

Code No: B4203

**R10**

**SET - 1**

**IV B. Pharmacy II Semester Supplementary Examinations, April - 2019**  
**CONTROLLED RELEASE & NOVEL DRUG DELIVERY SYSTEMS**

Time: 3 hours

Max. Marks: 75

Answer any **FIVE** Questions  
All Questions carry **Equal** Marks

1. a) Explain the concept of controlled drug delivery and approaches for their design. (7M)  
b) Explain the formulation and evaluation of osmotic drug delivery systems. (8M)
2. a) Write about formulation additives for transdermal drug delivery systems. (8M)  
b) Explain the evaluation tests for transdermal drug delivery systems. (7M)
3. a) Explain the theories of mucoadhesion. (7M)  
b) Give the advantages of mucoadhesive systems. Write about qualities of polymers suitable for these systems. (8M)
4. a) Mention the need for drug targeting and explain different types of targeting with suitable examples. (8M)  
b) What are nanoparticles? Give their characteristics and advantages. How they are different from liposomes? (7M)
5. a) Give the structure of CDSCO and its duties. (9M)  
b) Briefly describe the process of ANDA submission. (6M)
6. a) Write about manufacturing controls. (9M)  
b) Give the differences between quality control and quality assurance. Why quality assurance is gaining significance? (6M)
7. a) Write about GMP requirements for factory and premises as per Drugs and Cosmetics Act. (8M)  
b) Write about CFR part 211 relating to responsibilities of quality control. (7M)
8. a) Write about cleaning validation and acceptance criteria. (8M)  
b) Explain the validation procedure for UV analytical method. (7M)