Year and Program- T Y B Pharmacy	**School of Pharmaceutical Sciences**	**Department : Pharmacy**
Course Code : BP606T	**Course Title : Pharmaceutical Quality Assurance**	**Semester – VI**
Date 03/06/2024 **Day :** Monday **Time:** 10:30AM To 01:30PM	**Examination: End Semester**	**Max Marks: 75**

Instructions: 1) All questions are compulsory.
2) Draw a neat labeled diagram if necessary.

		Marks	Bloom's Level	CO
Q.1	**Objective Type Questions (10X2)**	**20**		
a)	Enlist the objective of ICH	02	2	CLO1
b)	What are the benefits of ISO 9000?	02	2	CLO1
c)	What are the elements of QBD?	02	2	CLO1
d)	Define validation master plan.	02	1	CLO5
e)	Explain the concept of FIFO	02	2	CLO2
f)	What are personnel requirement as per GLP?	02	2	CLO3
g)	Write the importance of SOP in manufacturing	02	2	CLO4
h)	Enlist significance of batch manufacturing record	02	2	CLO4
i)	Define standard operating procedure (SOP)	02	1	CLO4
j)	Write the difference between QA & QC	02	2	CLO3
Q.2	**Long Answers (Answer 2 out of 3)**	**20**		
a)	Discuss in detail the design, construction, plant layout and requirement of environmental control in sterile manufacturing unit.	10	2	CLO2
b)	Discuss the importance of good manufacturing practice (GLP). Explain briefly the protocol content of non-clinical laboratory study.	10	2	CLO3
c)	Write in detail about personnel responsibility, training and hygiene in pharmaceutical industry	10	1	CLO2

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Q3	Short Answers (Answer 7 out of 9)	35	Bloom's Level	CO
a)	Write a note on ISO 9000 & ISO 14000	05	1	CLO1
b)	Discuss the SOP of handling of return goods	05	2	CLO4
c)	Explain guideline to be followed for waste disposal in pharmaceutical industry	05	2	CLO2
d)	Explain briefly CTD & its modules.	05	2	CLO5
e)	Describe the SOP for Purchase specification	05	2	CLO4
f)	Discuss the maintenance of raw material stores	05	2	CLO2
g)	Describe the methods to prevent product contamination in sterile manufacturing unit	05	2	CLO3
h)	Describe the protocol for conduct of non-clinical laboratory study	05	2	CLO4
i)	Explain the handling of market complaints.	05	2	CLO4

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