

1. Attempt **all** questions.
2. **All questions** carry **equal** marks.
3. Draw **neat labeled diagrams** wherever necessary.
4. For **Q 2, Q 3 and Q 4** attempt **A and B OR C and D**.

**Q 1 Do as directed (Any fifteen)****15**

1. Give any two Objectives of GLP.
2. Original copy of the documents called \_\_\_\_\_.  
a. Controlled copy b. Uncontrolled copy c. Master copy d. Obsolete copy
3. What is the full form of OECD?
4. What does SOP stand for?
5. Give one name of instruments which are used in the Microbiology department.
6. What do you understand by the term Biosecurity?
7. Sonicators and vortex mixers are proven sources of aerosols. State whether True or False.
8. \_\_\_\_\_ is the least resistant organism during decontamination.  
a. Lipid Viruses b. Mycobacteria c. Non-Lipid Viruses d. Prions
9. The pathogens that require BSL-3 laboratories include \_\_\_\_\_.  
a. *Plasmodium falciparum* b. Ebola virus c. HIV d. *Serratia marcescens*
10. What is the full form of CDC?
11. Define Biosafety.
12. Name one common organism that requires Biosafety Level-1 containment.
13. BSL-4 laboratories are not necessarily separated from the general traffic patterns in the building. State whether True or False.
14. Work can be performed on an open table in BSL-3. State whether True or False.
15. Define 'Pyrogen'.
16. Give one example of a flavouring agent used in pharmaceutical industries.
17. Antiseptic solutions cannot be metabolized by microorganisms. State whether the statement is true or false.
18. What is water activity?
19. Mention one observable effect of microbial attack on pharmaceutical products.
20. State one example of contaminants found in pharmaceutical products.

**Q. 2 A** Discuss any Four Guidelines to GLP.**08****Q. 2 B** Explain the potential hazards associated with Work Practices and Safety Equipment.**07****OR****Q. 2 C** Discuss Biological Risk Assessment.**08****Q. 2 D** Explain in detail documentation of laboratory work.**07**

- Q. 3 A Give a detailed account on Biosafety level 3. 08  
 Q. 3 B What are the examples of facility design considerations that should be provided in a biosafe lab? 07

OR

- Q. 3 C What are key considerations and best practices for waste management in a diagnostics laboratory? 08  
 Q. 3 D Discuss about Occupational hazards in health. 07

- Q. 4 A Discuss the factors affecting the microbial spoilage of pharmaceutical products. 08  
 Q. 4 B Give a detailed account on preservation of pharmaceutical products. 07

OR

- Q. 4 C Explain in detail 'microbial limit test for pharmaceutical products'. 08  
 Q. 4 D Discuss the source and types of microbial contaminants found in pharmaceutical products. 07

- Q. 5 Write Short notes on any three of the following 15  
 a. Calibration records  
 b. Cell culture  
 c. Personnel competence in Biosafety.  
 d. Transport of Biohazardous materials On Campus.  
 e. Chemical spoilage of pharmaceutical products.