

IVIVC correlations:

- It is a predictive mathematical model that describes the relationship between in-vitro property and the in-vivo response of the drug.

- In-vitro property is generally the rate of extent of drug dissolution and in-vivo property is the amount of drug absorbed.

- The main objective for developing & evaluating an IVIVC is to enable the dissolution to serve as an alternate to conduct bioavailability studies in human beings.

⇒ Objectives of IVIVC -

- (1) To reduce the number of human studies during formulation development.

- (2) To predict the in-vivo response on the basis of in-vitro properties of the drug.

- (3) To support and justify waivers.

- (4) Modification of formulations to achieve desired drug release profile & optimize drug delivery.

(5) To shorten the drug development period.

(6) Economize the resources.

(7) To ensure quality control and match-to-match consistency in the physiological performance.

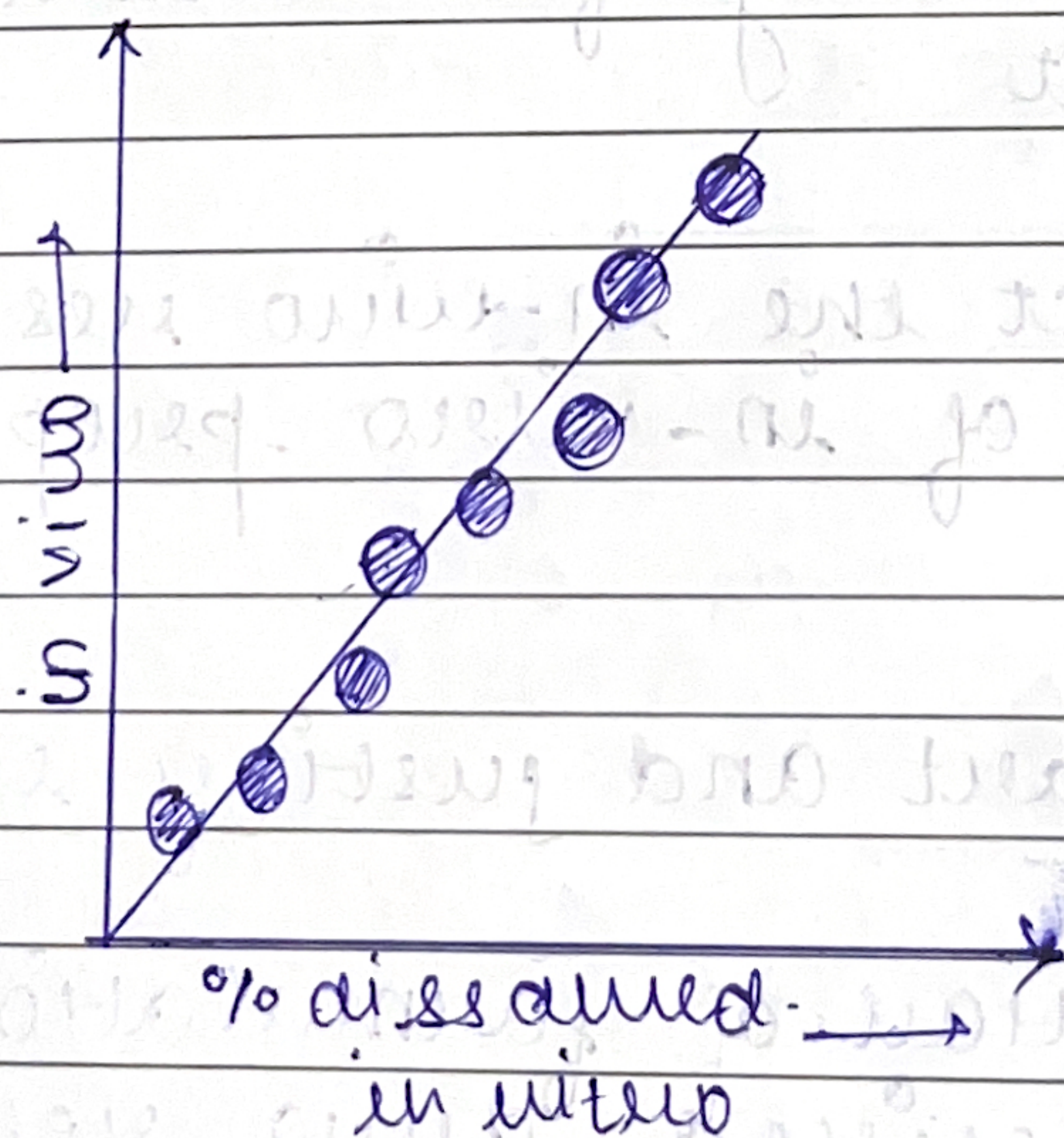
⇒ Levels of correlation -
There are 3 levels of IVIVC correlations.

