Total No. of Questions : 7] [Total No. of Printed Pages : 2

MPY–104

M. Pharm. (First Semester)
EXAMINATION, Jan.-Feb., 2008

PRODUCT DEVELOPMENT AND FORMULATION

(MPY–104)

Time : Three Hours

Maximum Marks : 75

Minimum Pass Marks : 38

Note : Attempt any *five* questions. All questions carry equal marks.

1. (a) Explain with examples the role of PKa and partition coefficient of drugs in formulation.

   (b) How Drug-Excipient and Excipient-Excipient interaction studies are done during performulation stage ?

2. (a) Explain the development and evaluation of directly compressible vehicle for the formulation of tablets of a drug having poor compressibility and low dosage.

   (b) What are the floating tablets ? Discuss the various technologies employed in the manufacturing of floating tablets.

3. (a) How could the solubility of a drug be enhanced by complexation with cyclodextrins ? Discuss the mechanism of solubilization and utility of various cyclodextrins.

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   (b) What are bio-degradable polymers ? How is biodegradability evaluated ?

4. Give the ideal features of the dissolution test apparatus. Discuss the mechanisms/theories of drug dissolution from solid dosage forms. Describe the dissolution test apparatuses based on forced convection sink technique.

5. (a) Discuss the various machine diagnostic systems used in fully automated operation to prevent problem and ensure optimal tablet compression machine performance.

   (b) What are stability indicating assays ? How is analytical method ascertained to be stability indicating ?

6. Define and differentiate between 'Small volume' and 'Large volume' parenterals. Discuss the following with respect to production of small volume parenterals :
   (i) Non-aqueous vehicles
   (ii) Preservatives used in multiple dose vials
   (iii) Parenteral suspension formulation
   (iv) Quality control of rubber closures used in packaging of parenterals

7. (a) What are the problem types and variables in selection of optimization parameters ?

   (b) Discuss in detail the simplex and Lagrangian methods of optimization.