Name: Enrolment No:	

UPES

End Semester Examination, December 2024

Course: Good Manufacturing & Laboratory Practice **Semester: 7th**

Program: BT-BIOTECHNOLOGY **Duration: 3 Hours**

Course Code: HSBT4002 **Max. Marks: 100**

Instructions: Attempt all questions

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Which phase of drug development is primarily concerned with ensuring safety in humans? a) Preclinical studies b) Clinical Phase I c) Clinical Phase II d) Post-marketing surveillance	**1.5**	**CO1**
Q 2	In GMP, which of the following is critical for maintaining product quality? a) Automated marketing b) Facility cleanliness c) Increased production speed d) Flexible documentation	**1.5**	**CO3**
Q 3	Which guideline focuses on risk management for pharmaceutical quality? a) ICH Q8 b) ICH Q9 c) ICH Q10 d) ICH E6	**1.5**	**CO3**
Q 4	The role of national and international regulatory authorities is to: a) Oversee research funding b) Enforce product quality and safety standards c) Create product marketing plans	**1.5**	**CO3**

	d) Organize training for pharmaceutical employees		
Q 5	In Design of Experiment (DOE), a factorial design is used to: a) Test one factor at a time b) Test multiple factors simultaneously c) Perform simple experiments d) Minimize testing costs	**1.5**	**CO2**
Q 6	Which of the following is *not* a purpose of Quality by Design (QBD)? a) Improve process understanding b) Ensure consistent product quality c) Reduce regulatory oversight d) Enhance product development	**1.5**	**CO2**
Q 7	Design of Experiment (DOE) helps identify optimal conditions for manufacturing processes. (True Or False)	**1.5**	**CO3**
Q 8	Good Manufacturing Practice (GMP) regulations are the same in all countries. (True Or False)	**1.5**	**CO2**
Q 9	Ethics in manufacturing includes ensuring that no shortcuts are taken to compromise product quality. (True Or False)	**1.5**	**CO3**
Q 10	GLP guidelines apply to clinical trials in humans. (True Or False)	**1.5**	**CO2**
Q 11	The ICH guidelines are mandatory for all pharmaceutical companies globally. (True Or False)	**1.5**	**CO3**
Q 12	Which regulatory guideline focuses on stability testing for drug products? a) ICH Q1A b) ICH Q8 c) FDA Part 11 d) GMP Annex 11	**1.5**	**CO1**
Q 13	In GMP, which document provides details of the manufacturing process for a product? a) Master Batch Record b) Risk Management Report c) Quality Manual d) Site Master File	**1.5**	**CO1**
Q 14	Which authority oversees drug approval in Europe? a) Food and Drug Administration (FDA) b) European Medicines Agency (EMA) c) World Health Organization (WHO) d) Medicines and Healthcare products Regulatory Agency (MHRA)	**1.5**	**CO1**
Q 15	Which phase of clinical trials is primarily concerned with determining a drug's efficacy? a) Phase I b) Phase II c) Phase III	**1.5**	**CO2**

	d) Phase IV		
Q 16	GMP requirements for training are outlined in: a) ICH Q9 b) WHO TRS 961 c) FDA 21 CFR Part 11 d) ISO 9001	**1.5**	**CO2**
Q 17	Which phase of drug development is primarily concerned with ensuring safety in humans? a) Preclinical studies b) Clinical Phase I c) Clinical Phase II d) Post-marketing surveillance	**1.5**	**CO2**
Q 18	Design of Experiment (DOE) is only applicable to chemical testing. (True or False)	**1.5**	**CO3**
Q 19	Define "Pharmaceutical Jurisprudence."	**1.5**	**CO2**
Q 20	GLP and GMP compliance are optional for clinical trials. (True or False)	**1.5**	**CO1**
	Section B **(4Qx5M=20 Marks)**		
Q 1	State the main purpose of ICH guidelines in drug development.	**5**	**CO1**
Q 2	Briefly explain the concept of "Quality by Design" (QBD).	**5**	**CO2**
Q 3	Describe the significance of batch records and how they contribute to GMP compliance.	**5**	**CO2**
Q 4	Explain the ethical importance of GLP in preclinical research and its impact on public health.	**5**	**CO3**
	Section C **(2Qx15M=30 Marks)**		
Q 1	Summarize the importance of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) compliance for regulatory approval of pharmaceutical products. ***(5 Marks)*** Comment on the ethical implications of these practices in the pharmaceutical industry, including how they protect public health and ensure product safety and quality. ***(5 Marks)*** Include examples of GMP and GLP requirements that are critical for maintaining ethical standards. ***(5 Marks)***	**15**	**CO2**
Q2	Describe the principles of Quality by Design (QBD) and its application throughout the product lifecycle. ***(5 Marks)*** Discuss how QBD can reduce risks in product quality and contribute to regulatory compliance. ***(5 Marks)*** Include examples of QBD tools and techniques, such as DOE. ***(5 Marks)***	**15**	**CO3**
	Section D		

(2Qx10M=20 Marks)			
Q 1	Explain the purpose and process of analytical method validation in drug development. ***(5 Marks)*** Identify the essential parameters requiring validation and demonstrate how validation processes enhance quality assurance and facilitate regulatory approval. ***(5 Marks)***	**10**	**CO2**
Q2	Comment on the importance of different phases of clinical trials.	**10**	**CO2**