

Code: 9R01801

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

NOVEL DRUG DELIVERY SYSTEMS & REGULATORY AFFAIRS

(For 2009 (LC), 2010, 2011, 2012 regular & 2011 (LC), 2012, 2013 lateral admitted batches only)

Time: 3 hours

Max. Marks: 70

Answer any FIVE questions
All questions carry equal marks

- 1 (a) Write the mechanism involved in the design of Ion exchange resins and add a note on Ion exchange resin drug delivery.
(b) Explain altered density systems.
- 2 Write the mechanism involved in transdermal drug delivery systems and explain different types of TDDS.
- 3 Write the formulation and evaluation of mucoadhesive drug delivery systems.
- 4 Explain the formulation and evaluation methods of liposomes.
- 5 Write a detailed note on constitution, objectives and functions of Indian CDSCO.
- 6 (a) Explain precautions necessary for warehousing of raw materials in production management.
(b) Write a note on quality control tests for liquid orals.
- 7 (a) Explain the design of manufacturing area as per GMP for the production of parenterals.
(b) Write the salient features of CFR 21 part 210 of USFDA.
- 8 Explain analytical method validation parameters in detail along with acceptance criteria.
