MPY - 103 M. Phanmicy I & 11 Semester Examination, December 2012

DKA, IPR and Quality Assurance

Time: Three Hours

Maximum Marks : 70

Note : 1. Attempt any four questions.

2. All questions carry equal marks.

1. a) Discuss the new developments in regulator, requirements in India.

b) Explain the ICH guidelines for data collection to establish the safety of drug products.

2. A) Explain the global patenting process for pharmaceutical products.

B) Discuss the regulatory guidelines As' stability testing in India.

3. a) Compare the preclinical and clinical regulatory requirements of bio technological products in India.

b) Explain the ISO 9000 scries of quality system standards.

4. Explain the current regulatory requirements of mutagenicity testing in India.

b) Write a note on Drug Master File.

5 a) What is the relevance of WHO guidelines in international registration of pharmaceutical products.

b) Discuss the guidelines of good clinical practice in European Countries.

6. Write notes on any two of the following:

a) ANDA.

b) GLPS

c) CGMP.

d) Sewage Disposal.