Total No. of Questions : 8] *[Total No. of Printed Pages : 2*

Roll No

MPY-103

M.Pharmacy I Semester

Examination, November 2019

DRA, Intellectual Property Rights and Quality Assurance

Time : Three Hours

Maximum Marks: 70

Note: i) Attempt any five questions.

ii) All questions carry equal marks.

1. Give the requirements of premises for pharmaceutical plant manufacturing sterile preparations according to WHO GMP. 14

2. Write your understanding about TQM. What are salient features of ISO 9000:2000? 14

3. What are the salient features of "Declaration of Helsinki"? 14

4. What do you mean by pre-grant opposition in patents? When it can be filed? What are conditions for the pre-grant opposition? 14

5. Write in detail about the In process quality control test of parenteral. 14

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

7. What are different types of sampling methods? What is sequential sampling plan? Explain the rule of thumb for truncation. 14

8. Write short notes on (any three): 14

   a) Quality Audit

   b) Biological Oxygen demand

   c) Classes of clean area

   d) Copy right

   e) Revalidation

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