assurance with reference to manufacturing and packing of solid dosage forms.
- 7 (a) Enumerate the design of manufacturing area as per GMP for the production of solid dosage forms.  
(b) Write the important features of CFR 21 part 211 of USFDA.
- 8 Explain the process validation of tablet punching machine.

\*\*\*\*\*