QP Code: 106329 Reg No:

First Year M.Pharm Degree Examinations—September 2014

(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. Classify packaging materials. Explain the various tests to ensure the quality of glass and plastic containers.
- 2. Explain in detail about patent regime and WHO certification. Add a note on procedure and record maintenance for waste disposal and scrap disposal in pharmaceutical industry.

Short Essays: (6 x10=60)

- 3. Discuss the concepts and philosophy of GMP.
- 4. Discuss quality audits. What are the protocols to be followed in selecting vendors.
- 5. Discuss the application of computer in quality control laboratory.
- 6. What is validation. Explain the protocols for process validation
- 7. Enumerate the standard operating procedure for coating and membrane filtration.
- 8. Explain protocols of analysis and preparation of analytical reports
