Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY
Winter Examination-2022

Subject Name : Quality Control and Quality Assurance

Subject Code : MQA103T **Branch: M.Pharm (PQA)**

Semester : 1 **Date : 15/03/2023** **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 **Attempt the following questions:** **(20)**

a) Define Trade mark
b) Define Patents
c) Give expiry date calculation
d) Differentiate Sterilize in Place & clean in place
e) What is IPR? Enlist IPR
f) Classify types of DMF
g) What is Geographical Indication in IPR?
h) Give format for Batch Manufacturing Record
i) Describe out of Specification
j) Comment on Penicillin can be manufacture with Paracetamol in same plant

Q-2 **Attempt any two of following :** **(20)**

A What is meant by SOP? Describe any two SOPs used in production department. **10**

B Explain importance of Documentation in Quality Control Department. Discuss the case study of Change Control procedure. **10**

C Define and differentiate Quality Control and Quality Assurance. Write scope of QA and QC in Pharmaceutical Company. Enlist and explain in brief IPQC tests Tablet. **10**

Q-3 **Attempt any Seven of following :** **(35)**

A Outline GLP guideline for animal house facility and animal care in a non-clinical testing laboratory **5**

B Write note on waste & scrap disposal **5**

C Write different tests and methods for testing of primary packing materials. **5**

D Write a note on purchase specifications and maintenance of stores For raw materials **5**

E Write the contents & interrelationship between Master Manufacturing, **5**

	Batch Manufacturing & Batch Packing records	
F	Draw triangle of CTD and discuss Module 5	**5**
G	Write the protocol to conduct non clinical testing.	**5**
H	Draw the flow chart for Establishing Acceptance Criterion For a Degradation Product in a New Drug Product as per ICH Q6 A guidelines.	**5**
I	Discuss need for protection of Patent rights in Pharma.	**5**