

M. Pharm. (First Semester)

EXAMINATION, Dec., 2011

(Grading/Non-Grading)

PRODUCT DEVELOPMENT AND FORMULATION

(MPY – 104)

Time : Three Hours

Maximum Marks : $\begin{cases} GS : 70 \\ NGS : 75 \end{cases}$

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

1. (a) What are the obstacles in new product design ? Discuss with suitable examples.
(b) What is Polymorphism ? How does polymorphism of drug influence the development of suitable formulation of it ?
(c) How does particle size and surface area of the drug influence bioavailability of drug ? Explain.
2. (a) Give the stability protocol for stability testing of solid dosage forms according to ICH guidelines.
(b) How is the shelf life of a product determined ?
3. (a) Write a note on various additives used in pharmaceutical formulations. Support your answer with suitable examples and their mechanism of action, if any.

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- (b) Write a note on biodegradable polymers.
4. (a) What are the problem types and variables in selection of optimization parameter ?
(b) Discuss in the detail Simplex and Lagrangian methods of optimization.
5. (a) How are multilayer tablets prepared ? Explain with suitable examples.
(b) Enumerate the problems encountered in the preparation of compressed tablets using rotatory multistation compression machine. Explain, how these problems are encountered.
6. Write short notes on the following :
 - (a) Stability of packages
 - (b) Adjuvants used in the formulation of parenteral products
 - (c) Tablet compression theory.
7. (a) Describe the pharmacopoeial tests for glass containers.
(b) Write a note on new concepts in Pharmaceutical Packaging.