# Stability Studies Made Reliable.

## GMP Storage and Analytics at One Site.


Why stability data are more than a regulatory requirement.

### Executive Summary

Stability studies are essential to pharmaceutical development, quality control and regulatory approval. They show how a product behaves under defined storage conditions over time and provide the scientific basis for shelf life, storage instructions and transport conditions.

At CUP Contract Labs, GMP storage, defined pull points and analytical testing can be coordinated at one site. This integrated setup reduces interfaces, avoids unnecessary transport steps and supports reliable stability data for development, quality assurance and regulatory decision-making.

### Market Context and Regulatory Framework

Pharmaceutical products must remain safe, effective and within specification throughout their intended shelf life. Stability data help define shelf life, storage conditions, transport requirements and packaging strategies. They also make degradation trends, physical changes or potency losses visible before they become quality risks.

The regulatory framework is shaped by ICH Q1 guidance and GMP requirements. In practice, stability strategies must also reflect the intended target market, climatic zone, product characteristics and packaging configuration.

Therefore, stability testing should be planned early as an integrated part of product development, not treated as a separate regulatory exercise.

### Scientific Background

Stability studies investigate chemical, physical and product-specific changes over time. Chemical degradation may include hydrolysis, oxidation or photochemical reactions. Physical instability may become visible through precipitation, discoloration, viscosity changes, particulate formation or loss of potency.

Key influencing factors include temperature, humidity, light exposure, product matrix and packaging. Analytical testing translates these changes into quality-relevant data such as assay, degradation products, pH value, water content, appearance, particulate matter, identity, purity or further product-specific parameters.

| Framework | Relevance for Stability Studies |
|---|---|
| ICH Q1A(R2) | Stability data package, shelf life and recommended storage conditions. |
| ICH Q1B | Photostability testing for light-sensitive products. |
| EU GMP | Controlled, documented and scientifically justified stability programs. |
| Climatic Zones | Market-specific storage strategy based on temperature and humidity. |

# Stability Studies Made Realiable.

## Study Designs in Practice

Stability programs are designed according to product characteristics, target market, regulatory strategy and intended storage conditions. Different study types answer different questions — from long-term shelf-life confirmation to accelerated stress evaluation, photostability testing or in-use simulation.
A well-defined study design ensures that storage conditions, pull points, sample quantities and analytical parameters are aligned before the study starts.

### Common Stability Study Types

| Study type | Purpose | Typical Setup |
|---|---|---|
| Long-term Stability | Confirms product quality over the intended shelf life | Storage under defined climatic or temperature-controlled conditions over the planned shelf-life period |
| Accelerated Stability | Detects early degradation trends under stress conditions | Increased temperature and humidity, often used for early risk assessment |
| Intermediate Stability | Bridges long-term and accelerated conditions | Used when additional data are required between long-term and accelerated storage |
| Photostability | Evaluates sensitivity to light exposure | Light exposure according to ICH Q1B, followed by agreed analytical testing |
| In-use Stability | Simulates product handling during use | Product- and application-specific study design after opening or preparation |
| On-going Stability | Monitors product quality during lifecycle | Usually long-term studies to confirm continued product quality |

## From Pull Points to Reliable Data

Stability studies are long-term quality programs. Pull points may extend over months or years and require reliable planning, documentation and communication.

Typical long-term pull points may include:

**0 → 3 → 6 → 9 → 12 → 18 → 24 → 36 → 48 → 60 months**

Accelerated and intermediate studies usually follow shorter schedules, depending on the storage condition, regulatory strategy and product-specific requirements. Each pull point represents a defined decision point: samples must be removed under controlled conditions, tested according to plan and documented in a traceable way.

Precise pull-point management helps ensure that stability data remain consistent, comparable and suitable for development, quality assurance and regulatory use.

## Practical Challenges in Stability Programs

In practice, stability studies often become challenging when operational details are not fully defined at study start.
Typical challenges include:

- limited storage capacity for long-term studies
- unclear responsibilities for pull-point notification
- incomplete or late stability protocols
- insufficient sample quantities for planned analytics
- additional interfaces between storage site, client and external laboratories
- transport steps between storage and analytical testing
- delayed trend recognition due to fragmented workflows

These challenges show why stability testing should be managed as an integrated quality process — not only as sample storage under defined conditions.

