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

IV B. Pharmacy II Semester Supplementary Examinations, July/August - 2017
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) What are the goals of preformulation studies? Explain the protocol for preformulation studies for solid dosage forms. (10M)
   b) Write the significance of drug-excipient compatibility studies. (5M)

2. a) Write the GMP regulations under Schedule M for parenteral products. (10M)
   b) Write about master formula record and its significance. (5M)

3. a) Define validation. Write about process validation. (8M)
   b) Explain the validation protocol for UV-Visible spectrophotometer. (7M)

4. a) Write the regulatory requirements for primary packing materials. (8M)
   b) Explain the official testing methods for glass. (7M)

5. a) Explain the sterility testing of API as per ICH guidelines. (9M)
   b) Write about the significance of media in sterility testing. (6M)

6. a) Explain the Phase III clinical trials. (9M)
   b) Write the protocol for Phase II clinical trials. (6M)

7. a) Define intellectual property rights and give suitable examples. (8M)
   b) Write about international guidelines for intellectual property rights. (7M)

8. a) Write the salient features of Indian Patent Act. (8M)
   b) Explain the different stages in patent approval in India. (7M)
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