Total No. of Questions :8] *[Total No. of Printed Pages :1*

Roll No .....

MPY-203 (DRA)

M.Pharmacy II Semester Examination, June 2020

Advanced DRA-III

(Regulations of Other Important Countries)

Time : Three Hours

Maximum Marks: 70

Note: i) Attempt any five questions.
ii) All questions carry equal marks.

1. a) What are the roles of quality assurance department as per WHO GMP? 7
   b) Give the provisions of personnel requirements as per South Africa MCC. 7

2. What are the principles quality management systems? 14

3. a) Give the overview on the stability studies of parenteral product to be kept in refrigerator. Prepare the specifications to be analyzed during stability studies. 7
   b) What are impurities? Describe using their classification and examples. 7

4. a) While preparing CTD, what information you will collect from the formulation scientist, manufacturer, analytical scientist and analyst to include into the dossier under "drug product" head. Write the information separately for above individuals. 7
   b) What are the details to be incorporated in module 3.2.S.2.2 as per common technical document? 7

5. Give the role of health professional in reporting of adverse drug reaction? What information should be included in such report. 14

6. State the principles of ISO-9000. What is the need of ISO certification? 14

7. Give the regulatory requirements for equipments to be used in manufacturing area as per MCC guidelines? 14

8. Write short notes on (any three): 14
   a) Batch packaging record
   b) e-CTD
   c) Specification
   d) Standard operating procedures
   e) Analytical validation

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