## Industry Perspective

Stability data are only as reliable as the process behind them. Controlled storage conditions are essential, but they must be combined with clear pull-point planning, defined analytical parameters and consistent documentation.
For complex pharmaceutical products, sensitive formulations or products with specific storage requirements, reducing interfaces can be a major advantage. When storage, pull points and analytics are coordinated at one site, timelines become easier to manage and the risk of inconsistent handling is reduced.

### Our Stability Toolbox

| Storage condition | Typical Use |
|---|---|
| 25 °C / 60% RH | Intermediate conditions |
| 30 °C / 65% RH | Long-term stability for hot / very humid conditions |
| 30 °C / 75% RH | Long-term stability for hot / very humid conditions |
| 40 °C / 75% RH | Accelerated stability studies |
| Refrigerated Storage | Temperature-sensitive products |
| Frozen Storage | Products requiring frozen storage conditions |
| Light Exposure | Photostability testing according to ICH Q1B |

# Stability Studies Made Realiable.

## Integrated Stability Workflow at CUP

Reliable stability studies require more than controlled storage. They depend on clear responsibilities, defined pull points, suitable sample quantities, aligned analytics and consistent documentation throughout the full study lifecycle.
At CUP Contract Labs, stability storage, pull-point handling and analytical testing can be coordinated within one integrated setup. This reduces interfaces, supports reliable timelines and helps generate stability data that are suitable for development, quality assurance and regulatory decision-making.

### CUP Stability Workflow

1. **Project Request** - Client requests stability storage and, if required, related analytics.
2. **Technical Clarification** - Product handling, storage conditions, pull points are clarified.
3. **Capacity Check** - Storage capacity, feasibility and analytical requirements are reviewed.
4. **Protocol Alignment** - The stability protocol is provided by the client or prepared by CUP.
5. **Sample Receipt & Registration** - Samples are received, registered and assigned.
6. **Controlled GMP Storage** - Samples are stored under defined conditions.
7. **Scheduled Pull Points** - Samples are pulled as defined or upon notification.
8. **Analytics or Shipment** - Samples are analyzed at CUP, forwarded or returned as agreed.
9. **Documentation & Final Handling** - Results and remaining material are documented.

## Operational Reliability

Stability studies often run over several months or years. During this period, reliable coordination becomes just as important as the storage condition itself. Pull points must be monitored, samples must be available in sufficient quantity, and analytical testing must be aligned with the agreed stability plan.

At CUP Contract Labs, this operational reliability is supported by a structured workflow from sample receipt to storage, pull point, analytics and documentation. This helps reduce avoidable delays and supports consistent handling throughout the study lifecycle.

## Planning Stability Studies Early

The quality of stability data strongly depends on the decisions made before study start.

Storage conditions, packaging configuration, sample orientation, pull-point intervals, analytical parameters and responsibilities should be clearly defined before samples are submitted.

Early alignment helps avoid later uncertainty, especially in long-term studies with multiple pull points. It also supports realistic capacity planning, reliable timelines and data that can be used efficiently for development, quality assurance and regulatory documentation.

## Strategic Value

A structured stability strategy supports pharmaceutical development, quality assurance and regulatory decision-making. Reliable stability data help define shelf life, confirm storage and transport conditions, identify degradation trends early and support lifecycle decisions.

When stability storage, pull points and analytics are planned together, studies become easier to manage and data become more consistent, traceable and useful for regulatory documentation. This is particularly valuable for products with sensitive formulations, specific storage requirements or complex analytical needs.

## Conclusion

Reliable stability data are generated when storage conditions, packaging, analytical parameters and pull points are clearly defined from the beginning.

Stability studies are not isolated storage activities. They are structured quality programs that connect product understanding, regulatory expectations, controlled storage and analytical testing over time.

By combining GMP storage, defined pull points and analytics at one site, CUP Contract Labs supports clients in reducing interfaces, planning studies efficiently and generating robust data for development, quality control and regulatory submissions.

**Any questions?**
Let´s talk.

CUP contract labs
Leading the way in Complex Pharmaceutical Analysis.

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