Code No: RAB134212 **R13** RA - 1

IV B. Pharmacy II Semester Regular/Supplementary Examinations, April - 2019
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) Write the protocol for solubility testing in preformulation. (4M)
   b) Write about master formula record. (4M)
   c) Write differences between ICH stability testing and regular stability testing. (3M)
   d) Write about sample requirements for phase I clinical studies. (3M)
   e) Define patent and trade mark with suitable examples. (4M)
   f) What types of inventions are not patentable? (4M)

PART –B

2. Explain the need for conducting preformulation studies. Explain the preformulation studies to be conducted for solid dosage forms in detail. (16M)

3. a) Write about process validation with a suitable example. (8M)
   b) Explain the GMP requirements for raw materials. (8M)

4. a) Explain the stability testing protocol for drug substance as per ICH guidelines. (9M)
   b) Write about quality control testing of glass as per IP. (7M)

5. a) Give the differences between phase II and phase III clinical trials. Explain phase II clinical trials. (9M)
   b) Write about constitution of Institutional Ethics Committee. (7M)

6. a) Give the differences between national and international intellectual property rights. (6M)
   b) Write about rights and guidelines relating to trade mark and copyright. (10M)

7. Explain the filing of Indian patent and its approval process. (16M)
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