

QP Code: 106329

Reg No:

First Year M.Pharm Degree Examinations – September 2013

(2011 Scheme)

(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. What are the ideal properties packing materials used for pharmaceuticals. Enumerate the types of packaging materials for sterile preparations and its quality control (5+15)
2. Explain the roles of GMP and GLP in bringing the suitable pharmaceutical product in to the market (10+10)

Short Essays:

(6 x10=60)

3. Why pharmaceutical product are recalled from the market. How the records and documentation are maintained
4. Explain functioning of a good warehouse practice for pharmaceutical material management
5. Mention standard operating procedure for sterilization and coating operations
6. What are the differences between master formula and batch formula record documentation
7. Discuss the essential components of purchases specifications of raw materials
8. Essential concepts of ISO 18000
