M. Pharm. (First Semester) EXAMINATION, Dec., 2011

(Grading/Non-Grading)

DRUG REGULATORY AFFAIRS, INTELLECTUAL PROPERTY RIGHTS AND QUALITY ASSURANCE

(MPY–103)

Time : Three Hours

Maximum Marks : GS : 70, NGS : 75

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

1. (a) Briefly explain the provisions of Schedule M1 under Drugs and Cosmetics Act and Rules.

   (b) How should documents be prepared for export registration ?

2. (a) What records are to be maintained in manufacturing of parenteral formulations ?

   (b) How is master formula generated and maintained ?

3. (a) Explain the IPQC tests during the manufacture of tables.

   (b) How are IPQC problems solved during the manufacture of tablets ?

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4. (a) Compare the requirements of WHO guidelines and ISO 9000 series.

   (b) Describe the pollution control measures to be adopted by pharmaceutical industries.

5. Write notes on any *three* of the following :

   (a) Copyright

   (b) Process validation

   (c) Sampling plans

   (d) ICH guidelines

6. Discuss in detail on any *two* of the following :

   (a) ANDA

   (b) Sewage disposal

   (c) GMP