Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Winter Examination-2018

Subject Name: Product Development and Technology Transfer
Subject Code: MQA104T **Branch:** M.Pharm (QA)
Semester: 1 **Date : 03/12/2018** **Time : 02:30 To 05:30** **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 **Attempt the following questions:** **(20)**

a) Orphan drug
b) Polymorphism
c) Temper proof packaging
d) e-CTD
e) RLD
f) Sponsor
g) Investigator
h) Child resistant container
i) INDA
j) Enteral Packaging

Attempt the following questions:

Q-2		**Attempt any two of following :**	**(20)**
	A	Explain various phases of Drug Development and Approval process as per USFDA	**10**
	B	Discuss Design and Construction features in context to Building and facilities under GMP	**10**
	C	Discuss technology transfer plan and it Exhibit	**10**
Q-3		**Attempt any Seven of following :**	**(35)**
	A	Explain in detail about Investigator Brochure	**5**
	B	Write a note on review process of NDA	**5**
	C	Write a note on qualitative and quantitative technology models in technology transfer	**5**
	D	Write a short note on solubility enhancement techniques	**5**
	E	Discuss importance of DSC study in prefromulation	**5**
	F	Write a note on matrixing and bracketing in stability study.	**5**
	G	Explain the Quality control test of secondary packing materials	**5**
	H	Write a note Aseptic packaging systems.	**5**
	I	Prepare departmental layout with equipment required for liquid orals	**5**