

AIR on

course - Biostatistics & DOE for pharmaceutical Industry.

Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Ran Swarup, Chattopadhyay.

18901920001

B. Pharm 4<sup>th</sup> year.

## MID TERM Examination

Full Marks - 30

Time - 1 hrs.

- 1) Write short notes on - a) Hypothesis testing b) Central tendency of dispersion c) Multiple Linear Regression and its application in DOE.
- 2) D: Differentiate b/w F test, z-test, A student's t test. F test is done prior to performing t-test.
- 3) With example differentiate b/w two way and one way ANOVA. ANOVA: Name a few non parametric test which can be used in the place of one way ANOVA and two way ANOVA.
- 4) A pharmaceutical company launched ~~an~~ an active anti-diabetic drug and perform a survey on a set of population. It is has been found depends on both dose & time of administration assuming 6 doses of the drug and 6 times of administration a Draw a latin square design. do the clinical trial. ~~Differentiate~~  
Differentiate b/w latin square design & 2<sup>2</sup> factorial, with example.



  
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Mid-Term Examination

Adv on Course :- Biostatistics and QA for pharmaceutical Industry

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Name : Binchan Kumar Roy

Roll no : 18901920101

Year : B. Pharm 4<sup>th</sup> year.

Full marks : 30

Time :-

1 hour

Question :-

[3x5=15]

1. Write short notes on a. Hypothesis Testing. b. Central Tendency Dispersion. c. Multiple linear regression and its application in DoE.

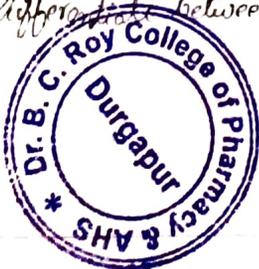
2. Differentiate between F Test, Z test & student T test. F is done prior to performing T test why? [2.5 x 2 = 5]

3. With example differentiate between two way ANOVA & one way ANOVA.

Name a few non-parametric test which can be used in place of one way ANOVA and two way ANOVA. [5]

4. A pharmaceutical company launched an anti-diabetic drug and perform Statistical survey over a set of population. It has been found that the drugs efficacy depends on both dosage and time of administration. Assuming 6 dosage of the drug & 6 time of administration in a day. Construct a latin square design to do this trial.

Differentiate between latin square design & 2<sup>2</sup> factorial design with example.



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## a. Hypothesis Testing :-

Hypothesis Testing is a method in statistical analysis of a data based on an design made on the basis on the theoretical hypothesis. Hypothesis

Testing can be done to find the result of a particular set of data or ~~the~~ on the data the researcher want to find out. It can help the researcher to determine the data collect whether match between the supposed result or alternate result.

Two types :-

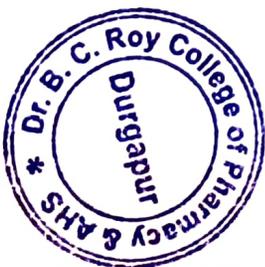
- i. Null Hypothesis ( $H_0$ )
- ii. Alternate Hypothesis ( $H_1/H_0$ )

### i. Null Hypothesis :-

- i. Denoted by  $H_0$  (in general)
- ii. The data result compared to the natural set of data.
- iii. The data states that there is no difference.

### ii. Alternate Hypothesis :-

- i. Denoted by  $H_1/H_0$ .
- ii. The data result compared to the natural set of data and state that it is different from the natural data set.
- iii. Mainly show the difference between the data.



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# Central Tendency Dispersion :-

• Mean :- Mean is referred the average value of the data set. Mean is referred to ~~the~~ a statistical parameter which is used to determine the average value of the data. It is determined by the ratio of the sum of the data and the number of data factor present.

$$\text{Mean} = \frac{\text{Total Sum of the Data}}{\text{Number of Datafactor}}$$

• Median :- Median is referred to the ~~statistical~~ statistical used mid data of the data set. The exact middle data in a data sheet is the value of the median in that particular data set.



