

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Ph. - SEMESTER- II EXAMINATION – SUMMER -2018**Subject Code: MPT201T****Date: 14/05/2018****Subject Name: Pharmaceutical Production Management & Technology****Time: 10:30AM TO 01:30PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) Describe the facilities required in an area for sterile product manufacturing. **06**
(b) Discuss the FFS technology for manufacturing of parenterals. **05**
(c) Discuss in brief about Needle free Injections. **05**
- Q.2** (a) What is waste management? Discuss its importance in in Pharmaceutical industry. **06**
(b) Describe techniques of waste water treatment. **05**
(c) How is fire hazard prevented and monitored in a Pharmaceutical industry? **05**
- Q.3** (a) Write a note on Unit dose packaging. **06**
(b) Describe Strip packaging materials in brief. **05**
(c) Discuss evaluation of packaging materials. **05**
- Q.4** (a) What is pilot Plant Scaleup? Discuss general considerations for pilot plant scaleup. **06**
(b) Discuss various technical aspects to be addressed during scale up. **05**
(c) With a suitable diagram describe the pilot plant layout design **05**
- Q.5** (a) Describe tablet manufacturing process by wet granulation with a suitable flow diagram. Discuss the in process quality tests required during manufacturing of tablets. **06**
(b) Discuss in brief rapid mixing granulators in tablet manufacturing. **05**
(c) Describe equipments for tablet coating. Discuss fluidized bed coater in brief. **05**
- Q. 6** (a) Describe production management and production organization in brief. **06**
(b) Discuss quality estimation of a process using control charts and using Cp & CpK **05**
(c) Discuss Scale up of liquid dosage forms **05**
- Q.7** (a) Describe in process quality control tests for hard and soft capsules **06**
(b) Explain the principle and process of lyophilization technology. **05**
(c) Write a note on HVAC system in a Pharmaceutical industry. **05**
