C.U.SHAH UNIVERSITY
Winter Examination-2022

Subject Name : Research Methodology and Biostatistics

Subject Code : MRM301T   **Branch: M.Pharm (PQA, Pharmaceutics)**

Semester: 3   **Date: 21/11/2022**   **Time: 11:00 To 02:00**   **Marks: 75**

Instructions:
(1) Use of Programmable calculator & any other electronic instrument is prohibited.
(2) Instructions written on main answer book are strictly to be obeyed.
(3) Draw neat diagrams and figures (if necessary) at right places.
(4) Assume suitable data if needed.

Q-1	**Attempt the following questions:**	**(20)**

    a) Enlist main parts of research papers.
    b) Enlist the sources of literature review.
    c) What is χ^2 -test? Under what conditions is it applicable?
    d) Write steps to perform Mann-Whitney U test with its equations.
    e) Define: Contract research organization.
    f) State the main responsibilities of Institutional Ethics Committee.
    g) Define: Euthanasia.
    h) What do you mean by transgenic animals?
    i) Enumerate different type of referral in medical research.
    j) Enlist the characteristics of a good sample design.

Q-2		**Attempt any two of following :**	**(20)**
	A	Give classification on different research designs. Write a note on Randomized block design and Latin square design with suitable example.	**10**
	B	Write classification of parametric and non-parametric tests. Explain in detail on t-test and One-way ANOVA.	**10**
	C	Discuss the objective and functions of IAEC. Write a note on personal hygiene and experimentation involving hazardous agents during handing of animal.	**10**

Q-3		**Attempt any Seven of following :**	**(35)**
	A	Define: Research. Write in detail about objectives of research.	**5**
	B	Discuss in brief about various sources of literature review.	**5**
	C	A Contract research organization conducted a Pharmacokinetic study in 12 human volunteers. The maximum concentration of the therapeutic agent in plasma (Cmax) was studied after administration of a new formulation and established formulation. The data are given below. Test whether there is statistical significance of difference between the two formulations ($t_{11,0.05} = 2.20$ at 5% significance level)	**5**

Established Formulation (Cmax, µg/ml)	New Formulation (Cmax, µg/ml)
5.6	9.6
6.9	5.7
5.8	7.8
5.8	8.5
6.0	9.4
5.6	7.9
7.1	8.4
5.8	13.7
5.1	26.9
5.7	21.0
5.9	17.5
4.8	19.6

D	Write a note parametric test and explain about Type-I and Type-II error for Hypothesis testing.	**5**
E	Explain brief overview on Institutional Review Board.	**5**
F	Define: ICH-GCP. Explain advantages of ICH-GCP.	**5**
G	Write a note on concept of 4R.	**5**
H	Write a note Investigator brochure.	**5**
I	What are the principles of the Declaration of Helsinki? Explain in detail.	**5**