

PREFORMULATION



DEFINATION:

Preformulation may be defined as a stage of the research and development

process where the Preformulation scientist characterizes the physical, chemical,

biopharmaceuticals mechanical properties of a new drug substance, in order

to develop stable, safe and effective dosage form.

GOALS OF PREFORMULATION:

- To find the necessary physicochemical properties like solubility, crystal

Form of new drug substances.

- To determine kinetic release of drug from dosage form.
- To establish physical characteristics.
- To establish compatibility (no interaction) with common excipients.

OBJECTIVE:

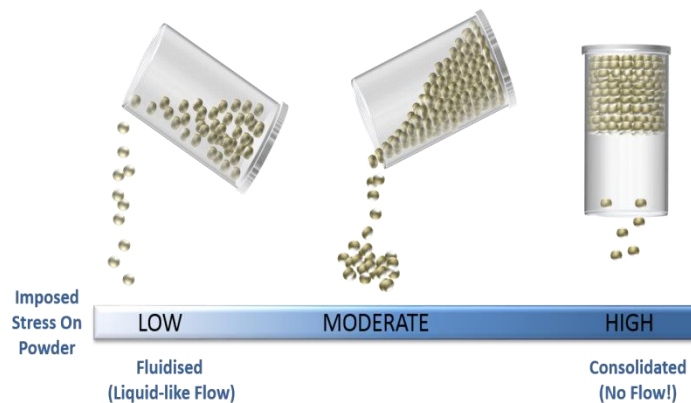
- ✚ To generate useful information to the formulator to design an optimum drug delivery system.
- ✚ The formulation scientist uses this information to develop dosage forms.
- ✚ Preformulation is a multidisciplinary development of a drug candidate.

Preformulation is branch of Pharmaceutical science that uses biopharmaceutical principles in the determination of physicochemical properties of the drug substance. Prior to the development of any dosage for a new drug, it is vital that certain fundamental physical and chemical properties of drug powder are found out. This information may dictate many of subsequent event and approaches in formulation development.

PHYSICAL PROPERTIES:

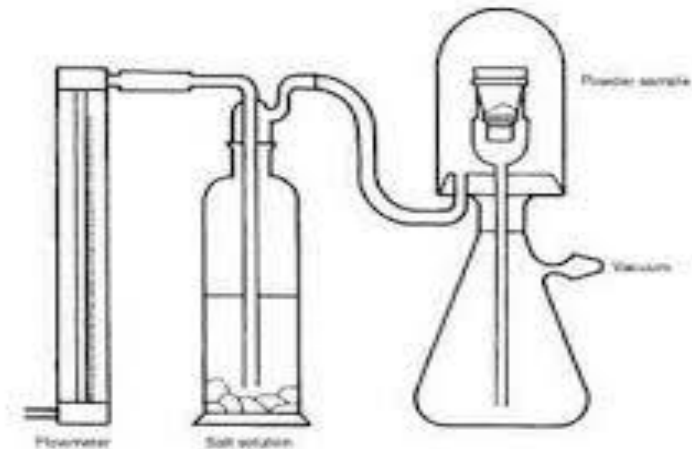
NATURE OF SOLID DRUG :

Powder flow



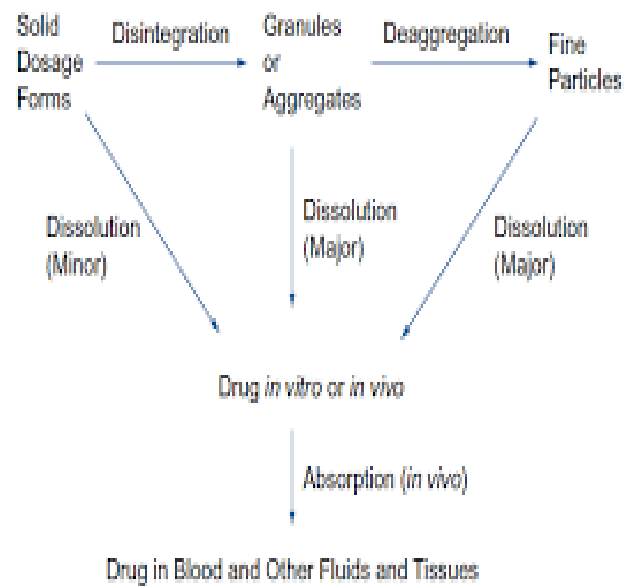
Hygroscopicity

Fig. 1 Apparatus for determination of hygroscopicity



SOLUBILITY DATA:

Dissolution



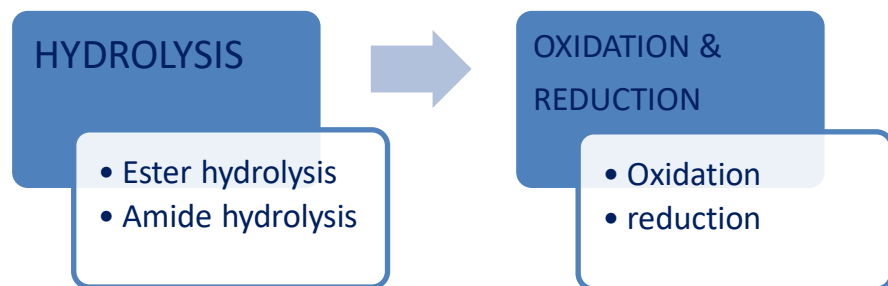
SOLUBILITY ANALYSIS:

Solution stability



The capacity of a drug or a product to remain within established specification of identity, quality, purity in a specific period of time

CHEMICAL PROPERTIES:



REFERENCE : 1. Theory and practice of industrial pharmacy by liberman & lachman vol .1&3
2. Industrial pharmacy-1 by Dr.Rani Kankate, Dr.K.L Senthilkumar, Thakur publication

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