They are:

(1) Level A.

- Highest category of correlation
- Point-to-point relation between in-vitro dissolution and in-vivo rate of absorption.

- Also called as "WAGNER-NELSON" method.



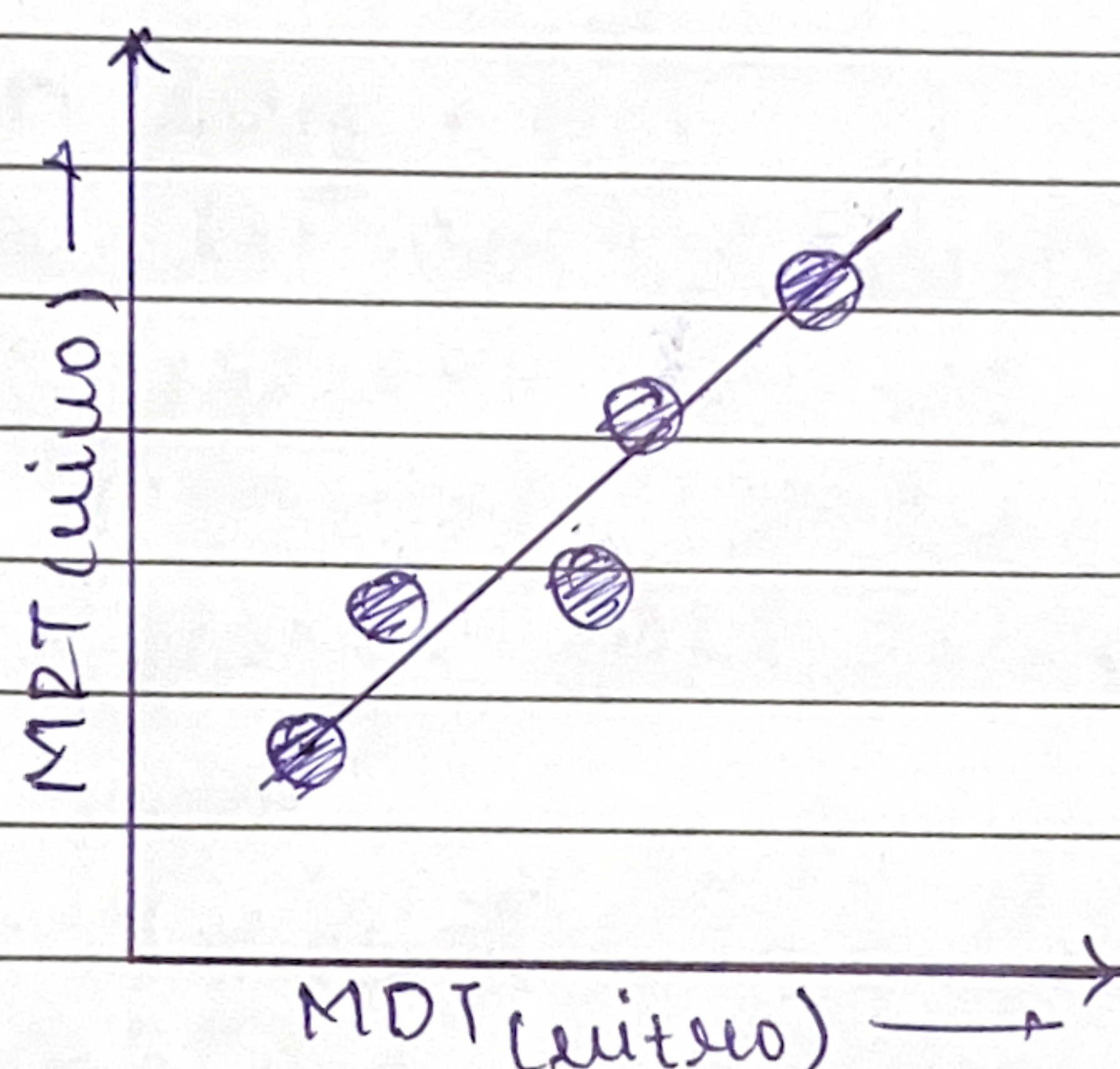
(2) Level B -

- It is based on the principles of statistical moment theory.
- It is a predictive mathematical model which compares.

$MDT_{(in\text{ vivo})} \longrightarrow MDT_{(in\text{ vitro})}$

$[k_d \longrightarrow k_a]$

- It is least useful for regulatory purpose.



(3) Level C -

- Predictive mathematical model which describes relationship between the time required for in-vitro dissolution of the drug and a mean pharmacokinetic parameter such as C_{max} , t_{max} , $t_{1/2}$ or AUC.

- It is the weakest correlation as only partial relationship b/w absorption and dissolution is achieved.

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