Q.3	i.	What is GMO and LMO?	**2**	1	1	2	1
	ii.	Explain the guidelines for using radioisotopes.	**8**	2	1	2	1
OR	iii.	Write about Cartagena protocol in details.	**8**	1	1	2	1
Q.4	i.	What is medical negligence?	**3**	2	2	3	1
	ii.	Write the ethical issues in clinical trials.	**7**	2	3	3	1
OR	iii.	Write ethical issues in associated with molecular technologies.	**7**	2	5	3	2
Q.5	i.	What is trademark and its role in intellectual property rights?	**4**	1	5	4	1
	ii.	What are different types of intellectual property rights?	**6**	2	5	4	1
OR	iii.	Write about intellectual property laws. Why it is necessary?	**6**	2	5	4	1
Q.6		Attempt any two:					
	i.	Write about patent filing procedures.	**5**	2	5	5	3
	ii.	What are the rights and duties of patent owner?	**5**	2	5	5	3
	iii.	Write about general agreement on tariffs and trades (GATT) & trade related aspects of intellectual property rights (TRIPS) treaty.	**5**	2	5	5	3

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Total No. of Questions: 6 *Total No. of Printed Pages:4*

Enrolment No.....

Faculty of Science
End Sem Examination Dec 2024
BT3GE01 Biosafety, Bioethics & IPR

Programme: B.Sc. Specialisation: Biotechnology

Duration: 3 Hrs. **Maximum Marks: 60**

Note: All questions are compulsory. Internal choices, if any, are indicated. Answers of Q.1 (MCQs) should be written in full instead of only a, b, c or d. Assume suitable data if necessary. Notations and symbols have their usual meaning.

			Marks	BL	PO	CO	PSO
Q.1	i.	Which biosafety level (BSL) requires the highest level of containment due to the high risk of life-threatening diseases? (a) BSL-1 (b) BSL-2 (c) BSL-3 (d) BSL-4	**1**	1	1	1	1
	ii.	What is the primary purpose of containment levels in biotechnology labs? (a) To ensure the accuracy of results. (b) To maximize productivity. (c) To improve equipment usage efficiency. (d) To protect laboratory staff and the environment from biohazard exposure.	**1**	1	1	1	1
	iii.	According to the Cartagena Protocol on Biosafety, the term "Living Modified Organism" (LMO) refers to organisms that: (a) Are synthetically produced in laboratories without any genetic modifications. (b) Have novel genetic combinations obtained through modern biotechnology. (c) Are naturally occurring and have not been modified by humans. (d) Are hybrids created through traditional breeding methods.	**1**	1	1	2	1

iv.	According to IAEA (International Atomic Energy Agency) guidelines, the disposal of radioactive waste from laboratories requires: (a) Storing radioactive waste in secure containment until it decays to safe levels. (b) Neutralizing the radioactivity before disposal. (c) Mixing radioactive waste with chemical waste for safe degradation. (d) Burning low-level radioactive waste to reduce volume.	**1**	2	1	2	1
v.	In clinical trial ethics, the concept of "informed consent" requires that: (a) Participants are compensated for their time and participation. (b) The trial is approved by a bioethics committee. (c) Participants are fully aware of the risks, benefits, and purpose of the study. (d) The study results are disclosed to participants immediately.	**1**	2	1	3	1
vi.	Which international declaration primarily addresses the ethical principles of medical research involving human subjects? (a) The Nuremberg Code (b) The Helsinki Declaration (c) The Belmont Report (d) The Cartagena Protocol	**1**	1	1	3	1
vii.	Which of the following types of intellectual property (IP) rights protects the unique visual appearance of a product, such as its shape, pattern, or color combination? (a) Copyright (b) Trademark (c) Patent (d) Industrial Design	**1**	1	1	4	1

viii.	The patenting of life forms, such as genetically modified organisms (GMOs), is contentious because: (a) It involves human intervention in natural processes, challenging ethical boundaries. (b) It is universally accepted across all international jurisdictions. (c) It requires minimal scientific evidence to support the patent claim. (d) It does not offer any form of commercial benefit.	**1**	2	1	4	1
ix.	The Patent Cooperation Treaty (PCT) application process is beneficial primarily because it: (a) Grants immediate patent rights across all member states. (b) Allows a single international application to streamline national filings in multiple countries. (c) Ensures quicker approval of patents compared to national applications. (d) Eliminates the need for national phase filings altogether.	**1**	2	1	5	1
x.	Which form of patent infringement involves the use of a patented invention to create an identical product without authorization, often resulting in court litigation? (a) Direct infringement (b) Contributory infringement (c) Indirect infringement (d) Reverse infringement	**1**	1	1	5	1
Q.2	i.	What is biosafety?	**2**	1	1	1	1
	ii.	What is risk group 2 and 3 in biosafety?	**3**	2	1	1	1
	iii.	Write about different levels of biosafety.	**5**	1	1	1	1
OR	iv.	Write about good laboratory practices & mention their outcome if good laboratory is not followed properly.	**5**	2	1	1	1

Answers Of Multi-choice questions

Faculty of Science

Dept. of Biotechnology

End Sem Examination Dec 2024

Biosafety, Bioethics & IPR (T) - BT3GE01 (T)

Q. No 1	Answer	Answer Explanation
I	D	BSL-4
II	D	To protect laboratory staff and the environment from biohazard exposure
III	B	Have novel genetic combinations obtained through modern biotechnology
IV	A	Storing radioactive waste in secure containment until it decays to safe levels
V	C	Participants are fully aware of the risks, benefits, and purpose of the study
VI	B	The Helsinki Declaration
VII	D	Industrial Design
VIII	A	It involves human intervention in natural processes, challenging ethical boundaries
IX	B	Allows a single international application to streamline national filings in multiple countries
X	A	Direct infringement

Q2. (i) Definition with an example [2]

(ii) Elaboration of risk group with an example [3]

(iii) Need to write different level of biosafety, their role for safety and why they are important. [5]

(iv) Mention about good laboratory practice in details and what are the repercussions if it will not be followed. [5]

Q3.(i) Difference between GMO & LMO with example [2]

(ii) Guidelines to use radio isotopes, why necessary such guidelines. If not followed proper guideline what will be the issue [8]

(iii) To mention Cartagena protocol in details & why it was executed/enforced [8]

Q4.(i) Definition with suitable example. [3]

(ii) Ethical issues in clinical trials & why it is important. [7]

(iii) Ethical issues in molecular technologies & why it is required. Any classic example will be good [7]

Q.5.(i) Write about trademark and why it is important [5]

(ii) Different types of IPR with suitable example [6]

(iii) Details about intellectual property laws. Why it is required [6]

Q.6.(i) Basics steps of patent filing [5]

(ii) Rights & duty of patent owner, how they are important. [5]

(iii) Detail agreement on tariff and trades in intellectual property right treaty. [5]