

# **Rajiv Gandhi Proudyogiki Vishwavidyalaya**

**M. Pharma (I Sem.) EXAMINATION, Nov.-Dec, 2014**

**Advance Quality Assurance Techniques-1**

**MPY-105-QA**

**Time : Three Hours**

**Maximum Marks : 70**

**Note: Attempt any five questions. All questions carry equal marks.**

- Q.1 Discuss the importance of personnel training and personnel Hygiene in a pharmaceutical industry. How unhygienic condition can affect product quality and safety.
- Q.2 What is the importance of vendor qualification how the quality of input material can affect the quality of finished dosage form.
- Q.3 Discuss important parameters for installation and performance qualification taking a octagonal blender as a test case.
- Q.4 Discuss the importance of "Quality of water" in pharmaceutical industry. Draw a diagram of WFI water loop.
- Q.5 What special feature a hormone manufacturing facility to control the protection of environment and working personnel.
- Q.6 How cleaning of an equipment is an important step of operation during product change over. Prepare a checklist to demonstrate adequate cleaning verification.
- Q.7 How a rejected batch (product) should be handled so as to protect any contamination and prevent its misuse. Explain giving one example of a printed packing material and other example for a finished tablet dosage form.
- Q.8 Write notes on (any three) :
- (a) Appointment of a consultant
  - (b) Maintenance of working standard
  - (c) Building management system
  - (d) Disposal of waste.