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INTERPRETATION 0F DISSOLUTION STUDIES AND IN VITRO- IN VIVO CORRELATION

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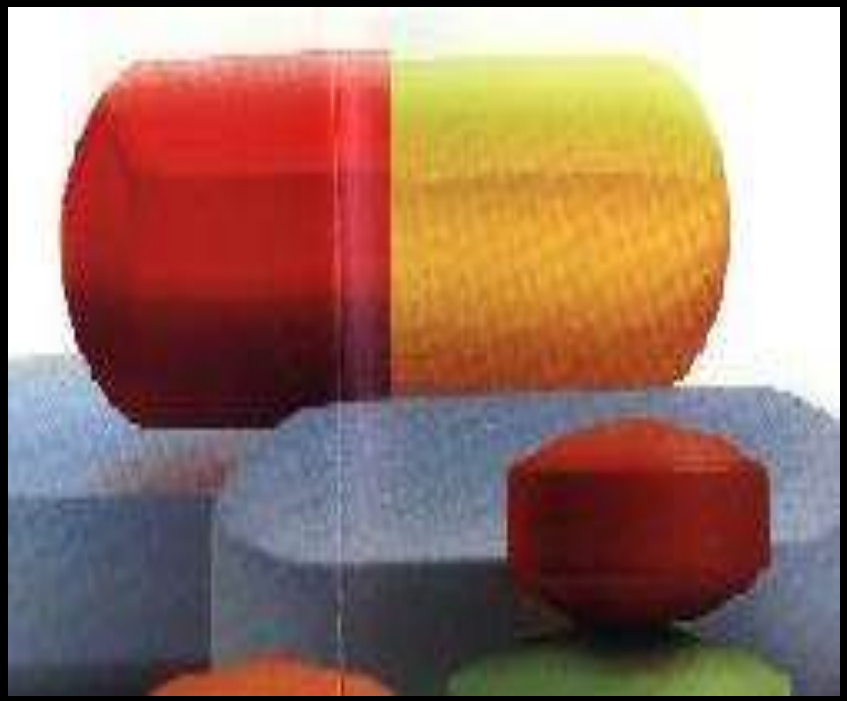
INTERPRETATION OF DISSOLUTION STUDIES AND IN VITRO - IN VIVO COREELATION



Interpretation of Dissolution Studies (or) Data :-

- In dissolution studies the product is passed (or) failed is determined by based on “Q” value.
- Q is the percentage of drug dissolved in specific period of time.
- The Q value for every drug is specified in individual monograph.
- According to FDA the dissolution studies performed in 3 stages.

1. Stage-1
2. Stage-2
3. Stage-3

Stage-1:-

- It is performed with 6 dosage units.
- If product is passed test, the each unit contains not less than Q+5%.

Stage-2:-

- If stage-1 is failed, this dissolution continues the additional 6 dosage units. The average of 12 units (S1+S2) greater than are equal to Q%.
- None of one is not less than Q-15%.

Stage-3:-

- If stage-2 is failed, test is continues with additional 12 dosage units.
- The average of 24 dosage units (s1+s2+s3) > Q.
- None of one is not less than Q-25%.

Comparison Dissolution:-

The in vitro dissolution of 2 dosage forms is compared by % dissolution value (Q).

Objectives Of Comparison Dissolution:-

- Develop new dosage form with same bioequivalence or same bio-availability.
- Optimizing dissolution specifications to get desired bioequivalence.
- Monitoring no changes in bioequivalence by small changes in formulation.

Conditions To Be Followed:-

- Not less than 12 dosage units are used.
- The dissolution studies for both test and reference is carried out for same conditions (or) same dissolution time points.
- Not less than 3 dissolution points are measured.

Calculation for comparison dissolution:-

The compare to dissolution is determined by using 2 factors like

1. Dissimilarity factor (f1)
2. Similarity Factor (f2)

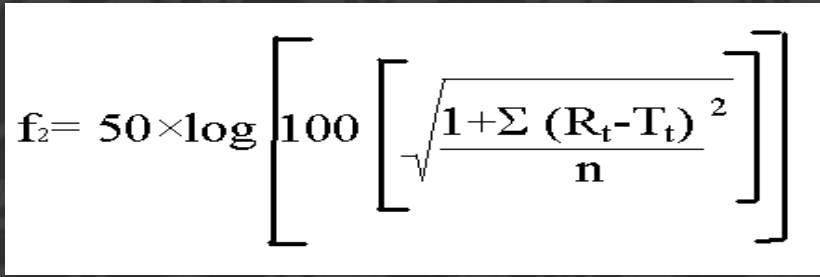
Dissimilarity Factor (f1):-

- The difference between the test and reference is determined from dissolution verses time curve.

$$f1 = \{[\Sigma D[1/\Sigma R_t]\} \times 100$$

Similarity Factor (f2):-

•Similarity is determined by dissolution verses time curve.



Where, n = number of dissolution points.

R_t = rate of dissolution of reference at time ‘t’.

T_t = rate of dissolution of test at time ‘t’.

Interpretation of data:-

- If f1 = 0-15%, when the product is difference (or) dissimilar with reference.
- If f2 = 50-100%, when the product is similar to the reference.
- If f2 = 100% it indicates ideal with reference.
- When the test and reference shows more than 85% of dissolution with in 15 minutes the compare to dissolution is not necessary.

In vitro-In vivo correlation (IVIVC):-

- A simple dissolution is not sufficient for determined therapeutic efficacy of the drug.
- A correlation between in vitro dissolution and in vivo bioavailability is used to determine therapeutic effect of drug.
- According to FDA, In vitro-In vivo correlation defined as an mathematical model explains the relation between in vitro dissolution and in vivo bioavailability

- Two approaches used to determine the correlation.

1. By establishing linear relationship between the in vitro dissolution and the in vivo bioavailability parameters.
2. By using the data from previous bioavailability studies to modify the method of dissolution to get same bio equivalency.

Some of the often used quantitative liner in vitro-in vivo correlations :-

1. Correlation based on plasma level data.
2. Correlation based on urinary excretion data.
3. Correlation based on pharmacological response.

In vitro-In vivo correlation levels:-

Level-A:-

- In which compare point to point variation between the in vitro dissolutions and in vivo bioavailability.
- The in vitro and in vivo curves are super imposable to each other.

Level-B:-

- It is based on statistical movement theory.
- In which compare the mean dissolution time with mean absorption time. It can’t be used in quality control process.

Level-c:-

- In which compare single point between the in vitro dissolution and in vivo bioavailability studies.

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Thank you