

Stability Studio

Estimate shelf life from long-term data by ICH Q1E regression with batch poolability testing, and write a stability report with chart, tables, conclusion and the post-approval commitment.

WRITES

3.2.S.7

3.2.P.8

Stability
report

PRODUCT TYPE

Small molecule

GUIDANCE IT FOLLOWS

ICH Q1A(R2), ICH
Q1E

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/stability-studio.html>. This guide is also online at <https://cmcfy.com/guides/stability-studio.html>

1. What this module does

Paste the long-term results for one attribute (batch, time in months, value). The tool fits a regression per batch, tests whether batches can be pooled (ANCOVA at the 0.25 significance level, slopes first, then intercepts), and finds where the one-sided 95% confidence bound meets the acceptance criterion.

The proposed shelf life is capped by the ICH Q1E extrapolation limits: no more than twice the data period and no more than 12 months beyond it. The report includes study design, results, poolability tests, the chart, the conclusion, the storage statement and blank sign-off lines.

What you get

- A stability report in Word or PDF for one attribute, including the post-approval stability protocol and commitment (3.2.S.7.2 / 3.2.P.8.2).
- A summary file for the QOS Composer & Dossier Assembler, which checks the shelf life and stability batches against the other sections.

2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- Product, report number, stability protocol number and storage condition.

- The attribute, unit and acceptance criterion (lower limit, upper limit or both).
- Results as a table of batch, time (months) and value. Excel, CSV, PDF and scanned tables can be loaded.
- A summary of accelerated, intermediate and photostability results, and whether the batches are production scale.

Your data stays on your computer. The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/stability-studio.html. The example (Assay of three registration batches, 0 to 18 months at 25 °C/60% RH) is loaded when the page opens. Press [Load example](#) at any time to bring it back.

1 Describe the study

Enter the product, report and protocol numbers, the storage condition, the attribute and its unit. Choose the acceptance criterion: lower limit only (values fall over time, for example assay), upper limit only (values rise, for example a degradation product) or both.

CMCfy Stability Studio Projects All modules Training Security

Runs entirely on this device Training guide Protocol builder

PROJECTS Keep this work in a project, with version history and your company logo on every report. [Choose projects folder](#) [Keep in this browser](#)

- Network requests since load: 0**
Counted live by your browser. Your data is never sent anywhere.
- Works offline**
Everything the tool needs is inside this page. You can disconnect from the internet and keep working.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked by the browser.

STUDY

Product: CMX-101 Tablets, 50 mg

Report number: STB-2026-014 Stability protocol: SP-2025-006

Storage condition: 25 °C / 60% RH Attribute: Assay

Unit: % label claim

Acceptance criterion: Lower limit only (value falls over time)

Lower limit: 95.0 Upper limit: 105.0

SHELF-LIFE ESTIMATE

STATISTICAL ESTIMATE: 31.9 mo EXTRAPOLATION LIMIT: 30 mo MODEL: Common slope, separate intercepts

DATA: 3 batches, 18 points, to 18 mo CRITERION: NLT 95 % label claim

30 months

REGRESSION WITH 95% CONFIDENCE BOUND

RAW DATA: CSV with columns batch, time (months), value

2 Enter the raw data

Paste or load the data with three columns: batch, time in months, value. Press [Upload data](#) (Excel, CSV, PDF, scan) to read a file; check the columns after loading.

RAW DATA

CSV with columns batch, time (months), value

```
batch,time_months,value
LOT-2401,0,100.4
LOT-2401,3,99.9
LOT-2401,6,99.5
LOT-2401,9,99.0
LOT-2401,12,98.7
LOT-2401,18,97.8
LOT-2402,0,100.1
LOT-2402,3,99.8
LOT-2402,6,99.1
LOT-2402,9,98.9
LOT-2402,12,98.3
```

[Upload data \(Excel, CSV, PDF, scan\)](#)

[Load example](#)

Example data loaded: three registration batches, 0 to 18 months.

The raw data panel.

