[LL 355] OCTOBER 2017 **Sub. Code: 2916**

M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE

Q.P. Code : 262916

Time : Three hours **Maximum : 100 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) How the quality control of packing material is achieved?
   b) What are the tests to be performed for assuring quality of glass?
   c) Write a detailed note on concepts and philosophy of Total Quality Management.

2. What is inprocess quality control? Add a note on its importance. Discuss briefly the various inprocess quality control tests carried out for the following dosage forms.
   a) Liquid orals b) Tablets c) Capsules.

II. Write notes on: **(10 x 6 = 60)**

1. Briefly write the quality review.
2. Write the importance of patenting drug products and process.
3. Sop for coating.
4. Consumer protection act.
5. Role of master formula in record maintenance.
6. Give an account on product recall with reference related records and documents.
7. What are the responsibilities of a Quality Control Laboratory?
8. List out the various responsibilities of qualified personnel in a manufacturing unit.
9. WHO certification.
10. Discuss the salient features of environmental protection act.

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