• Mode :- Mode is referred to the highest frequency of the data occurred in a data set. The number of times a data repeat itself in a data set is known as Mode.

Example :

| Class | Height | Weight (kg) |
|-------|--------|-------------|
| I     | 20     | 20          |
| II    | 30     | 30          |
| III   | 40     | 40          |
| IV    | 50     | 20          |

• Mean =  $\frac{20+30+40+50}{4}$   
 $= \frac{120}{4} = 30$

• Mode = 30, 30, 40, 50

• Median = 30, 30, 40, 50

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# Multiple linear Regression :-

Multiple linear Regression is an statistical technique to shortening a large data set. We can delete that data set which is less than 0.05 and run the program <sup>then the</sup> that ~~with~~ analysis result be nearly same as the previous one. Minor change can be there.

## Application :-

1. Factorial Design ( $2^k$  factorial Design)
11. It used to reduce the data set and optimize the data.

### F Test

1. Data set is  $< 30$ .
2. Formula =  
Used to determine whether the data value is equal variant or unequal variant.

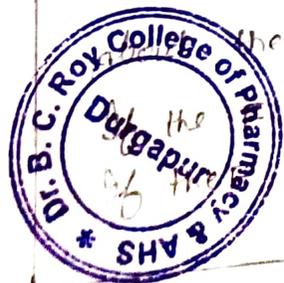
### Z Test

1. Data set is  $\geq 30$ .
2. Formula =  
$$Z = \frac{|\bar{x} - \mu|}{\frac{\sigma}{\sqrt{n}}}$$
  
 $\bar{x} \rightarrow$  Statistical mean of data  
 $\mu \rightarrow$  Hypothesis mean  
 $\sigma \rightarrow$  Standard Deviation.  
 $n \rightarrow$  no. of data.

### T Test

1. Large Data Set.
2. Formula =  
$$T = \frac{|\bar{x} - \text{Mean}|}{\text{Standard Deviation}}$$
  
 $\bar{x} \rightarrow$  Statistical Mean  
 $\mu \rightarrow$  Hypothesis mean

F test done prior to the T test because F test helps us to know the data ~~at~~ together is unequal variant or equal variant. value is less than 0.05, it is equal variant. value is more than 0.05, it is unequal variant.



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### FACTORIAL CHART QUESTION 4

$2^3$  factorial.

| A  | B  | C  | AB | BC | CA | ABC |
|----|----|----|----|----|----|-----|
| +1 | -1 | +1 | +1 | +1 | +1 | -1  |
| -1 | +1 | +1 | -1 | +1 | -1 | -1  |
| +1 | -1 | +1 | -1 | -1 | +1 | -1  |
| -1 | -1 | +1 | +1 | -1 | -1 | +1  |
| +1 | +1 | -1 | +1 | -1 | -1 | -1  |
| -1 | +1 | -1 | -1 | -1 | +1 | +1  |
| +1 | -1 | -1 | -1 | +1 | -1 | +1  |
| -1 | -1 | -1 | +1 | +1 | +1 | -1  |

*[Handwritten signature]*

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*[Handwritten scribble]*

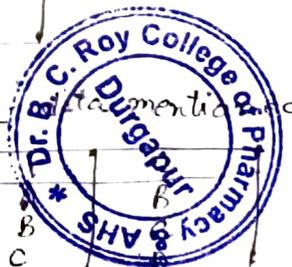
30 :-

Table

| Subject | Dosage | Time of Administration |
|---------|--------|------------------------|
| 1       | 2 = A  | 7 = B                  |
| 2       | 3 = B  | 6 = C                  |
| 3       | 5 = C  | 4 = D                  |
| 4       | 4 = D  | 5 = A                  |
| 5       | 5 = E  | 3 = F                  |
| 6       | 6 = F  | 2 = E                  |

| Row | COLUMN | TREAT | RESULT |
|-----|--------|-------|--------|
| 1   | 1      | A     | 2      |
| 1   | 2      | B     | 7      |
| 1   | 3      | B     | 8      |
| 1   | 4      | C     | 6      |
| 2   | 1      | C     | 5      |
| 2   | 2      | D     | 4      |
| 2   | 3      | D     | 4      |
| 2   | 4      | A     | 5      |
| 1   | 5      | E     | 5      |
| 1   | 6      | F     | 3      |
| 2   | 5      | F     | 6      |
| 2   | 6      | E     | 2      |

