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**3 (Sem-3/CBCS) BIT HG/RC**

**2023**

**BIOTECHNOLOGY**

(Honours Generic/Regular)

Paper : BIT-HG/RC-3016

**(Bioethics and Biosafety)**

Full Marks : 60

Time : Three hours

***The figures in the margin indicate full marks for the questions.***

1. Define the following terms : 1×7=7
- (a) Intellectual property
  - (b) Trade secret
  - (c) Bioethics
  - (d) Patent
  - (e) Tangible property
  - (f) Copyrights
  - (g) Biohazards

Contd.

2. Differentiate between : 2×4=8

(i) Intellectual property and Industrial property

(ii) Trademark and Trade secret

(iii) Bioethics and Biosafety

(iv) Process patent and Product patent

3. Write short notes on : *(any three)* 5×3=15

(a) Concept of containment level

(b) Good manufacturing practices

(c) Ethical issues against molecular techniques

(d) Biopiracy

(e) Procedure of patent filing

4. Write *any three* from the following : 10×3=30

(i) Discuss various biosafety issues in biotechnology.

- (ii) What do you mean by patent litigation? What are the statutory laws exist in India pertaining to patent litigation? —Discuss. 2+8=10
- (iii) Discuss the roles played by World Trade Organization (WTO) with respect to intellectual properties of a nation.
- (iv) Do Good Laboratory Practices (GLP) have to be adhered to while conducting safety studies to identify the possible drug abuse characteristics of a test article? Is it possible to obtain an exemption from specific provision of the GLP for special non-clinical laboratory studies? Discuss. What are the GLP requirements for labelling of reagents purchased directly from manufacturers? 2+4+4=10
- (v) Citing examples discuss the bioethics principle.
- (vi) Discuss various national bioethics paradigms.