

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**M. Ph. - SEMESTER- I • EXAMINATION – SUMMER 2018****Subject Code: MPH103T****Date: 07/05/2018****Subject Name: MODERN PHARMACEUTICS****Time: 02:30PM TO 05:30PM****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 strategy for analytical method development for a new solid dosage form and discuss any two validation parameters as per ICH guidelines. **06**  
(b) Write a note on computer system validation. **05**  
(c) What are main functions of WHO? What is significance of WHO guidelines? **05**
- Q.2** (a) Discuss matrixing and bracketing methods of sampling as per ICH. **06**  
(b) What is process validation? Discuss the advantages and disadvantages of organizational structures for process validation. **05**  
(c) Describe evaluation of the stability data as per ICH guidelines. **05**
- Q.3** (a) Give the organization of ICH, & its objective. **06**  
(b) Enlist various methods for Drug – Excipient Interaction study, discuss any one in details. **05**  
(c) Describe formulation details to prepare small volume parenterals. **05**
- Q.4** (a) Enlist various evaluation parameters for Large Volume Parenterals and discuss any two in details. **06**  
(b) Enlist various techniques of optimization for pharmaceutical formulation, discuss any one detail. **05**  
(c) Enlist various applications of factorial design in pharmaceutical formulation. **05**
- Q.5** (a) Discuss criteria for selection of pharmaceutical manufacturing plant location. **06**  
(b) Enlist various objectives of cGMP. **05**  
(c) Write a note on batch packaging records. **05**
- Q.6** (a) Describe importance of self inspection and quality audit as per GMP. **06**  
(b) Enlist various factors affecting compression of tablet and discuss any one in detail. **05**  
(c) Write a note on distribution of forces in preparing tablet formulation. **05**
- Q.7** (a) Enlist various parameters affecting Dissolution and describe any one in detail. **06**  
(b) What is Heckel Plot? Describe its role in tablet physics. **05**  
(c) Enlist various applications of similarity factor  $f_2$  and  $f_1$  and ANOVA test in pharmaceutical formulation. **05**

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