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MPY–103

M. Pharm. (First Semester) EXAMINATION, July 2008

DRUG REGULATORY AFFAIRS, INTELLECTUAL PROPERTY RIGHTS AND QUALITY ASSURANCE

(MPY–103)

Time : Three Hours

Maximum Marks : 75

Note : Attempt any *five* questions. All questions carry equal marks. It is required to solve subpart of a question in continuation.

1. (a) What are the Special Pharmaceutical Products as per the WHO-GMP guidelines ? Describe in short any *one* of them. 5

   (b) Describe the air classification systems for sterile pharmaceutical products as recommended by WHO. 5

   (c) Write a short note on WHO-GMP certification scheme. 5

2. (a) Describe the concept of validation and discuss its importance in pharmaceutical manufacturing. 5

   (b) Discuss DQ and PQ. 5

   (c) Describe the important steps in process validation. 5

3. (a) What is a patent ? What is the utility of a patent system ? When can an invention be patented ? $7\frac{1}{2}$

   (b) Discuss the types of patents as per Indian Patent Act, 1970. $7\frac{1}{2}$

4. Explain the difference between document and record. Discuss various types of documents and application such as DMF, SMF, INDA, NDA and CID required for new drug approval and export registration. 15

5. (a) Why is Drug Regulatory Affairs becoming important these days ? Which activities are covered under DRA ? $7\frac{1}{2}$

   (b) Discuss the conditions for the grant or renewal of a license in Form 28 or drugs classified in schedule C and C_1. $7\frac{1}{2}$

6. (a) What is the principle of quality control ? How does it differ from quality assurance ? 5

   (b) Discuss the validation of analytical method development as per the ICH guideline. 10

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

   (i) Sewage disposal

   (ii) Master formula record

   (iii) Sampling plans

   (iv) ISO 9000 series