

**BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI**  
**DEPARTMENT OF PHARMACY**  
**Comprehensive Examination**

**Principles of Toxicology PHA G624 (Closed Book)**

**Maximum Marks 35**

**Duration: 180 Min**

**Date: 16/12/2023**

**Instructions:**

- ✓ Write correct and precise answers.
- ✓ No spelling mistakes.
- ✓ Marks will only be given to correct and well-explained answers and not to partial answers.
- ✓ Write in clear and legible handwriting.
- ✓ Answer the questions in exact sequence. Write each question on a separate sheet.

1. Distinguish "toxicology from toxinology" and "Toxicity from Adverse drug reactions" with proper examples. (1M)
2. Describe and distinguish genotoxicity and mutagenicity (1M)
3. Specify the importance of DNAase in the RT-PCR procedure of mRNA Quantification. (1M)
4. What do you understand by therapeutic ratio, standard safety margin, and chronicity factor? Discuss their importance in toxicological research (2M)
5. Based on the toxins listed in column A from the table, answer the question asked in column B. (3M)

<b>A</b>	<b>B</b>
<i>Amanita phalloides</i>	Site of toxicity? Mechanism of toxicity?
Ordeal bean	Site of toxicity? Mechanism of Toxicity?
Banded krait	Main toxin? Site of action (Receptor)?
Acetaminophen	Toxic metabolite (full name, only)? Site of toxicity?
Regulatory body of pharmaceutical products	In Australia? Japan?
REACH regulation	REACH full form? Area of jurisdiction?

6. Describe the significance of adaptor and linker molecules in the cloning technique within molecular biology. (3M)
7. What guidelines will you follow for genotoxicity assessment according to OECD and ICH? Write a detailed procedure for the Ames test, including its limitations, and recommendations based on the outcome. (1+3M)
8. Discuss the steps involved in constructing a cDNA library and explain the importance of using Oligo dT primer in its preparation. (4 M)

PTO

9. Which ICH guideline addresses toxicokinetics? In a hypothetical scenario, a 60 kg depressed patient intentionally ingested an entire bottle of a rapidly and fully absorbable medication, totaling 2 g in 50 ml. Following ingestion, the medical team promptly examined the patient and determined a plasma drug concentration of 33.33 mg/L and a drug clearance rate of 1.67ml/min. Based on the provided information, is dialysis a suitable treatment option, and what are the factors that contribute to this recommendation? **(5M)**

10. As a toxicologist, carefully analyze the following case report of poisoning. Thoroughly examine each detail and assess its relevance to commonly reported toxins suitable for this case. It is essential that your response includes logical reasoning for every small detail provided.

**Case report** “A 20-year-old male student was admitted to the ICU following a seizure, altered mental state, bronchospasm, and excessive sweating. Upon hospitalization, vital signs indicated a pulse rate of 62 beats per minute and a blood pressure of 120/80 mmHg. The patient's relatives suspect heavy smoking over the past week, attributed to undisclosed personal issues. Pinpoint pupils were observed without any sign of fasciculation. A chest X-ray indicated bilateral haziness, suggesting acute respiratory distress syndrome. Normal results were obtained in renal and liver function tests and electrolyte balance. Brain scans and cardiac enzyme levels were within normal ranges, and both blood and urine cultures were sterile”

Note- Marks will only be awarded if your final answer is properly justified, not if it coincidentally matches the actual answer. **(5M)**

11. What do you understand by the Fixed Dose Procedure and Acute Toxic Class Method of toxicity determination? What are the major differences in the procedure and its outcome? Name the OECD test guideline number of these procedures. Write down the general experiment planning to perform acute toxicity testing. **(2+2+2M)**