

SEAT No. \_\_\_\_\_

[A-25/A-26/A-27]

Sardar Patel University

Final Theory Examination, April '2018

M.Sc. Integrated Biotechnology (EBT/IBT/MBT) Semester X  
PS10CIGEB4/ PS10CIGIB4/ PS10CIGMB4 – Bioethics, Biosafety and IPRTuesday, 17<sup>th</sup> April 2018

Maximum marks: 70

Time: 10:00 am to 1:00 pm

Q.I

**Multiple choice questions:**

- 1 The first International Statement on the ethics of medical research using human subjects formulated in 1947 was  
(a) Nuremberg Code (b) ICMR code  
(c) Edinberg Code (d) Helsinki Declaration
- 2 Which is the property of stem cells?  
a) Plasticity c) Develop into many diverse cell types  
b) Self-renewal d) All of above
- 3 \_\_\_\_\_ is applicable to dangerous agents which pose a moderate individual risk of life-threatening disease but for that medication is available.  
a) Biosafety level 1 c) Biosafety level 3  
b) Biosafety level 2 d) Biosafety level 4
- 4 For the import and shipment of GMO \_\_\_\_\_ is final approval authority.  
a) RCGM c) DBT  
b) GEAC d) None of above
- 5 A person is entitled to apply for patent if he is  
a) True and first inventor c) legal representative of the person  
b) An assignee of the true and first inventor d) all of these
- 6 The Patent office falls under the ministry of  
a) Human Resource Development c) Science and Technology  
b) Commerce and Industry d) Finance Ministry
- 7 Patent Cooperation Treaty is effective from \_\_\_\_\_ at Washington  
a) 1978 c) 1987  
b) 1972 d) 1985
- 8 \_\_\_\_\_ is on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure  
a) Paris convention c) Doha declaration  
b) Budapest Treaty d) TRIPS

(08)

Q.II

**Answer the followings (Any 7)**

1. Narrate: Bioethical conflicts of stem cell research.
2. Write down the basic principles of bioethics.
3. What is risk assessment?
4. Write in brief about Host vector system.

(14)

[P.T.O.]

5. Define : rDNA & biosafety
6. Differentiate between tangible and intangible properties
7. What are the basic requirements of patentability?
8. Narrate the role of TRIPS.
9. Define: Biopiracy and Biodiversity.

**Q.III** (a) Write about Bioethical conflicts in biotechnology research (06)  
(b) Describe criteria and principles of Good clinical practice. (06)

**OR**

(b) Discuss with examples, the need for formulating guidelines for conducting medical research on human subjects. (06)

**Q.IV** (a) Describe role of RCGM, GEAC and OECD. (06)  
(b) Write a detail note on types and elements of containment. (06)

**OR**

(b) Explain in detail about biosafety levels according to risk group organisms (06)

**Q.V** (a) Describe in detail about types of patent application. (06)  
(b) What is patent infringement? Explain types of Infringement in detail. (06)

**OR**

(b) Write a note on forms of IPR. (06)

**Q.VI** (a) Write a detail note on Convention on Biodiversity. (06)  
(b) Describe Traditional knowledge and prior art in detail (06)

**OR**

(b) Explain protection of plant varieties and Farmers Right Act. (06)

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