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Subject Code: B133205/R13

III B. Pharmacy II Semester Supplementary Examinations Nov. - 2016

REGULATORY AFFAIRS, IPR & PATTENTS

Time: 3 hours **Max. Marks: 70**

Question Paper Consists of **Part-A** and **Part-B**
Answering the question in **Part-A** is Compulsory,
Three Questions should be answered from **Part-B**

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PART-A

1. (a) Write the packaging specification for liquid orals.
   (b) What is the significance of patents in pharmaceutical industry?
   (c) Define process validation.
   (d) Explain is the role of PCT.
   (e) What is drug-excipient compatibility?
   (f) Define Pharmacovigilance.

[4+4+3+4+4+3]

PART-B

2. Explain the regulatory requirements in formulation development of solid and liquid dosage forms.

[16]

3. (a) List out the various forms using for patent filing in India.
   (b) Explain the time line in patent filing in India.

[8+8]

4. (a) Explain the regulatory process involved in clinical trials.
   (b) Explain the reporting of adverse events.

[12+4]

5. (a) Explain the regulatory guidelines for selection of packing materials for solid dosage forms.
   (b) Explain the evaluation of packaging materials.

[6+10]

6. (a) Describe the GMP for the manufacturing of semisolid dosage forms.
   (b) Write a note on validation of pharmaceutical excipients.

[12+4]

7. (a) What is intellectual property? Explain industrial designs and trademarks with examples.
   (b) Explain the role of WIPO.

[10+6]

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