Latin square design is in a square form with specific particular row & column.



|   |   |   |
|---|---|---|
| 1 | A | B |
| 2 | B | C |
| 3 | C | D |
| 4 | D | A |

•  $2^B$  factorial design is a design of data set there is several data / factors !

For Example :-  $2^3 = 8$

| A  | B  | C  | AC | BC | CA | ABC |
|----|----|----|----|----|----|-----|
| +1 | +1 | +1 | +1 | +1 | +1 | +1  |
| -1 | +1 | +1 | -1 | +1 | -1 | -1  |

and so on.

Refer to page I.

Q3. One-way ANOVA :-

Anova stand for the analysis of variants. One way ANOVA means there is only one factor that effects the result of the data set.

Example :- The ~~body temp~~ body temperature before and after administration of anti-pyretic drug. *different?*

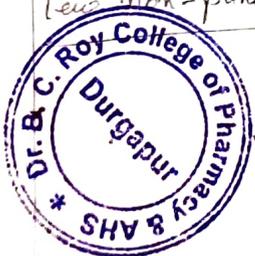
Two way ANOVA :-

Two way ANOVA means there are two factors that effect the result of the data set.

Example :- The Anti-diabetic drug depends on the dose and the time of the administration.

Two non-parametric Test :-

- i. Wilcoxon Test
- ii. Rank Signed Test
- iii. Mann-Whitney Test.



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. Mid Term Examination.

Add on Course → Biostatistics & DOE for Pharmaceutical Industry.

①

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Name → Pritam Jana.

Univ. Roll NO. → 18901920073.

Year → B. Pharm. 4th year.

Time → 1hr.

F.M. → 30.

(A) Question 1:- write some notes on; A) Hypothesis testing. B) Central tendency of Dispersion. C) Multiple linear regression & its application in DOE.

(3x5=15)

(2.5+2.5=5)

(B) Differentiate between F test, z test & student t test.

F test is done prior to performing t test why?

(C) with example differentiate b/w two way & one way ANOVA. Name a few parametric test which can be used in place of one way & two way ANOVA

(5)

(D) A Pharmaceutical company launched an Antidiabetic drug & perform a statistical survey over a set of population; It has been found that the drugs efficacy depends on both dose & time of administration assuming 6 doses of the drug & 6 times of administration in a day, construct a Latin square design to do this clinical trial.

(3+2) Differentiate b/w LSD & 2<sup>3</sup> factorial design. with example.

Answer:-

A) a) Hypothesis testing:- Hypothesis testing is determine/measure the difference between Hypothesized or standard mean value and sample mean value; which we get after calculation.

There are several types of hypothesis testing → like null hypothesis and alternate hypothesis. For null hypothesis there is no significant difference between Hypothesized and calculated mean.

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Null hypothesis is represented by  $H_0$ , defined as  $\mu$  "can be at 50% data lies for a d.c."

