

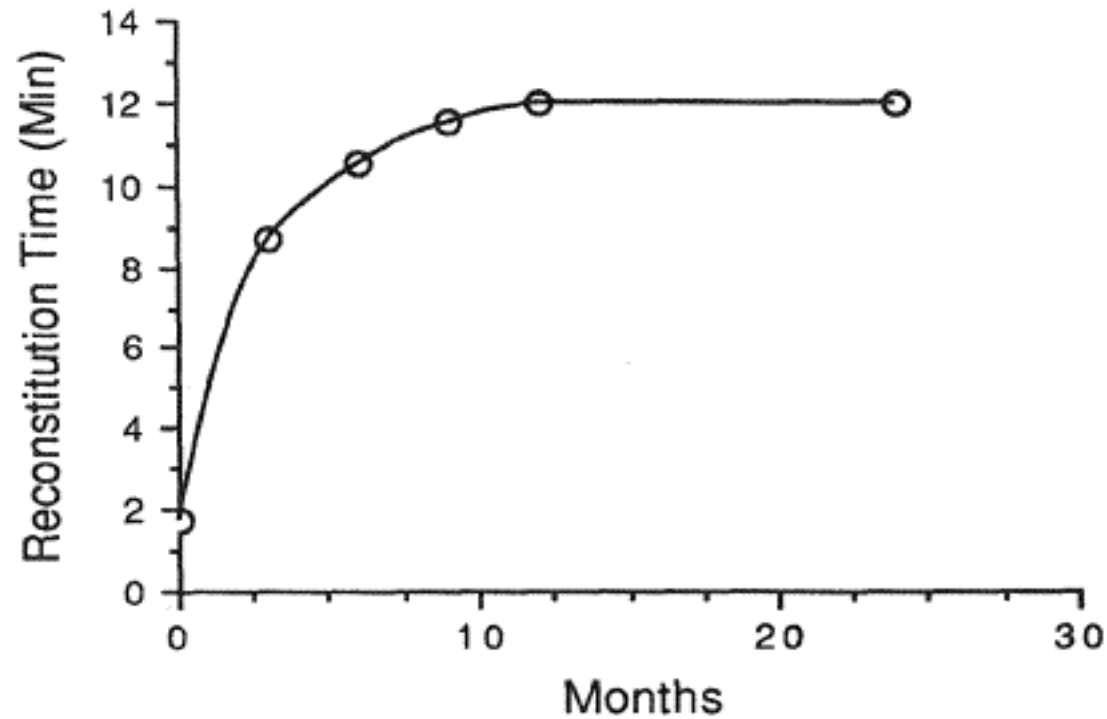
Powders

- Basic physical points to note about dusts:
 - product appearance,
 - organoleptic properties,
 - easy reconstitability

- As a function of storage time, there are several reasons why dusts affect the release of active substance. The most common causes are:
- cohesion,
- crystal growth,
- humidity sorption

Powders

- Over time, these interactions between the dust particles change the time at which the resulting powder can be reconstituted.
- The storage time is prolonged as needed to reconstitute the powders.





HARD AND SOFT GELATIN CAPSULES

- Grimm and Schepky have shown that, depending on the sorption isotherms of the capsule contents, the capsule wall may lose moisture and become brittle to the capsule contents, or vice versa, in the case of sorption isotherms, the capsule content may become dehydrated and fragile.

HARD AND SOFT GELATIN CAPSULES

- Gel isotherms for moisture
- The moisture content of gelatin
- The gelatin swelling property can be examined in stability studies.

Tablets for oral use are classified according to EP 5 as follows:

- Uncoated tablets 
- Coated tablets 
- Effervescent tablets
- Water-soluble tablets
- Water-dispersible tablets
- Oral dispersion tablets
- Stomach resistant tablets
- Modified release tablets

Stability test parameters for tablets

- Organoleptic controls
 - Appearance (swelling, adhesion, crystal formation, dust formation on the bottom of the bottle, cracking, breaking)
 - Color (spotting, losing color)
 - Smell
- Determination of the amount of active substance, disintegrating products
- Weight deviation
- Dissolution rate
- Moisture
- Mechanical durability
 - Hardness
 - Wear
- Microbiological limits

Test parameters for coated tablets

- **Organoleptic controls**
 - Appearance (cracking, breaking, sticking of the coating, sticking of the tablets together)
 - Color (spotting, losing color)
 - Smell
- **Determination of the amount of active substance, disintegrating products**
- **Dispersion**
- **Dissolution rate**
- **Moisture**