

Code: 9R01801

R09

B.Pharm IV Year II Semester (R09) Supplementary Examinations April 2017

NOVEL DRUG DELIVERY SYSTEMS & REGULATORY AFFAIRS

Time: 3 hours

Max. Marks: 70

Answer any FIVE questions
All questions carry equal marks

- 1 Explain in detail diffusion and dissolution controlled mechanism in oral drug delivery system.
- 2 Discuss different evaluation systems for transdermal drug delivery.
- 3 (a) Write the mechanism involved in bioadhesion.
(b) Add a note on mucoadhesive materials with their properties.
- 4 Enumerate the formulation and evaluation of nanoparticles.
- 5 With the regulatory approval submission protocol for abbreviated new drug application and US food and drug administration.
- 6 Outline the quality assurance concept with respect to warehouse and manufacturing control.
- 7 Discuss good manufacturing practice schedule followed in India.
- 8 Explain process validation using suitable examples.

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