Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Winter Examination-2020

Subject Name: Quality Control and Quality Assurance

Subject Code: MQA103T **Branch: M.Pharm (Quality Assurance)**

Semester: 1 **Date: 10/03/2021** **Time: 11:00 To 02:00** **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) Quality Audit
b) Batch Manufacturing Record
c) Quality Assurance
d) Enlist IPQC tests of Parenteral dosage form.
e) Importance of SOP
f) Enlist scopes of QA
g) Importance of IPR
h) Enlist ICH Q series guidelines
i) Trade mark
j) Copyright

Attempt the following questions:

Q-2		**Attempt any two of following :**	**(20)**
	A	Enlist the ICH Q series guidelines and discuss ICH guideline Q3B (R2) Impurities in New Drug Products.	**10**
	B	Write brief note on CPCSEA guideline.	**10**
	C	Explain process deviation, change control and reprocessing.	**10**
Q-3		**Attempt any Seven of following :**	**(35)**
	A	Discuss the IPQC tests for tablet dosage form.	**5**
	B	Discuss the importance of Intellectual Properties Rights.	**5**
	C	Discuss the way to control mix ups and cross contamination at manufacturing site.	**5**
	D	Write a note on finished product quality control tests for Ointments.	**5**
	E	Differentiate the CTD submission for regulated & non-regulated market.	**5**
	F	What is GLP? Describe the responsibilities of the quality assurance unit of a non-clinical testing laboratory.	**5**
	G	Handling of waste and scrap disposal in manufacturing operation.	**5**
	H	Note on CTD and eCTD	**5**
	I	Explain different methods for the determination of shelf life of product	**5**