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

III B. Pharmacy II Semester Regular/Supplementary Examinations, April - 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) Write a short note on regulatory requirements of Packaging material. (4M)
   b) Explain about "Trade mark" and "Service mark". (3M)
   c) What do you understand by formulation development? (4M)
   d) What is the scope of Intellectual Property Rights (IPR)? (4M)
   e) Write about equipment validation as per GMP. (4M)
   f) What is "patent pending" and "patent applied for"? (3M)

PART -B

2. a) Explain the regulatory requirements in the formulation development of solid dosage forms. (8M)
   b) Discuss pre formulation development of semi solid dosage form. (8M)

3. a) Write about validation types and equipment validation as per GMP. (8M)
   b) Explain GMP requirements for validation of excipients in detail. (8M)

4. a) Describe regulations in detail for stability testing of solid dosage form. (8M)
   b) Discuss in detail evaluation of packaging material. (8M)

5. Discuss the regulation requirement for Phase-I, II, III & IV in clinical Trails. (16M)

6. a) Explain the regulatory requirement for reporting of adverse events in clinical trails. (8M)
   b) Define Intellectual Property Rights (IPR) and explain various types of IPR. (8M)

7. a) Describe the Patent Filing procedures, Specification, Claims and Grant of Patent in India. (8M)
   b) Explain about patent cooperation treaty and ever greening of patents. (8M)
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