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**NEW STORAGE  
FACILITIES**

Solvias – your partner for  
comprehensive stability services

## Our Facilities

### NEW Walk-in Chambers

5°C  
25°C/60% r.H.  
50 m<sup>2</sup> total storage capacity/walk-in chamber

### Climate Cabinets

5°C  
25°C/60% r.H.  
30°C/65% r.H. and 30°C/75% r.H.  
40°C/75% r.H.  
-20°C  
-80°C

*Other storage conditions available on request.*

### Standard Storage Conditions Climate Zones I and II

Type of Study	Storage Conditions	Minimum Time Period
Intermediate	30 ± 2 °C / 65 % r.H. ± 5 % r.H.	6 months
Accelerated	40 ± 2 °C / 75% r.H. ± 5 % r.H.	6 months
Long term	25 ± 2 °C / 60 % r.H. ± 5 % r.H. or 30 ± 2 °C / 65 % r.H. ± 5 % r.H.	12 months

## Stability Studies for All Phases of The Drug Development Cycle

- Long-term stability studies according to ICH guidelines
- On-going and follow-up stability studies
- Comparability studies
- Stress tests, forced degradation
- Photostability testing according to ICH guidelines
- In-use tests, freeze-thaw cycles
- Excipient/API compatibility
- Interaction studies with primary packaging
- Stability protocols, reports and interim reports
- Stability indicated method development and validation
- Identification of unknown/new impurities

## Features

- Wide storage capacity for all climate zones according to ICH guidelines and other storage conditions upon request
- Fully GMP qualified
- 24/7 monitoring and alert system enabling secure and controlled environment
- Emergency power supply
- Back-up cabinets for complete sample retrieval
- Disaster recovery plan in place
- Labware LIMS (CFR 21 part 11 compliant) for professional management and data handling
- Know-how and experience to deal with unexpected situations such as new degradation products, out of trend results etc...

## Analytical Power and Know-How to Cover Your Stability Projects

### For Small Molecules

- HPLC (numerous detectors), IEX, GC, TLC
- HPLC-MS, GC-MS
- Dissolution
- Water (Karl-Fischer)
- Titrations (e.g. assays)
- Solid-state: XRPD, thermal methods
- Viscosity/rheology
- Microbiology
- and many more...

### For Biopharmaceuticals

- HPLC, IEX-HPLC, SEC-HPLC
- HPLC-MS (ion trap, Q-TOF), MALDI-TOF/TOF
- CE, cIEF, iCE280
- Gel electrophoresis (PAGE, SDS-PAGE, IEF)
- Peptide mapping (by LC-MS and/or LC-UV)
- Oxidation, deamidation, charged variants
- Glycosylation, sialylation
- Assays (in-vitro, ELISA)
- and many more...

Stress Tests of APIs

Stability Testing Preformulation

Stress Tests of Scale-ups

Stress- and Long Term Tests for Registration

Follow-up Stability Testing

On-going Stability Tests