

Seat No.:-----

Enrolment No.:-----

**UKA TARSADIA UNIVERSITY**

**Maliba Pharmacy College**

M. Pharm 1<sup>st</sup> Semester Internal Examination Nov 2012

**040120102 - Pharma Technology - I**

Time: 3 Hours.

Max. Marks: **70**

Date: 29/11/2012

**Instructions:**

- Question no. **1 is compulsory.**
- From Q.2 to Q.7 attempt any **four** questions.
- Make suitable assumption whenever necessary.
- Figures to the right indicate full marks.

- Q.1** (a) Answer the following: (any six) **06**
- 1 What is meant by continuous process verification?
  - 2 Define product life cycle
  - 3 Define technology transfer
  - 4 Define process robustness
  - 5 Enlist different types of glass
  - 6 What do you understand by overages?
  - 7 What are cullets?
- (b) Describe in brief: (any four) **08**
- 1 What is meant by space design?
  - 2 Write briefly importance of technology transfer.
  - 3 What is importance of validation in technology transfer?
  - 4 Write criteria of successful technology transfer.
  - 5 What are Q8 & Q9 ICH Guidelines?
- Q.2** (a) Discuss the key objectives of product development guidelines. **04**
- (b) What do you understand by ICH guidelines? Discuss their objectives. **05**
- (c) How does manufacturing process development differ with formulation development? What is the purpose of including microbiological and compatibility aspects in the pharmaceutical product development studies? **05**
- Q.3** (a) Describe the plan of technology transfer of Risperidone low dose tablet. **04**
- (b) Discuss the technology transfer in various departments of pharmaceutical industry. **05**
- (c) Discuss the technology transfer team with their responsibilities. **05**
- Q.4** (a) Explain the pre transfer consideration aspects of technology transfer. **04**
- (b) Write a brief note on Q10 ICH guidelines **05**
- (c) Explain technology transfer of tablet. **05**
- Q.5** (a) Explain factors affecting selection of packaging material. **04**
- (b) Write a note on plastic as packaging material. **05**
- (c) Explain child resistant packaging system. **05**
- Q. 6** (a) Explain mixing with reference to formulation and production of pharmaceuticals. **04**
- (b) Discuss continuous processing of solid dosage forms, **05**
- (c) Write a note on metal as packaging material. **05**

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| Q.7 | (a) | Explain various tests to be performed on glass.        | <b>04</b> |
|     | (b) | Discuss ideal properties of packaging material.        | <b>05</b> |
|     | (c) | Enlist properties of glass used as packaging material. | <b>05</b> |