$\mu$  = Hypothesized mean;

$\mu_a$  = Calculated mean;

For a tablet avg. wt is 325 mg, is Represent as  $H_0$

If null hypothesis not follow then alternate hypothesis says that Hypothesized mean is not equals to calculated mean;

$H_0: \mu \neq \mu_a$ ;

For the above same example for alternate Hypothesis;

$\mu_a \neq 325 \text{ mg}$ ;

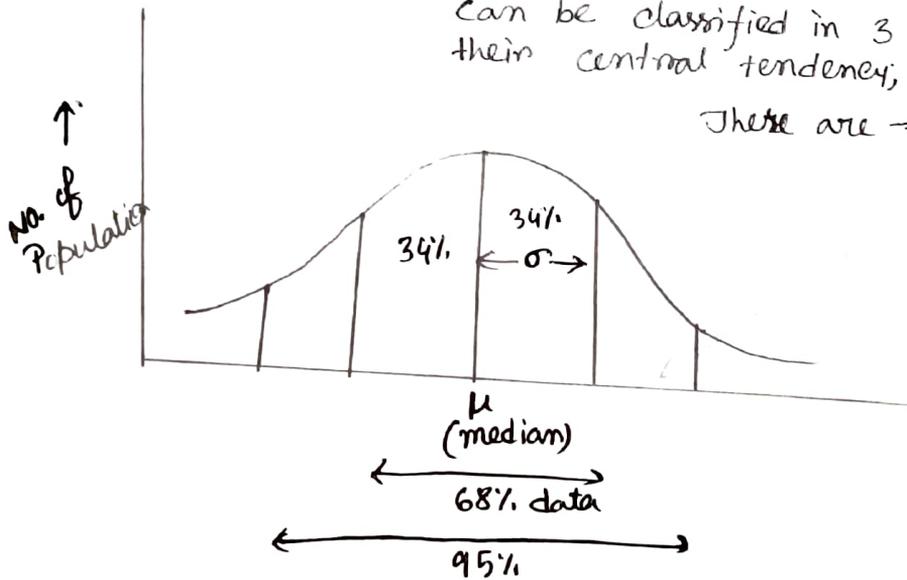
It might be greater than 325 mg or less than 325 mg

Central tendency of Dispersion: - For a set of data there is several dissimilarities which can be classified in 3 classes; which is their central tendency;

These are  $\rightarrow$  Mean.

Median.

Standard deviation



Mean: Mean is nothing but the arithmetic average or mean of a set of data; which is lies in the centre of the data on histogram Plot; represent as  $\rightarrow \bar{X} = \frac{\sum X}{N}$   $N$  = No. of operation.

In statistical evaluation median separates higher half of value to lower half of the values.



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Median is represented by (M) and defines the 50% value; means at 50% of the value/middle value; upon which the 50% greater data lies & below which 50% lesser data lies.  
 For a data set; for odd no. variables;  $M = \left(\frac{n+1}{2}\right)^{th}$  Position.

Standard deviation ( $\sigma$ ):- It is represented by  $\sigma$ ; which defines the deviation of data/value from standard one.  
 How much difference is there between standard value & calculated value,

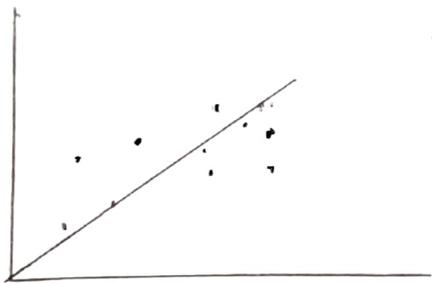
Formula is -  $\sigma = \sqrt{\frac{\sum (x - \bar{x})^2}{n-1}}$ ; where  $\bar{x} = \frac{\text{sum}}{n}$

(5)

MLR or Multiple Linear Regression is a Statistical Evaluation Tool.

Multiple Linear Regression, is a statistical technique that uses several explanatory variables to predict the outcome of response variables.

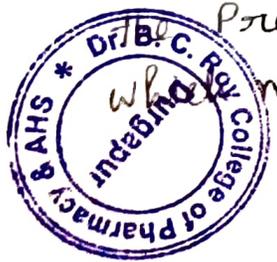
It allows us to obtain predicted values for specific variables under certain conditions.



→ By applying MLR; we nullify the unessential Process or Parameter in DOE; and Perform the Process optimization.

