

BIOETHICS & IPR
(BIOT 4231)

Time Allotted : 2½ hrs

Full Marks : 60

Figures out of the right margin indicate full marks.

Candidates are required to answer Group A and any 4 (four) from Group B to E, taking one from each group.

Candidates are required to give answer in their own words as far as practicable.

Group – A

1. Answer any twelve:

12 × 1 = 12

Choose the correct alternative for the following

- (i) Preclinical trial does not involve
(a) *in vitro* model
(b) *in vivo* animal model
(c) both *in vivo* animal model and *in vitro* model
(d) human model.
- (ii) Montreal protocol is aimed to
(a) reduce the use of CFCs
(b) minimize the use of GHG
(c) minimize the harm posed towards the non-annex-I countries
(d) none of these.
- (iii) According to the Belmont Report, research involving human subjects demands
(a) Informed consent (b) Risk assessment
(c) Benefit assessment (d) Subject selection
- (iv) Which of the following condition are not essential to qualify as a “Start-up” as per the Patent Rules, 2003?
(a) More than five years have not lapsed from the date of its incorporation or registration
(b) It is working towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or intellectual property
(c) During the five to ten years of incorporation, the turnover should not exceed thirty crores
(d) The turnover for any of the financial years, within five years of incorporation or registration, did not exceed rupees twenty-five crores.
- (v) Which of these is a geographical indication?
(a) BMW (b) Champagne
(c) Hogwarts (d) World Wide Web.

- (vi) What is the full form of WTO?
 (a) World Trademark Organisation (b) World Trade Organisation
 (c) World Trade and Traffic Organisation (d) None of these.
- (vii) By India patent act 1970, a patent gives protection for
 (a) 14 years from the date of publication
 (b) 20 years from the date of grant
 (c) 21 years from the next calendar year in which the patent is granted
 (d) none of these.
- (viii) Genetic enhancement is
 (a) an IPR (b) a bioethics issue
 (c) distributive justice (d) all of these
- (ix) What ethical theory applies to the statements “Donated organs should be made available to patients on the basis of medical need and not on the basis of social status or other consideration”?
 (a) Justice (b) Rights
 (c) Double effect (d) Preference utilitarianism.
- (x) An entrepreneur who enters the market with a product or service offering similar to those existing in the market is called
 (a) Innovative entrepreneur (b) Opportunity entrepreneur
 (c) Necessity entrepreneur (d) Replicative entrepreneur.

Fill in the blanks with the correct word

- (xi) Full form of G A T T _____.
- (xii) According to the Indian version, copyright is valid for a period of _____ years after the death of the author.
- (xiii) Validity of the patent right in India for _____ years.
- (xiv) Full form of TRIPS _____.
- (xv) The planned pathway to convert a vision into reality is called _____.

Group - B

2. Discuss about of the following with real life examples in the context of bioethics: (i) The responsible conducts of biotechnological research. (ii) Research with human subjects. (iii) Declaration of Helsinki (1964) by World Medical Association (WMA).
[[CO1](Analyse/IOCQ)]
(3 × 4) = 12
3. (a) What is bioethics? Describe the principle of bioethics and explain with real example from your life.
[[CO1](Remember-Explain/IOCQ)]
- (b) What is plagiarism? “Plagiarism is the road block in modern biotechnology” explain with example.
[[CO2](Understand/IOCQ)]
(1 + 5) + (1 + 5) = 12

Group - C

4. (a) Define r-DNA guidelines for modern drug research. [[CO2](Understand/HOCQ)]
(b) Explain different level of biosafety in biotechnology work. [[CO3](Remember/LOCQ)]
6 + 6 = 12
5. (a) Write the name different regulatory bodies and their functions in field of biotechnology in India. [[CO3](Analyse/HOCQ)]
(b) Explain biosafety concern related to GM crops? [[CO3](Remember/LOCQ)]
6 + 6 = 12

Group - D

6. (a) Why product of nature cannot be patented? [[CO4](Analyse/HOCQ)]
(b) Discuss about the product patent and process patent. [[CO4](Remember/IOCQ)]
(c) (i) Define freer trade. (ii) Explain the rights and obligation of patentee. [[CO2](Remember/IOCQ)]
2 + (3 + 3) + (2 + 2) = 12
7. (a) What do you understand by the term “ Geographical indication. [[CO4](Analyse/HOCQ)]
(b) Explain in brief the main objective of W T O. [[CO4](Remember/LOCQ)]
(c) GATT concept as a basic backbone of W T O system, justify with own logic. [[CO4](Understand/IOCQ)]
(d) Explain the basic concept behind the following with reference to W T O :
Trade without discrimination, National treatment, Promoting fair competition and Encourage development and economic reform. [[CO4](understand/IOCQ)]
2 + 3 + 3 + 4 = 12

Group - E

8. (a) Describe about four types biotechnology with example. [[CO5](Remember/LOCQ)]
(b) Describe the market opportunities of a humanized monoclonal antibody. [[CO5](Remember/IOCQ)]
(c) Describe the market opportunities of a humanized monoclonal antibody. [[CO5](Apply/IOCQ)]
4 + 4 + 4 = 12
9. (a) Write two differences between invention and innovation? Write about the fundamental idea for marketing and selling of a bioproduct or bioservice. [[CO5](Remember,Explain/LOCQ)]
(b) What is bioentrepreneurship? Why it is important? Which five most important characters necessary to become bioentrepreneur? Discuss all the characters you motioned, with an example of bioentrepreneur from India (other than Kiran Shaw Majumdar). [[CO5](Remember,Explain/IOCQ)]
(2 + 3) + (1 + 1 + 2 + 3) = 12

Cognition Level	LOCQ	IOCQ	HOCQ
Percentage distribution	37.5	45.83	16.67

Course Outcome (CO):

After the completion of the course students will be able to

- CO1. Interpret basics of biosafety and bioethics and its impact on all the biotechnology and the quality of human life.
- CO2. Understand and analyse the different ethical, legal and social issues aspects related to biological, biomedical, health care, biotechnology and biotechnology research.
- CO3. Understand the historical background, importance and levels of biosafety at laboratory and industrial scale and explain the biosafety-regulatory framework in India & international Level.
- CO4. Gain an understanding of the basic concepts of patents, trademarks, copy rights, geographical indications and patent data base and their protection in biotechnology.
- CO5. Gain entrepreneurial skills to apply the different objectives and fundamentals of entrepreneurship in biotechnology.
- CO6. Identify scope for entrepreneurship in biotechnology.

**LOCQ: Lower Order Cognitive Question; IOCQ: Intermediate Order Cognitive Question; HOCQ: Higher Order Cognitive Question.*