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Course Name: MSc Toxicology, Semester-III End term Examination (2022-23)

Paper Name: Regulatory Toxicology

Time: 3h

Paper Code: MTX-301

Maximum Marks: 60

(Note: This paper has 3 section A, B and C, Attempt all the three sections. Section A: Answer all the questions; Section B: Answer any 4 and Section C attempt any two questions)

Abbreviations Used

CO-Course Outcome, PO-program Outcome, BTL-Bloom Taxonomy Level: BT level 1-Remember; BT level 2-Understand; BT level-3 Apply; BT level 4 Analyse; BT level 5-evaluate, BT level 6 Create

SECTION A

Very Short Type Questions (1 X20)

[20]

Q. No.	Question	BTL	CLO	PLO
1.	Write the full form of GPMT	1	2	3
2.	In which test FCA is used?	1	1	1
3.	What is the full form of NOAEL	1	1	2
4.	If a vaccine needs to be developed within 3 months' time, which study would be performed?	1	1	2
5.	Name the two methods used in Ames assay	1	2	2
6.	Define C_{max}	1	3	2
7.	1ppb = $\mu\text{g/L}$	1	4	2
8.	Stimulation index	1	4	1
9.	Define Point of Departure.	2	1	1
10.	Differentiate between Toxicokinetics and Toxicodynamics	2	3	1
11	Mention any 3 haematological estimations, which are measured in repeated dose toxicity studies.	2	2	1
12	The most rapid exposure would occur through which route?	3	2	1
13	Write the full form of OECD.	3	2	1
14	Market surveillance falls under Phase of Clinical Trail	3	2	3
15	Any two mammalian models used for toxicity testing	1	2	3
16	Define LD_{50}	2	2	3
17	In which year Indian GCP guidelines were given?	3	5	2
18	Write the full form of ICH.	4	6	2
19	DGHS and DCGI fall under which ministry?	1	3	2
20	Define T_{max}	1	2	3

SECTION B

Short-type Questions. (Attempt any four questions) (4X5)

[20]

Q. No.	Question
1.	Appendices to Schedule Y
2.	Regulations pertaining to pre-clinical testing of drugs
3.	ICMR ethical guidelines for biomedical research on human participants
4.	Poison Information Centre
5.	Regulations related to transport, storage and disposal of hazardous chemicals
6.	Role of ICH guidelines on genotoxicity testing
7.	Future of toxicity testing

SECTION C

Long-type Questions. (Attempt any two questions) (2X10)

[20]

Q. No.	Question
1.	Importance of in vitro and in vivo testing of chemicals
2.	Describe different types of dose-response relationship
3.	Acute, chronic, sub-chronic toxicity testing
4.	Define various routes of administration

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