

Enrollment No: _____ Exam Seat No: _____

C.U.SHAH UNIVERSITY
Winter Examination-2022

Subject Name: Product Development and Technology Transfer

Subject Code: MQA104T

Branch: M.Pharm (PQA)

Semester: 1

Date: 16/03/2023

Time: 10:30 To 01:30

Marks : 75

Instructions:

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
- (2) Instructions written on main answer book are strictly to be obeyed.
- (3) Draw neat diagrams and figures (if necessary) at right places.
- (4) Assume suitable data if needed.

-
- Q-1 Elaborate the following questions: (20)**
- | | | |
|----------|--------------------------------------|----------|
| A | SUPAC | 2 |
| B | Technology transfer plan | 2 |
| C | BACPAC | 2 |
| D | Orphan drug | 2 |
| E | ANDA | 2 |
| F | Polymorphism | 2 |
| G | Product registration for USFDA | 2 |
| H | Quality control of semi solids | 2 |
| I | Technology transfer plan and exhibit | 2 |
| J | Documentation in technology transfer | 2 |
- Q-2 Attempt any two of following : (20)**
- | | | |
|----------|--|-----------|
| A | What is Pre-formulation study? Enumerate various parameters in pre-formulation study and explain methods to improve solubility of drugs. | 10 |
| B | Qualitative and quantitative model for technology transfer | 10 |
| C | Explain different pharmaceutical packaging systems with their evaluation. | 10 |
- Q-3 Write short notes on any Seven of following: (35)**
- | | | |
|----------|---|----------|
| A | Post marketing surveillance | 5 |
| B | Pilot plant scale up | 5 |
| C | Technology transfer from R&D to production | 5 |
| D | Stability study during product development | 5 |
| E | Clinical research process | 5 |
| F | Opportunities and challenges for the scale up | 5 |
| G | Investigators brochure | 5 |
| H | CDSCO | 5 |
| I | Modern drug packaging issues | 5 |

