

The logo of Galgotias University is a stylized 'G' composed of several curved, overlapping bands in shades of yellow, orange, and blue, set against a light background.

MODULE 1: Preformulation Studies

Lecture 6

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DISCLAIMER

All the content material provided here is only for teaching purpose

The logo of Galgotias University is a stylized, circular emblem. It features a central white swirl that transitions into a blue swirl, which then transitions into a yellow swirl, and finally into a red swirl. The entire emblem is set against a light blue background.

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Application of Preformulation studies

Solubility Profile

- Hygroscopicity
- Thermal stability (Melting point, Polymorphism)
- Chemical stability

Determination of expire date

- Determination of preliminary specifications
- Release of clinical batches
- Monitoring of samples during the clinical phases
 - Definition of storage condition
 - Definition of

Tests for registration stability Up to 36 month

Selection of samples

- API, excipient, batches

Solid dosage

- Physical-chemical properties – Appearance – Elasticity – Mean mass – Moisture – Hardness – Disintegration – Dissolution
- Chemical properties – Assay – Degradation • Microbial properties
- Container closure system properties – Functionality tests (e.g. extraction from blister) Tablet & Capsule

Oral liquid form

- Physical-chemical properties – pH – Color & clarity of solution – Viscosity – Particle size distribution (for oral suspensions only)
- Chemical properties – Assay – Degradation products – Degradation preservatives – Content antioxidants • Microbial properties
- Container closure system properties

SEMI LIQUID FORMS

Physical-chemical properties – Appearance, odor, homogeneity, consistency – Loss on weight, Viscosity – Content uniformity (within the container)

- Chemical properties – Assay – Degradation products & preservatives – Content preservatives – Degradation– Content antioxidants • Microbial properties

- Container closure system properties –
Functionality tests

Stability Studies

- Stability studies at different stages
Stress- and accelerated Testing
with drug substances
- Stability on pre-formulation
batches
- Stress testing on scale-up
Batches • Accelerated and long
term testing for registration
- On-going Stability testing

- **References**

- Lachman L Lieberman H.A, Kanig J.L, The Theory and Practice of Industrial Pharmacy, 3rd edition
- Michael E.Aulton. Pharmaceutics, The science of Dosage form design.

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