Code No: B4204 **R10** SET - 1

IV B. Pharmacy II Semester Supplementary Examinations, April - 2018
REGULATORY AFFAIRS, IPR & PATENTS

Time: 3 hours Max. Marks: 75

Answer any **FIVE** Questions
All Questions carry **Equal** Marks
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1. a) Write the regulatory requirements for carrying out preformulation studies for liquid dosage forms. (7M)
   b) Mention the significance of preformulation studies and give the protocol for preformulation studies for tablets. (8M)

2. a) Write about the preparation of master formula record and mention its significance. (8M)
   b) Write about different records to be maintained during production for solid dosage forms as per GMP. (7M)

3. a) Give the types of validation and explain process validation. (7M)
   b) Mention the need for vendor qualification for supply of raw materials and briefly explain the procedure. (8M)

4. a) Explain the testing of glass as per Indian Pharmacopoeia. (9M)
   b) Mention the quality control tests for blister packing and their significance. (6M)

5. a) Explain the sterility testing as per Indian Pharmacopoeia. (9M)
   b) Explain the ICH guidelines for sterility testing of liquid dosage forms. (6M)

6. Give the salient differences between Phase I and II clinical trials and explain the protocol for Phase I clinical trial. (15M)

7. a) Give the differences for patent, trade mark and copy right with suitable examples. (7M)
   b) Write about patentable and non-patentable inventions as per Indian Patent Act. (8M)

8. Explain the process of patent filing and its approval as per Indian Patent Act. (15M)
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