

Roll No. ....

Total Pages : 03

LMDE/M-24

**7029**

INDUSTRIAL BIOCHEMISTRY

BCH-201

(wef 2023-24)

Time : Three Hours]

[Maximum Marks : 80

**Note :** Attempt *Five* questions in all, selecting *one* question from each Unit. Q. No. **1** is compulsory. All questions carry equal marks.

**(Compulsory Question)**

**1.** Explain the following terms : **8×2=16**

- (i) Bioethics
- (ii) Standard operating procedures
- (iii) Accuracy of a method
- (iv) Limit of quantification of a method
- (v) Clinical research
- (vi) Components of diagnostic kit
- (vii) Copyright
- (viii) Embryonic stem cells.

### Unit I

2. (a) What is biosafety ? Discuss its significance.  
(b) Explain the bio-hazards of a laboratory.  
(c) Discuss WHO guidelines for testing. **6,5,5**
3. (a) Discuss the quality control and quality assurance of laboratory.  
(b) Why record keeping is important for a laboratory ? Discuss documentation that should be maintained for a diagnostic laboratory.  
(c) Describe standards of Quality Control of India (QCI). **6,6,4**

### Unit II

4. (a) Explain the criteria of selecting the drug targets. Also discuss the techniques used for validating the pharmaceutical/drug targets.  
(b) Write a note on drug toxicity. **10,6**
5. (a) Enlist the applications of industrial biochemistry.  
(b) Explain the different stages of product development process. **6,10**

### Unit III

6. (a) Discuss animal cell culture technology.  
(b) Explain the role of artificial intelligence in health care. **8,8**

7. Discuss the regulatory affairs in : **5,5,6**  
(i) Research and documentation  
(ii) Product management  
(iii) Clinical trial.

### Unit IV

8. Write notes on the following : **4,4,4,4**  
(i) Industrial designs  
(ii) Plant genetic resources  
(iii) Trademarks  
(iv) Patentable and non-patentable IPRs.
9. (a) Discuss ethical and socio-economic aspects related to gene therapy.  
(b) What is genome project ? Explain human gene project. **8,8**