• Those value which is far beyond the straight line are neglected; generally these P value is  $> 0.05$ ; are not ~~calculate~~ taken for DOE and Process Perform.

• So, By applying Multiple Linear Regression; we optimize Process by reject the unnecessary Parameters; not influence the result on outcome.



(35)

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(B)

### Z-test

A one sample Z-test is used to check if there is a difference b/w the sample mean and Population mean when standard deviation is known.

calculate by-

$$Z \text{ test} = \frac{\bar{x} - \mu}{\frac{\sigma}{\sqrt{n}}}$$

- $\bar{x}$  = mean of sample
- $\mu$  = " " Population
- $\sigma$  = std. deviation

→ when Population is > 30 then Z test Perform

### student t-test

student-t test is used to determine or perform to see whether the difference between response of two group is statistically significant or not.

calculated by -  $t = \frac{\bar{x} - \mu}{\frac{s}{\sqrt{n}}}$

→ If Population is < 30 then t-test Perform.

### F-test

F-test also known as Fischer is performed before t-test to evaluate the data is come from same population, or source or not; It perform to measure the P value and observe if there is any significant difference or not.

Handwritten notes:  $\frac{VSD}{\text{mean}} \rightarrow$  and other scribbles.

•• F test is done prior to performing t test, becz →  
 F test or Fischer test is performed before t-test to evaluate the data is come from same population or source or not;  
 To analyse that the data should be proper for performing t-test;  
 By running F-test we have a P value;  
 If the P value is < 0.05 that defines that there some significant difference b/w the values;  
 The P value must be > 0.05 for further performing t-test.



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Text about Fisher's LSD

LSD

Latin sq. design is use of most experiment dosage experiment limit are heterogenous and the heterogeneity in two direction

(5)

2<sup>k</sup> factorial design.

F.D. is an experiment whose design consist of two or more factor each with different possible values.

• Latin square Design construction: -

Time of Administration. →

|                |   |   |   |   |   |   |   |
|----------------|---|---|---|---|---|---|---|
|                |   | A | B | C | D | E | F |
| No. of doses ↓ | 1 | A | B | C | D | E | F |
|                | 2 | B | C | D | E | F | A |
|                | 3 | C | D | E | F | A | B |
|                | 4 | D | E | F | A | B | C |
|                | 5 | E | F | A | B | C | D |
|                | 6 | F | A | B | C | D | E |

A, B, C, D, E, F defines 6 times a day.

Q

Main difference between one way ANOVA & two way ANOVA is ~~number~~ number of independent variables. A - one way anova has one independent variables; where as two way anova has 2 or more than two variables; which are independent and ~~one~~ one can be dependent variable.

of Non parametric test are → Wilcoxon signed test.

- Signed test
- Wilcoxon rank sum test.

- Kruskal - Wallis
- Mann whitney Test etc.



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Mid-term examination

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Time - 1 hr.

Full Marks - 30

Q.1) Write short notes on

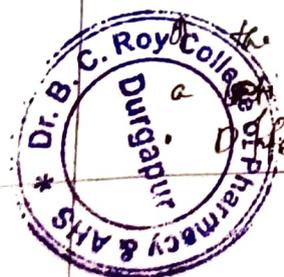
3x5 = 15

a) Hypothesis testing

b) Central Tendency of dispersion.

c) Multiple Linear regression and its application in  
DOE.

d)

