# Stability and Storage Testing

Accurate and reliable analytical data are foundational to ensuring the quality, safety, and efficacy of pharmaceutical and advanced therapy products. From assay development to contract testing for clinical and commercial products, partnership with a contract testing organization (CTO) or contract development and manufacturing organization (CDMO) at any phase requires trust in their ability to deliver the right answers at the right time. With deep expertise and a broad range of cutting-edge technologies across our facilities, SK pharmteco has the capacity and capabilities to support partners in analytical development and testing for projects of every scope and scale.

## Ensuring the Safety and Efficacy of Your Pharmaceutical Products

At SK pharmteco (SKPT), we understand the importance of stability and storage testing for pharmaceutical products. These critical tests help ensure the safety, efficacy, and quality of your medications throughout their shelf life.

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# Our Stability Testing Services

We offer a comprehensive range of stability testing services to meet your specific needs. Our on-site testing allows for samples to be shared across testing laboratories. We have validated shipping to testing site locations.

## Stability Testing

**ICH Stability Testing:** We conduct stability studies according to the International Council for Harmonization (ICH) guidelines. These guidelines provide a standardized approach to stability testing, ensuring that your data is recognized by regulatory agencies worldwide.

**Forced Degradation and Stress Stability Testing:** Stress stability testing helps to identify potential degradation pathways of your product and establish its robustness to harsh environmental conditions.

**Photostability Testing:** Photostability testing assesses the impact of light on your product, ensuring its stability under various lighting conditions.

**Long term and accelerated conditions**

## Method Devleopment

Full Testing capabilities to support Method Development, Transfer, and Validation on-site where stability storage is located.

- Our analytical development experts provide you with a stability-indicating method or perform a technical transfer for existing methodology
- Phase-appropriate method validation to support stability studies across all stages of drug development
- Process Development and R&D Studies

## Study Design

Study Design including standard ICH conditions and custom protocols

- SK pharmteco maintains standard ICH, and some custom conditions, to support long term and accelerated storage conditions and provides guidance on the duration of the study, the determination of stability indicating methods, and the pull schedule.
- Protocol authoring, trending and custom timepoint reporting of results

## Storage and Chamber Capacity

- Stability storage is available at multiple locations.
- Electronic environmental monitoring for all stability storage locations

## Storage Conditions

We have 30+ storage chambers and provide a variety of conditions to meet the requirements of your product, including:

### ICH Storage Conditions:

We offer a full range of ICH storage conditions, including:

- 25° C ± 2° C / 60% RH ± 5% RH (room temperature)
- 30° C ± 2° C / 65% RH ± 5% RH
- 40° C ± 2° C / 75% RH ± 5% RH
- 2-8° C
- -20° C
- -80° C
- Cyrostorage / Liquid Nitrogen

### Custom Storage Conditions

We can also accommodate custom storage conditions to meet your specific product requirements.

## Testing Capabilities

SK pharmteco's stability centers include full service analytical laboratories.

- HPLC-UV, IC, GC, HSGC
- Karl Fischer Titrators
- FTIR
- NMR
- DSC and TGA
- XRPD
- GCMS, LCMS, LC-MS/MS
- In-house micro USP <61> and <62> and sterility

  Container closure integrity testing (CCIT) can be offered in place of Sterility Testing on site to minimize sample volumes for testing

  - Vacuum decay
  - Dye ingress

## Our Commitment to Quality

All of our stability testing chambers are:

- CGMP compliant
- Maintained at set points and tolerances outlined in the ICH guidelines.
- Fully mapped and qualified to ensure consistent and reliable testing conditions.
- Continuously monitored by validated computerized chart recorders to ensure data integrity.
- 24/7 monitoring and alarms
- Validated LIMS (Laboratory Information Management System)
- Electronic QMS (Quality Management System)
- Dedicated storage temperatures with redundancy, reporting, and trending.

In addition, you'll have a dedicated Program Director to ensure full regulatory oversight. By partnering with SK pharmteco for your stability and storage testing needs, you can be confident that your products meet the highest quality standards and remain safe and effective throughout their shelf life.

To learn more about our stability and storage testing services or to request a quote, please contact us. Our team is ready to assist you in ensuring the safety and quality of your pharmaceutical products.

About SK pharmteco:

At SK pharmteco our mission is to build strong relationships that create happiness for our customers through the shared goal of producing and delivering life-changing therapies that improve patient outcomes and save lives. With our network of seven global, cutting-edge, facilities our capabilities cover the entire product lifecycle, from initial development to commercial manufacturing. We work with customers in a flexible 'One Team' approach, prioritizing collaboration, transparency, and trust to make every interaction easy and seamless.

SK pharmteco offers CDMO services for small molecule APIs and cell and gene therapies as well as analytical testing services; contact our experts to learn more!

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