Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

BPHARM – SEMESTER II • EXAMINATION – WINTER • 2014

Subject code: 220001 Date: 26-11-2014

Subject Name: Applied Mathematics (Biostatistics)

Time: 02:30 pm - 05:30 pm Total Marks: 80

Instructions:

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1 (a) What is rank correlation? State the difference between regression and correlation. **06**

(b) Explain in brief chi square test or goodness of fit test. **05**

(c) Tablet dissolution was measured in vitro for 10 generic formulations. These products were also tested in vivo. Result of these studies showed the following: time to 80 % dissolution and time to peak (in- vivo). Calculate correlation (r2) between given set of data. **05**

Formulation	1	2	3	4	5	6	7	8	9	10
Time to 80% dissolution (min)	17	25	15	30	60	24	10	20	45	28
Tp(hr) time to peak	0.8	1.0	1.2	1.5	1.4	1.0	0.8	0.7	2.5	1.1

Q.2 (a) In an experiment to study the dependence of hypertension on smoking habits, the following data were obtained on 180 individuals. Test the hypothesis that presence or absence of hypertension is independent of smoking habit ($x^2_{2,0.05} = 5.991$) **06**

	Non smokers	Moderate smokers	Heavy smokers
Hypertension	21	36	30
No Hypertension	48	26	19

(b) Powder compacts for 8 observations were prepared at different compaction pressure and hardness of tablet and following data were obtained. Find the equation of two lines of regression and correlation coefficient between X and Y. **05**

Pressure in (tons)	0.25	0.75	1	1.5	2	2.5	3	4
Hardness (KG)	1	1.3	1.9	2.6	2.8	3.3	4.2	5.3

(c) Discuss the advantages and disadvantages of non parametric test. **05**

Q.3 (a) Describe the different sampling methods used in biostatistics. **06**

(b) Describe the advantage of random sampling. **05**

(c) A population is divided in to three strata consisting N1 individual values. From each stratum a sample is drawn. The observations of certain characteristics X on individuals in the samples are shown below: Estimate total of population and mean of population. **05**

Stratum	N1	n1	Values of X
1	30	4	7,6,3,8
2	40	3	12,15,16
3	60	6	3,4,8,2,16,13

Q.4 (a) Write a note on ANOVA and summarized the assumption of ANOVA. **06**

(b) In preclinical study animal were treated with two antihypertensive experimental drugs and control with 12 animal randomly assigned to three groups, four per group. One animal died from nondrug related cause and was lost during experimentation. Changes in pressure from base line are shown in table. Perform the one way ANOVA analysis and find out the treatment difference and inherent variation in animal group response ($F_{2,8}$=4.46). **05**

Drug - 1	15	12	19	11
Drug - 2	8	14	13	6
Control	-	16	20	22

(c) Eight laboratories were requested to participate in experiment whose objective was to compare the dissolution rates of two generic product and standard product. The purpose of experiment was to determine ($F_{2,14}$=3.74, $F_{7,14}$=2.14) **05**

(i) If product had difference rate of dissolution

(ii) To estimate laboratory variability and / or test the significance difference among laboratories. The experimental result are shown in table below. Carry out two way ANOVA for the given data and give your conclusion.

Laboratory		1	2	3	4	5	6	7	8
Generic	A	89	93	87	80	80	87	82	68
	B	83	75	75	76	77	73	80	77
Standard		94	78	89	85	84	84	75	75

Q.5 (a) Define following terms related to testing of hypothesis (any three) **06**

- Null hypothesis
- Level of significance
- Degree of freedom
- Critical region

(b) Two types of drug were used on 5 and 7 patients for reducing their weight. Drug A is imported and drug B indigenous. The decrease in weight after using the drugs for six months was recorded as given below. Is there significant difference in efficiency of two drugs? If not which drug should be used ? ($t_{10,0.05}$ = 2.225) **05**

Imported A	11	13	12	14	10		
Indigenous B	12	9	8	15	14	9	10

(c) The nicotine content in (milligrams) of two samples of tobacco was found to be as follows. Can it said that the two samples came from the normal distribution? **05**
($t_{9,0.05}$ = 2.262 ,$F_{5,4,0.05}$ = 6.26)

Sample A	24	27	26	21	25	
Sample B	27	30	28	31	22	36

Q.6 (a) Differentiate the following pairs of concept (any two) **06**

- Population and sample
- One tail and two tail
- One way ANOVA and two way ANOVA

(b) A study was conducted to compare immediate– and sustained–release formulations of codeine. Thirteen healthy patients received each formulation (in random order, and blinded). Among the pharmacokinetic parameters measured was maximum concentration at single–dose (C_{max}). Test whether or not the population mean C_{max} is higher for the sustained–release (SRC) than for the immediate–release (IRC) formulation ($t_{12} = 4.318$). **05**

Table represented Cmax measurements for sustained– and immediate–release codeine

SUBJECTS	SRC	IRC	SUBJECT	SRC	IRC
1	195.7	181.8	8	243.5	78.5
2	167.0	166.9	9	141.6	85.9
3	217.3	136.0	10	127.2	85.3
4	375.7	221.3	11	345.2	217.2
5	285.7	195.1	12	112.1	49.7
6	177.2	112.1	13	223.4	190.0
7	220.3	84.2			
MEAN	217.8	138.8			
STD.DEVI.	79.8	59.4			

(c) The computations and analysis using an experiment in which data were obtained from preclinical experiment in which rats, injection with two dose of an experimental compound and a control (a known sedative) were observed for sedation. The time to sleep for control and two for animal after injection was recorded. If an animal did not fall a sleep within 10 min of drug injection. The time to sleep was arbitrarily assigned a value of 15 min. The experimental results are shown in table. One data point was lost from control group was lost from control group because of an illegible recording obliterated in the laboratory note book. Using Kruskal Wallis Test, Test the average "time to sleep" differ for at least two of three treatment groups(Control, high dose and low dose) at 5 % level of significance at 2 degree of freedom.(X^2 at 5% level for 2 d. f. = 5.99) **05**

Control	Low dose	High dose
8	10	3
1	5	4
9	8	8
	6	1
9	7	1
6	7	3
3	15	1
15	1	6
1	15	2
	7	2

Q.7 (a) What are the merits and demerits of cross over designs. **06**

(b) Discuss carryover or residual effect in bioequivalence study. **05**

(c) Define errors and Bias with reference to clinical research and state various techniques to overcome them. **05**

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