

FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) II-Semester (PCI) (Suppl.) Examination,
February 2019**

Subject: Quality Controls and Quality Assurance

Time: 3 Hrs

Max. Marks: 75

Note: Answer any five questions. All questions carry equal marks.

- 1 Write a short note on the following
 - a) Quality control. (5)
 - b) Quality assurance. (5)
 - c) Non clinical testing. (5)
- 2 Explain the various CPSCEA guidelines for laboratory animal facility. (15)
- 3 Define IPQC. Explain in detail about various IPQC tests for
 - a) Capsules. (8)
 - b) Parenterals. (7)
- 4 Give a brief note on
 - a) Quality audit plan. (5)
 - b) Protocols and reports. (5)
 - c) Distribution records. (5)
- 5 Discuss the Good laboratory practices for a quality control laboratory in detail. (15)
- 6
 - a) Explain the various documents to be maintained by the quality control department. (7)
 - b) Explain Master formula and Batch formula records. (8)
- 7 Explain various cGMP guidelines according to schedule M.
- 8 Write a note on
 - a) Sanitation of manufacturing premises (5)
 - b) Drug product inspection. (5)
 - c) Production record review. (5)
