Enrollment No._____

NAVRACHANA UNIVERSITY
a UGC recognized University

School: School of Science
Program/s: B.Sc.
Year: 3rd **Semester:** 5th
Examination: End Semester Examination
Examination year: December 2022

Course Code: SE201 **Course Name:** **Essential Laboratory Practices**
Date: 07/12/2022 **Total Marks:** 40
Time: 02:30 pm to 04:30 pm **Total Pages:** 2

Instructions:

- *Write each answer on a new page.*
- *Use of a calculator is permitted/not permitted.*
- ** COs=Course Outcome mapping. # BTL=Bloom's Taxonomy Level mapping*

Q. No.	Details	Marks	COs*	BTL#
Q.1	**Do as directed:** 1. Which of the following is an example of GLP (Good laboratory Practice)? a) Taking hematology data for control animals from control groups not connected with the study b) Deleting gross necropsy observations because the histopathologist received no specimens of these lesions c) Keeping a proper record of all the data without manipulation. d) None of the above. 2. Which of the following is NOT true about GLP? a) One of the purpose of the GLP is to promote the development of quality test data b) It provides a tool to ensure a sound approach to the management of laboratory studies c) It is permissible to partially implement GLP requirements and still claim GLP compliance d) None of the above 3. GCPs provide public assurance that the rights and safety of participants in human subject research are protected but does not assure that the data that arises from the study is credible. State true or false with reason. 4. Which of the following is true about the FDA logo? a) It should not be used to misrepresent the agency b) It should not be used to suggest that FDA endorses any private organization, product, or service c) Misuse of the FDA logo may violate federal law d) All of the above 5. State any two information the participants volunteering in the clinical studies are required to know under GCP. 6. Write full form of IND 7. Drugs can be directly tested on humans in India. State true or false. 8. Name any two cell lines 9. _____ and _____ enzymes are used to break cellular glue and detach the cells from each other.	5	CO1 CO2 CO3 CO4 CO5	BT1, BT2 BT4

	10. Clinical trials are done under the guide line of _____.			
Q.2	**Answer in brief (Any 7)** 1. What is regulatory affairs? 2. What are characteristics of continuous cell lines? 3. What is animal testing? 4. Name the instruments used in cell culture. 5. What are the different types of inspection conducted by the FDA (Food and Drug Administration)? 6. One of the precautions to be followed while checking the pH using a pH meter is to make sure that there is no vibration on the table where you are measuring. What do you think is the importance of this step? 7. State two importance of following GMP. 8. What is meant by Quality System Regulation? Why is it important?	**14**	CO1, CO2 CO3 CO4 CO5	BT1, BT2, BT4
Q.3	**Write short notes on (Any 2)** 1. Safety aspects required in cell culturing. 2. Primary culture. 3. Approaches used in drug discovery (Explain any one in detail).	**6**	CO1 CO2 CO3 CO4 CO5	BT1 BT2
Q.4	**Answer in detail (Any 2)** 1. Explain in detail the phases of preclinical trials. 2. What are the core principles of the consolidated GCP (Good Clinical Practice) guidelines? 3. What is meant by GMP (Good Manufacturing Practices)? Write the main principles of GMP.	**10**	CO1 CO2 CO3 CO4	BT1 BT2

**********End of Question Paper**********