BRAINWARE UNIVERSITY

Term End Examination 2024-2025
Programme – B.Sc.(MLT)-2022
Course Name – Clinical Research & Toxicology
Course Code - BMLTC503
(Semester V)

Full Marks : 60 **Time : 2:30 Hours**

[The figure in the margin indicates full marks. Candidates are required to give their answers in their own words as far as practicable.]

Group-A
(Multiple Choice Type Question) 1 x 15=15

1. *Choose the correct alternative from the following :*

(i) What is the hallmark for Cohort study?
a) Follow up b) QSEM
c) followed over time in continues manner d) All of these

(ii) Which of the following is NOT a characteristic of a double-blind study?
a) Both participants and researchers are unaware of group assignments b) Reduces bias
c) Only participants are unaware d) Enhances validity of results

(iii) What type of study design uses historical data for comparison?
a) Prospective cohort study b) Retrospective cohort study
c) Case-control study d) Cross-sectional study

(iv) What is a cohort study?
a) A study comparing outcomes in different groups b) A study following a group over time
c) A study examining historical data d) All of these

(v) What does ADE stand for?
a) Adverse Drug Effect b) Adverse Drug Event
c) Adverse Drug Experience d) Adverse Drug Exposure

(vi) How is an ADR defined?
a) A therapeutic outcome b) An expected side effect
c) A noxious and unintended response to a drug d) A minor inconvenience

(vii) What is a medication error?
a) A correct dosage given to a patient b) A mishap during any phase of drug therapy
c) An adverse drug reaction d) A type of allergic reaction

(viii) What is an example of a noxious response?
a) A headache after taking medication b) A rash from an allergic reaction
c) Drowsiness from an antihistamine d) Improved symptoms

(ix) What type of studies are conducted before clinical trials?
a) Post-clinical studies b) Pre-clinical studies
c) Longitudinal studies d) Case studies

(x) What is the participant number range in Phase I trials?
a) 10 to 20 b) 50 to 100
c) Up to a few dozen d) Over a thousand

(xi) What does pharmacokinetics primarily study?
a) Drug interactions b) Drug absorption, distribution, metabolism, and excretion
c) Therapeutic effects of drugs d) Drug formulations

(xii) What is the primary site of drug metabolism?
a) Kidney b) Lungs
c) Intestines d) Liver

(xiii) In pharmacodynamics, what does agonist refer to?
a) A drug that blocks a receptor b) A drug that activates a receptor
c) A drug that has no effect d) A drug that enhances enzyme activity

(xiv) Which of the following factors influences drug metabolism?

a) Age
b) Genetics
c) Liver function
d) All of these

(xv) What does LD50 represent?

a) The lethal dose for 50% of a population
b) The effective dose for 50% of a population
c) The dose that causes no effect in 50% of the population
d) The dose required for 50% absorption

Group-B

(Short Answer Type Questions) 3 x 5=15

2. How do heavy metals, like lead and mercury, affect the nervous system? (3)
3. Describe four topics of ICH in brief. (3)
4. Describe key points of phase 1 clinical train in brief. (3)
5. Discuss in brief phase II bioabsorption of drugs. (3)
6. In the case of cohort study, it is important to calculate RR and AR. How do you correlate the term? (3)

OR

RR for a population cohort study is 15 but AR is 93%. Analyze the statement. (3)

Group-C

(Long Answer Type Questions) 5 x 6=30

7. If you have to start case control study, explain the criteria with proper analyzation to conduct the study. (5)
8. Discuss strength and weakness of case control study. (5)
9. Does the treatment work?- illustrate the statement properly with respect to clinical trail. (5)
10. Discuss 5 points of schedule Y. (5)
11. Give a comparative Analysis of Phase I, II, III, and IV Clinical Trials. (5)
12. (5)

Cohort study of vaping and pulmonary illness followed for 1 year.

Exposure: vaping **Outcome:** pulmonary illness

Cohort	Pulmonary Illness	No Pulmonary Illness	Total
vaping	42	27,000	27,042
No vaping	7	63,000	63,007
Total	49	90,000	90,049

Estimate Incidence rate and RR with proper explanation.

OR

(5)

	Varicella	Non-case	Total
Vaccinated	a = 18	b = 134	152
Unvaccinated	c = 3	d = 4	7
Total	21	138	159

Estimate incidence rate and RR with proper explanation.