Roll No :

MPY-103

M.Pharmacy I Semester

Examination, November 2018

DRA, Intellectual Property Rights and Quality Assurance

Time : Three Hours

Maximum Marks: 70

Note: i) This question paper contains EIGHT questions. Attempt any FIVE questions.
ii) All questions carry equal marks.

1. What are the requirements of premises for pharmaceutical plant manufacturing Liquid orals according to WHO GMP? 14

2. Give the importance of ISO in pharmaceutical industry. Write short notes on quality system documents and design control of ISO 9001. 14

3. a) Describe about Batch Processing Record (BPR)? Give the details to be included in preparation of BPR? 7
   b) Explain details to be included in SOP. What is its importance in Pharmaceutical industry? 7

4. a) Explain the procedure to determine BOD. 7
   b) Write in detail about various phases of schedule Y of Drug and Cosmetic Act. 7

5. a) What do you mean by Intellectual property rights? Write briefly about important forms of IPR. 7
   b) What is Provisional specification and complete specification? Give the standard format of complete specification. 7

6. a) How will you do Sampling plan for Pharmaceutical manufacture? What do you understand by single and multiple sampling? 7
   b) What is sequential Sampling Plan? Explain the rule of thumb for truncation. 7

7. What do you mean by prospective validation and retrospective validation? Write down the process summary for prospective validation of a tablet formulation. 14

8. Write short notes on (any three): 14
   a) Good laboratory practice
   b) ICH Guidelines
   c) Analytical validation
   d) Stability protocol
   e) Personnel qualification as per CGMP

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