



School: School of Science
Program/s: B.Sc. – M.Sc. Integrated Program in Biomedical Science (BMS)
Year: 2nd **Semester:** 3rd
Examination: End Semester Examination
Examination year: December 2022

Course Code: BM206 **Course Name:** GOOD LABORATORY PRACTICES
Date: 15/12/2022
Time: 11:30 am to 01:30 pm

Total Marks: 40
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	<p>Choose the correct answer:</p> <ol style="list-style-type: none"> 1. As far as pharmaceutical development is concerned, the GLP Principles, in their regulatory sense, apply only to studies which: <ol style="list-style-type: none"> a. Are non-clinical, mostly studies on animals or in vitro, including the analytical aspects of such studies b. Are designed to obtain data on the properties and/or the safety of items with respect to human health and/or the environment c. Both (a) and (b) d. None of the above 2. According to GCP, the medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of: <ol style="list-style-type: none"> a. A qualified physician b. A qualified physician or, when appropriate, of a qualified dentist c. A qualified medical representative with vast experience d. None of the above 3. Which of the following is the correct sequence for SOP of pH meter? <ol style="list-style-type: none"> I. Connect the unit to 230v mains power supply and press the ON/OFF key, II. Place the instrument on clean and flat surface near a power point III. After completion clean the instrument and record the activity in log book of pH meter IV. Rinse the electrode with purified water, wipe and dip in the sample <ol style="list-style-type: none"> a. II-I-III-IV b. I-IV-III-II c. I-III-IV-II d. II-I-IV-III 4. Which of the following is NOT true about invitro studies? <ol style="list-style-type: none"> a. It permits a species-specific, simpler and convenient analysis b. Human cells can be studied without "extrapolation" from an experimental animal's cellular response. c. Can be miniaturized and automated, yielding high-throughput screening methods for testing molecules d. None of the above 	4	C01 C02 C04 C05	BT1, BT2, BT4

Q.2	<p>Fill in the blanks.</p> <ol style="list-style-type: none"> 1. A set of step-by-step instructions compiled by an organization to help workers carry out routine procedures is known as _____. 2. The full form of OECD is _____. 3. Studies in which the effects of various biological entities are tested on whole living organisms are known as _____. 4. The hemocytometer is also known as _____. 5. EPA stands for _____. 6. The _____ professional facilitates the collection, analysis and communication about the risks and benefits of health products to the regulatory agencies, medical, and health systems and the public. 	6	CO1, CO2 CO3 CO4 CO5	BT1, BT2
Q.3	<p>Do as directed.</p> <ol style="list-style-type: none"> 1. Why are clinical trials conducted? (Give two reasons) 2. State the difference between drug development and drug discovery. 3. What is meant by Declaration of Helsinki? State one importance of Declaration of Helsinki. 4. Ethidium Bromide (EtBr), used in Gel Electrophoresis should be handled with caution when mixed in the gel. State true or false with reason. 5. State specifically why new drugs and biological products for people must be FDA approved. 	10	CO1, CO2, CO3, CO4, CO5	BT1, BT2
Q.4	<p>Answer <u>any four</u> from the following in detail.</p> <ol style="list-style-type: none"> 1. Discuss in brief any case study where GCP guidelines were not followed, emphasizing which GCP were not followed in the study. 2. Discuss the importance of a) Calibration b) Maintenance of laboratory equipment. 3. What is meant by Quality Systems Regulations? Explain in brief the history and applications of QSR. 4. Write short note on: Phases of Clinical trial. 5. What are the four types of FDA inspections? Explain each in detail. 	20	CO1, CO2, CO3, CO4 CO5	BT1, BT2, BT4

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