3 Read the shelf-life estimate

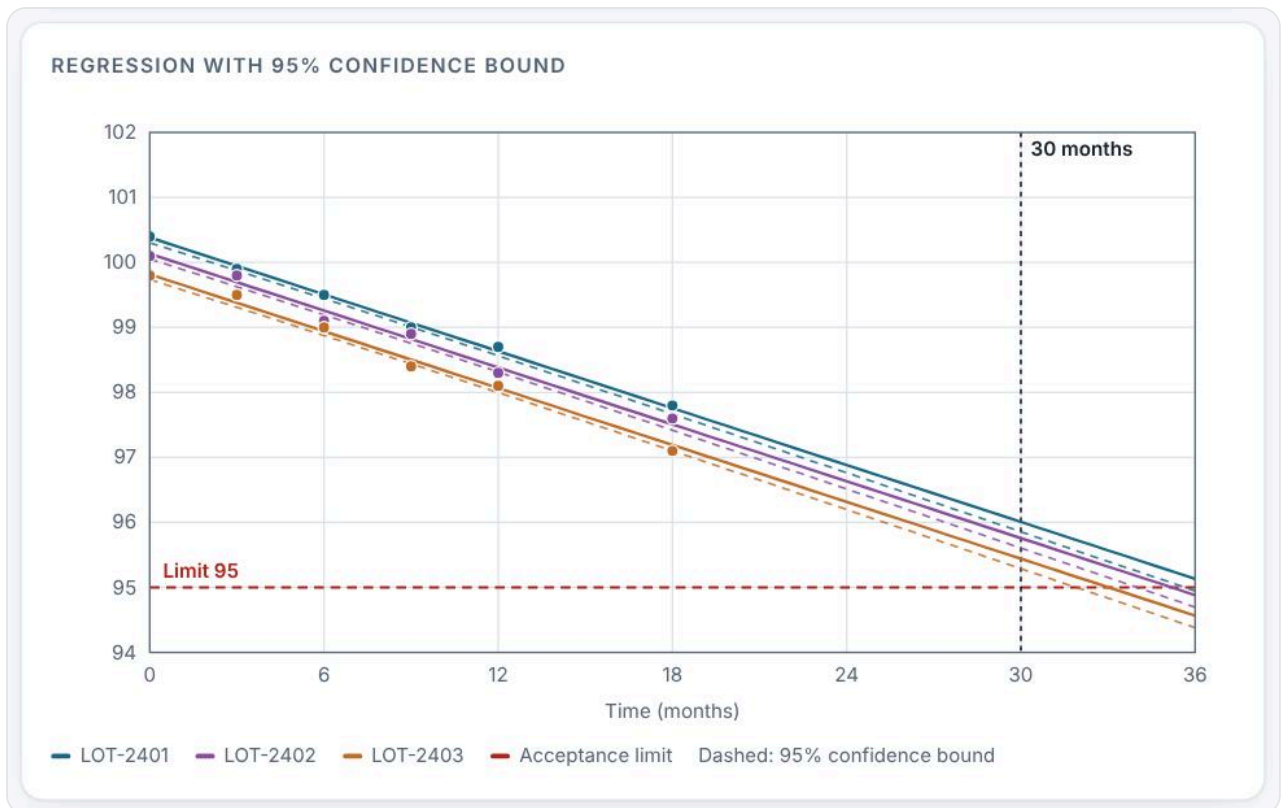
The result shows a proposed 30 months: the statistical estimate is 31.9 months, but with 18 months of data the extrapolation limit is 30 months. The model used is common slope, separate intercepts.

SHELF-LIFE ESTIMATE

30 months	STATISTICAL ESTIMATE 31.9 mo	EXTRAPOLATION LIMIT 30 mo	MODEL Common slope, separate intercepts
	DATA 3 batches, 18 points, to 18 mo	CRITERION NLT 95 % label claim	

4 Read the chart and the statistics

The chart shows each batch with its regression line, the dashed 95% confidence bound and the limit. The statistics panel gives the poolability tests (slopes $p = 0.4088$, poolable; intercepts $p < 0.0001$, not poolable) and the line for each batch. LOT-2403 reaches the limit first and sets the shelf life.



