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Code No: B133205 **R13** SET - 1

III B. Pharmacy II Semester Supplementary Examinations, Nov - 2018
REGULATORY AFFAIRS, IPR& PATENTS

Time: 3 hours Max. Marks: 70

Note: 1. Question Paper consists of two parts (**Part-A** and **Part-B**)
2. Answering the question in **Part-A** is Compulsory
3. Answer any **THREE** Questions from **Part-B**

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PART –A

1. a) What regulatory requirements are to be followed for preformulation studies of semisolids? (4M)
   b) Briefly explain the types of validation. (4M)
   c) What is stress testing of API as per ICH guidelines and mention its advantages. (4M)
   d) Write the significance of phase IV clinical trials. (4M)
   e) What are intellectual property rights? Give suitable examples (3M)
   f) What types of inventions are not patentable? Give suitable examples. (3M)

PART -B

2. a) Explain the protocol for formulation development of solid dosage forms as per Indian regulations. (8M)
   b) Write about problems of preformulation studies for liquid dosage forms and methods for overcoming them. (8M)

3. a) Explain the stability testing of drug product as per ICH guidelines and how the conclusions for stability are drawn? (10M)
   b) Explain the testing of glass as per Indian Pharmacopoeia. (6M)

4. a) Explain the validation of UV spectrophotometer. (8M)
   b) Write about GMP in relation to factory premises. (8M)

5. Explain the requirements for carrying out phase I clinical trials and procedure for carrying the same. (16M)

6. a) Give the salient differences between Indian and International intellectual property rights. (6M)
   b) Write about different intellectual property rights as per Indian laws. (10M)

7. Explain the procedure for obtaining Indian patent. (16M)

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