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

IV B. Pharmacy II Semester Supplementary Examinations, April/May - 2019
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) Explain the preformulation studies to be carried out for liquid and semisolid dosage forms highlighting the regulatory concerns. (8M)
   b) Mention the need for drug-excipient compatibility studies and write the principles of the techniques for studying this. (7M)

2. a) Write about the GMP regulations of Schedule M relating to equipment. (8M)
   b) Write the significance of master formula record. Give the procedure for its preparation and regulatory concerns to be followed. (7M)

3. a) Define validation. Write about concurrent, retrospective and process validations. (7M)
   b) Explain the validation of planetary mixer. (8M)

4. a) Give the types of packaging materials used for liquid orals and semisolids. Discuss their relative merits. (7M)
   b) Explain the water attack test and powdered glass test for glass containers as per Indian Pharmacopoeia and give the limits of acceptance. (8M)

5. a) Explain the validation of sterile area. (8M)
   b) Explain the sterility testing of parenterals as per Indian Pharmacopoeia. (7M)

6. a) Give the constitution of Institutional Ethical Committee and its duties in the clinical trials. (8M)
   b) Give the protocol for Phase IV clinical trials. (7M)

7. a) Define patent, trade mark and copy right and give suitable examples. (6M)
   b) Write about national and international guidelines for protecting the intellectual property rights. (9M)

8. a) Write about non patentable inventions with suitable examples. (7M)
   b) Explain the process of patent approval in India. (8M)
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