Your Roll No.....

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M. Pharm. I Semester Examination 2024

Subject: **Quality control and Quality assurance** Maximum Marks: **75**
Paper Code: **MQA 103T** Date: **13-03-24** Time: **Three hours**

(Write your Roll No. on the top immediately on receipt of this question paper)

Note: *This paper has **two Sections; A** and **B**.*
Attempt all the two sections.
***Section A**: Answer **all** the questions. **Section B**: Answer **any 4** out of 6 questions*

Abbreviations Used:
CO-Course Outcome, PO- Program Outcome, BTL- Bloom Taxonomy Level: BT level 1- Remember; BT level 2- Understand; BT level 3- Apply; BT level 4- Analyze; BT level 5- Evaluate; BT level 6- Create.

SECTION-A

Answer the following in brief (Attempt all questions) **5x3= 15 Marks**

Q. No 1	Question	BTL	CO	PO
(a)	Write differences between QC and QA. What are the key functions of QAU?	2	1, 2, 5	1,2,3
(b)	What do you understand by the term CCSEA guideline? Under which Govt organization does it fall. Give a preview of report preparation in an animal house facility.	4	4,5	1,2,3
(c)	What are the objectives and purposes of ICH guidelines? Define "S" guideline in very brief?	5	4,5	1,2,3
(d)	Give the factors affecting QA in a Pharmaceutical set up.	3	4,5	1,2,3
(e)	Highlight the Sanitation protocols for premises of Pharmaceutical manufacturing units, mix ups and cross contamination.	4	4,5	1,2,3

SECTION B

Long type Questions (Attempt any 4 out of 6) **4x15= 60 Marks**

	Question	BTL	CO	PO
Q. No 2	How the documentation in Pharmaceutical industry is done? Discuss the CTD and eCTD in detail	4	1, 2, 5	1,2,3
Q. No 3	What is SOP? Describe the usefulness of Batch Manufacturing record and Master batch record	4	4,5	1,2,3
Q. No 4	Write short notes on **any three** ● Composition of USFDA with emphasis on the drug centres ● WHO guidelines in relation with organization, personnel and plant layout ● Regulated and Non regulated markets ● Geographical Indication and Trade-secret ● GLP	4	4,5	1,2,3

Q. No 5	Define and elaborate the IPQC and FPQC test for **any one** solid dosage form.	5	4,5	1,2,3
Q. No 6	A patent-able entity needs to pass through certain tests. Mention these with an example. Also discuss why this is a negative right. How does grant of patent adds value to an individual/organization.Give a flow chart suggesting the most salient steps for grant of an Indian patent. Suggest any one example of patent infringement.	4	4,5	1,2,3
Q. No 7	Define cGMP guidelines in relevance to modern techniques. Which schedule describes this guideline? How does it differ from GMP guidelines.	4	4,5	1,2,3