

PARUL UNIVERSITY
FACULTY OF PHARMACY
M.Pharm. Summer 2018 - 19 Examination

Semester: 1**Subject Code: MQA104T****Subject Name: Product Development and Technology Transfer****Date: 29/04/2019****Time: 10:00am To 01:00pm****Total Marks: 75****Instructions:**

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) (30)

1. Write a note on Scale Up Post Approval Changes (SUPAC)-MR.
2. Describe different types of pharmaceutical packaging materials. Discuss selection and evaluation of pharmaceutical packaging materials.
3. Give layout of pilot plant scale up. Discuss pilot plant scale up technique for solid dosage form.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) (25)

1. Write a short note on Polymorphism.
2. Describe optimization and production of technology transfer.
3. During product development how stability testing occurred?
4. Write a note on quality control tests for secondary packing materials.
5. Give format and content of IND in detail.
6. Briefly explain large scale manufacturing techniques of parenteral dosage form.

Q.3 Short Answers. (2 Marks Each) (20)

1. What is Post marketing surveillance?
2. Define co-solvency with example.
3. Write importance of Supplemental New Drug Application (SNDA)?
4. What is Pilot Plant design?
5. What are objectives of preformulation?
6. Explain term preformulation.
7. What is Technology Transfer?
8. Enumerate various solubility enhancement techniques.
9. What is Enteral packaging system?
10. What are the difference between NDA and ANDA?