

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2015

Subject Code: 930104**Date: 13-05-2015****Subject Name: Validation and Product Development****Time: 02:30 pm - 05:30 pm****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) Define and explain **06**
i) Validation ii) Design Qualification iii) Calibration
- (b) Discuss regarding Vendor certification. **05**
(c) Discuss in details for Validation of tablet machine. **05**
- Q.2** (a) Discuss briefly Validation Master Plan. **06**
(b) Explain the term validation protocol, validation report and SOP. **05**
(c) Write informative note on Validation of HVAC system. **05**
- Q.3** (a) Explain the term: i) Installation qualification **06**
ii) Operational qualification iii) Performance qualification
- (b) Write short notes on URS. **05**
(c) Discuss validation of membrane filtration. **05**
- Q.4** (a) What do you understand regarding cleaning validation? Why it is **06**
necessary?
- (b) Write a note on Validation of Autoclave. **05**
(c) Discuss in details regarding Validation of fluid bed dryer. **05**
- Q.5** (a) What do you understand regarding process validation? What is **06**
importance of process validation?
- (b) Write a note on Validation of Pharmaceutical water system. **05**
(c) Discuss validation of dissolution test apparatus. **05**
- Q. 6** (a) Discuss the important aspects regarding analytical method validation **06**
with respect to ICH.
- (b) Write a note on Validation of HPLC. **05**
(c) Discuss the brief idea regarding process validation of ointment **05**
- Q.7** (a) Explain the term **06**
i. Prospective validation
ii. Concurrent Validation
iii. Retrospective Validation
- (b) What do you understand regarding revalidation? Discuss merits and **05**
demerits of revalidation.
- (c) Discuss the validation protocol of capsule filling machine. **05**