QP Code: 106329 **Reg No: ……**

First Year M.Pharm Degree Examinations August 2016

(Pharmaceutical Analysis)

Paper II - Quality Control and Quality Assurance

Time: 3 hrs **Maximum Marks: 100**

- ***Answer all questions***
- ***Draw diagrams wherever necessary***

Essays: **(2x20 =40)**

1. Explain the concept of good laboratory practices (GLP) and validation of equipments
2. Explain the responsibilities, importance of training and hygiene of personnel in pharmaceutical manufacturing. Add a note on selection of vendors for purchase of raw materials

Short Essays: **(6x10=60)**

3. What is batch formula record and mention its objectives
4. Explain quality audits of manufacturing process
5. Describe the good warehousing practice in a pharmaceutical company
6. Describe packing materials used in pharmaceutical industry. Add a note on quality testing of primary packing material used for oral solid dosage formulation.
7. What are the procedures involved in waste and scrap disposal
8. Discuss the salient feature of ISO 14000

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