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 Mark: 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: 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: A Enlist the ICH Q series guideline. C Explain process deviation, change control and reprocessing. Attempt any Seven of following: A Discuss the importance of Intellectual Properties Rights.		Exam Seat No:	No:	Enrollment
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C Discuss the way to control mix ups and cross contamination at	5 5	1 0	*	



Write a note on finished product quality control tests for Ointments.

Handling of waste and scrap disposal in manufacturing operation.

Differentiate the CTD submission for regulated & non-regulated market.

What is GLP? Describe the responsibilities of the quality assurance unit

Explain different methods for the determination of shelf life of product

manufacturing site.

Note on CTD and eCTD

of a non-clinical testing laboratory.

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