M.Pharm. (I Sem.) EXAMINATION, May-June 2016

Rajiv Gandhi Proudyogiki Vishwavidyalaya

Product Development and Formulation

MPY-103

Time: Three Hours

Maximum Marks: 70

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

1 (a) Discuss the role of following pre formulation parameters in the formulation of various dosage forms :
(i) Particle size and poly dispersibility index
(ii) Solubility
(iii) PKa
(iv) Partition coefficient

(b) Explain the influence of racimization and polymerization on the stability of the formulation.

2. (a) How does prodrug help in solving the problems associated with stability and bioavailability? Explain with suitable examples.

(b) Discuss the factors influencing the selection of suitable excipients for particular dosage forms formulation.

3. (a) Discuss various theories of the dissolution.

(b) Enemurate the ideal characteristics of dissolution testing apparatus.

(c) How do you maintain the sink conditions in in-vitro dissolution of water insoluble drugs?

4 (a) Discuss various drug decomposition pathways which are influencing the stability of the drug.

(b) How do you calculate expiry date of a dosage forms? Explain.

5 (a) Classify various polymers? Discuss various methods of polymerization.

(b) Explain mechanism of biodegradation of biodegradable polymers.

6. Discuss the need of optimization techniques in the formulation of dosage forms. Classify various optimization methods. Discuss in detail simplex and lagrangian methods of optimization.

7 (a) What are the purposes and benefits of SOPS? Explain with examples.

(b) What are the different types of SOPS? Discuss SOP of oral liquids.

8. Write short notes on any three :
(i) Cyclodextrin as excipient in oral liquid formulation
(ii) EVOP
(iii) ICH guidelines for stability testing
(iv) In-vitro-invivo correlation.