Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY
Winter Examination-2018

Subject Name: Quality by Design and Process Analytical Technology

Subject Code: 4PS07QBD1 **Branch:** B.Pharm

Semester: 7 Date : 10/12/2018 Time : 10:30 To 01:30 Marks : 70

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 **Define the following terms** **(14)**

a) Quality by Design
b) Process Analytical Technology
c) Reference Listed Drug Product
d) Quality Target Product profile
e) Critical Quality Attributes
f) Critical Process Parameter
g) Significant factors
h) Abbreviated New Drug Application
i) Degrees of freedom
j) Design of Experiments
k) In Vitro-In Vivo Correlation
l) Hazard Analysis and Critical Control points
m) Risk evaluation
n) Design Space

Attempt any four questions from Q-2 to Q-8

Q-2 **Attempt all questions** **(14)**

a. Explain the Benefits of Implementing Quality by Design for pharmaceutical Industry. **(7)**

b. Enlist and explain the elements of QbD. **(7)**

Q-3 **Attempt all questions** **(14)**

a. Write a note on QbD with concepts to abbreviated new drug applications **(7)**

b. Write a note on continual improvement of process performance and product quality **(7)**

Q-4 **Attempt all questions** **(14)**

a. Enlist the different parts of CTD. Explain any one in detail **(7)**

b. Explain in brief Risk Base Approach and Integrated System Approach **(7)**

Q-5 **Attempt all questions** **(14)**

a. Draw a process map for Modified Release Dosage Form by QbD. **(7)**

	b.	Write about QTPP with respect to Modified release dosage form.	**(7)**
Q-6		**Attempt all questions**	**(14)**
	a.	Write classification of optimization techniques and explain any one	**(7)**
	b.	Write about scope and principles of PAT	**(7)**
Q-7		**Attempt all questions**	**(14)**
	a.	Explain the manufacturing process variables with respect to Immediate Release Dosage Form.	**(7)**
	b.	Write on PAT Framework and Tools	**(7)**
Q-8		**Attempt all questions**	**(14)**
	a.	How can determine the Design Space?	**(7)**
	b.	Explain the Failure Mode Effects Analysis	**(7)**