Q.2) Differentiate b/w F-test, Z-test and Student t-test.  
2.5 x 2 = 5  
t-test is done prior to performing t-test. why? (5)Q.3) With example differentiate b/w Two way Anova and  
one way Anova.Name a few non parametric test which can  
be used in place of One Anova and Two way  
Anova.Q.4) A Pharmaceutical company launched an antidiabetic drug and  
performed the statistical survey over a set of population.  
It has been found that the drug's activity efficacy depends on  
on both dose and Time of administration. assuming 6 doses  
of the drug and 6 time of administration in a day construct  
LSD to do this clinical trial.  
Differentiate b/w LSD and  $2^3$  factorial design with example. (3x2)Prof. (Dr.) Samir Kumar Samanta  
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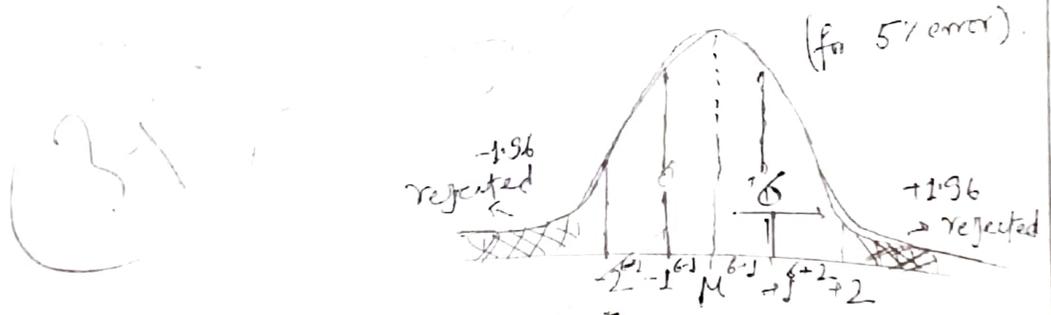
Q.1) Hypothesis testing :- Hypothesis testing is used to assess the output of datasets (Paired / non-paired) is same or different. Ultimately it used to check the result that the result is valid or not.

It uses null hypothesis and or Alternate hypothesis.

If there is any significant differences b/w two dataset then null hypothesis will be rejected otherwise it will be accepted.

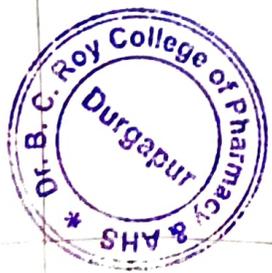
It depends on p-value (Probability of error).

If p-value < 0.05 then null hypothesis is accepted  
 If p-value > 0.05 then null hypothesis is rejected



- Types - a) F test b) T-test c) Z test d) One way Anova.  
 e) Two way Anova.

Hypothesis testing also done by some non parametric test like Wilcoxon signed rank test, Wilcoxon ranked sum test, Mann-Whitney test.



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b) Central Tendency of dispersion (Mean, Mode, Median).  
Suppose data set is

$f(x) = 2, 4, 3, 6, 2, 8, 3, 2, 5$

Mean:  $(\mu) = \frac{\sum x_i}{n}$   
 Mean  $(\mu) = \frac{2+4+3+6+2+8+3+2+5}{9} = \frac{35}{9} = 3.88$

Median  $\Rightarrow$

To calculate mean value we have to assigned numeric in ascending / descending order.

for  $f(x)$  ~~2, 2, 2, 3, 4, 5, 6, 8, 8~~

for odd number median will be  $\left(\frac{n+1}{2}\right)^{th}$  position

for even  $n$   $\left(\frac{n}{2} + \frac{n+1}{2}\right)$  position

For that data set, Median will be  $\frac{9+1}{2} = 5^{th}$  number  
 numerical. that is = 3

Mode  $\Rightarrow$  To assess mode of a data sets, we have to prepare frequency table of given data sets.

$f(x) = 2, 2, 2, 3, 4, 5, 6, 8$

| Numeric | Frequency (f) |
|---------|---------------|
| 2       | 3             |
| 3       | 2             |
| 4       | 1             |
| 5       | 1             |
| 6       | 1             |
| 8       | 1             |



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The data which having maximum frequency will Mode of the data sets.  
 Here, in this data set Mode is '2'

Multiple Linear Regression :-

Q2

| F-test  | Z-test   | T-test                                     |
|---|--|--|
| F test is <sup>done</sup> prior to the t-test | Z test is done for more than 30 popult. (i.e. $n > 30$ ) | t-test is done for less than 30 population |
|   | $Z = \frac{\bar{x} - M}{S}$                              | $t = \frac{\bar{x} - M}{S}$                |

Why F test is done prior to performing t-test.

