Subject Code: B133205/R13

III B. Pharmacy II Semester Regular Examinations April - 2017

REGULATORY AFFAIRS, IPR & PATTENTS

Time: 3 hours **Max. Marks: 70**

Question Paper Consists of **Part-A** and **Part-B**
Answering the question in **Part-A** is Compulsory,
Three Questions should be answered from **Part-B**

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PART-A

1. (a) What are Intellectual property rights?
   (b) Write the packaging specification for parenterals.
   (c) What is drug master file?
   (d) List out the solid state physico-chemical properties of the drug substance.
   (e) What is "Budapest Treaty"?
   (f) Write the procedure to report adverse drug reactions. [3+4+3+4+4+4]

PART-B

2. (a) Explain the stability testing of solid dosage forms as per ICH guidelines.
   (b) Explain the regulatory guidelines for selection of packing materials for liquid dosage form. [10+6]

3. (a) Define Trademarks and Copyrights with examples.
   (b) Explain the role of WIPO. [8+8]

4. (a) Explain the validation of active pharmaceutical ingredients.
   (b) Write a note on validation of process. [10+6]

5. (a) What are the inventions not patentable as per the Indian patent act 1970?
   (b) Explain the various forms using for patent filing in India. [7+9]

6. Explain the regulatory requirements in formulation development of liquid and semisolid dosage forms. [16]

7. (a) What are clinical trials? Explain GCP for clinical trials.
   (b) Explain the significance of clinical trials. [10+6]

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