Pharmaceutical Stability Studies

Determining pharmaceutical Stability, Storage and Testing

Sai Make it better together

Stability testing of products or drug substances forms a crucial part of the drug development process and involves a complex set of processes specifically designed to determine the impact of environmental factors on the product. The time, cost and scientific expertise invested in these studies contribute towards the efficacy, quality and safety of your product.

Pharmaceutical stability studies at Sai Life Sciences are conducted by a well-trained scientific team and best-in-class infrastructure to facilitate both real-time and accelerated stability studies to fulfill the regulatory requirements at each step of your drug development journey.

Highlights

- Stability studies conducted for over 70 pharmaceutical compounds
- GMP stability studies completed, and data included in regulatory filings, for >20 compounds
- Developmental stability studies conducted for several drugs, in varied conditions
- Dedicated and well-trained scientific team
- Stability Studies are carried out to ICH Q
- Comprehensive infrastructure set-up
- All stability chambers are supported with UPS power backup and conditions monitoring with alarm system

Capabilities and Infrastructure

- GMP stability studies as per the ICH Q1 norms for IND/ CTA, NDA/MAA, DMF regulatory filings
- Compound-specific developmental stability studies
- Studies to comply with various climatic zones (I, II, III, IVA and IVB) across the world
- Range of stability conditions include
  - 25±2°C/60 ± 5% RH (Real time)
  - 30 ±2°C/65 ± 5% RH (Intermediate)
  - 40 ±2°C/75 ± 5% RH (Accelerated)
  - 5 ±3°C
  - -20±5°C
  - -30±5°C
  - -80±5°C
  - Photo stability chamber
- 18000 litre capacity of Real time (25±2°C/60 ± 5% RH) walk-in chamber with equal capacity as backup
- Realtime monitoring of all stability chambers through an online server with alarm system

For more information contact: **contact@sailife.com**