⇒ In statistical data analysis, F test is done prior to t-test because t-test is depend on the result or outcome of the F-test.

Generally T-test is done with equal variants and unequal variants.

If two data sets come from homogeneous source To confirm the the variants of test is done before t-test.

From Interpretation of F-test result and its app<sup>n</sup> in the t-test ⇒

By performing F test we get a p-value. If the p value greater than 0.05 implies that there is no significant difference and data sets are homogeneous & hence, t-test is done with equal variants. If p value is less than 0.05, then unequal variance t-test is done.



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### One way Anova

One way Anova is done depends <sup>for</sup> data set that is depend on single factor.

Ex - Hardness testing of diff<sup>n</sup> tablets by same tester.



### Two way Anova

Two way Anova is conducted for data set that is depend on single factor.

Ex -> Hardness testing of diff<sup>n</sup> tabs by different tester.



▷ Non-parametric tests which are used in place of one way & two way Anova.

- Will-coxon signed-rank test (In place of one way Anova)
- Will-coxon ranked sum test (in place of one way Anova)
- Friedman test (In place of Two-way Anova).

(2-1)



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Time of administration (min)

|   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|
|   | A | B | C | D | E | F |
| 1 | A | B | C | D | E | F |
| 2 | C | F | D | B | E | A |
| 3 | D | A | F | C | B | E |
| 4 | F | C | E | A | D | B |
| 5 | E | F | A |   |   |   |
| 6 | B |   |   |   |   |   |

suppose  
 A - 6 am  
 B - 10 am  
 C - 2 pm  
 D - 6 pm  
 E - 10 pm  
 F - 2 am

Time of Administration (min)

|   |   |   |   |   |   |   |
|---|---|---|---|---|---|---|
|   | A | B | C | D | E | F |
| 1 | A | B | C | D | E | F |
| 2 | B | C | D | E | F | A |
| 3 | C | D | E | F | A | B |
| 4 | D | E | F | A | B | C |
| 5 | E | F | A | B | C | D |
| 6 | F | A | B | C | D | E |

➤ In LSD, rows and the number of row and column are. In this design, same data is not overlapped in same row and columns.

• But in  $2^3$  factorial design some data may overlap in same row / column.

$2^3$  factorial designs ignore intermediate level only and highest and lowest level both are intermediate level.



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Q.1

Multiple Linear Regression:

M&R means (Multiple Linear Regression) is a statistical technique that uses several explanatory variables to predict the outcomes of a response variables.

Application ->

- (i) To predict values for specific variable under certain condition.
- (ii) Forecasting of predicting result.
- (iii) Used to investigate relationship.
- (iv) Analyze and predicting queries.

Q.2

Diff<sup>2</sup> 2<sup>2</sup> & 2<sup>3</sup> factorial design

LSD

|   |   |   |   |
|---|---|---|---|
| A | B | C | D |
| B | C | D | A |
| C | D | A | B |
| D | A | B | C |

2<sup>2</sup> 4 D

| A  | B  | C  | AB | BC | CA | ABC |
|----|----|----|----|----|----|-----|
| +1 | +1 | +1 | 1  | 1  | 1  | 1   |
| 1  | 1  | -1 | 1  | -1 | -1 | -1  |
| 1  | -1 | +1 | -1 | -1 | +1 | -1  |
| 1  | -1 | -1 | -1 | 1  | -1 | +1  |
| -1 | +1 | +1 | 1  | 1  | 1  | -1  |
| -1 | +1 | -1 | 1  | -1 | -1 | +1  |
| -1 | -1 | +1 | -1 | -1 | +1 | +1  |
| -1 | -1 | -1 | -1 | +1 | -1 | -1  |