Regression with 95% confidence bound.

5 Complete the report details

In the report panel choose drug product or drug substance, the region and whether the batches are production scale, and summarise the accelerated, intermediate and photostability results. Press **Suggest storage statement for the region** for the regional wording.

REPORT: PREVIEW, REVIEW AND DOWNLOAD

The report opens in a preview first, with a review of gaps in the data, gaps in the report and differences from your stability protocol. Download it as Word or PDF from there. It includes study design, a results table, the poolability tests, the regression chart, the shelf-life conclusion and blank sign-off lines for your reviewer and approver.

Batch type Submission region

Drug product (3.2.P.8) US: FDA

Production-scale batches in these data

0

Accelerated, intermediate and photostability results

Accelerated 40 °C / 75% RH, 6 months: no significant change on any batch (report STB-2026-012). Photostability (ICH Q1B, Option 2): no significant change in the immediate pack (report STB-2025-031).

Storage statement

Store at 20–25 °C (68–77 °F); excursions permitted to 15–30 °C. Protect from moisture.

Suggest storage statement for the region

The report adds the post-approval stability protocol and commitment (3.2.S.7.2 / 3.2.P.8.2). Save the summary file to bring the shelf life and stability batches into the QOS Composer, which checks them against the other sections.

Preview and download report Download summary for QOS

6

Preview, review and download

Press **Preview and download report**. The review lists data gaps (for example missing time points or results outside the criterion) and report gaps, and you can load the stability protocol to compare conditions, time points, tests and criteria. Then download Word or PDF. Press **Download summary for QOS** to save the summary.

Preview and review before download

Close

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

No open gaps

No open gaps: the data, the report and the protocol (if given) match every rule checked, or you accepted the rest. Read the review before you sign.

Compare with the protocol

Load or paste stability protocol SP-2025-006 to check the conditions, time points, tests and acceptance criteria against the report.

Paste the protocol text here, or load the file.

Load protocol file

Compare

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix them. You see exactly what is sent before anything leaves this device. Results and pass/fail are not changed.

Run AI review

Stability Report: Assay

CMX-101 Tablets, 50 mg · 25 °C / 60% RH

Report number	STB-2026-014
Stability protocol	SP-2025-006
Product	CMX-101 Tablets, 50 mg
Attribute	Assay (% label claim)
Acceptance criterion	NLT 95 % label claim
Storage condition	25 °C / 60% RH
Date drafted	2026-10-29

1. Purpose

This report evaluates long-term stability data for Assay of CMX-101 Tablets, 50 mg stored at 25 °C / 60% RH, and estimates a shelf life following ICH Q1E, Evaluation of Stability Data. The study was performed under stability protocol SP-2025-006.

2. Study design

3 batches were tested at 6 time points (0, 3, 6, 9, 12, 18 months), giving 18 results in total. Batches: LOT-2401, LOT-2402, LOT-2403.

3. Results

Time (months)	LOT-2401	LOT-2402	LOT-2403
0	100.4	100.1	99.8
3	99.9	99.8	99.5
6	99.5	99.1	99.0
9	99.0	98.9	98.4

Download Word (.docx)

Download PDF

4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

Study

FIELD	WHAT TO ENTER
Product, Report number, Stability protocol	Type them in; they appear on the report and the protocol number is used in the protocol comparison.
Storage condition	The long-term condition, for example 25 °C / 60% RH. Used for the storage statement.
Attribute, Unit	One attribute per report, for example Assay and % label claim.
Acceptance criterion	Choose lower limit only, upper limit only, or both; then enter the limit or limits.

Raw data

FIELD	WHAT TO ENTER
CSV with columns batch, time (months), value	One row per result. Paste from Excel or press Upload data (Excel, CSV, PDF, scan).

Report

FIELD	WHAT TO ENTER
Batch type	Drug product (3.2.P.8) or drug substance (3.2.S.7).
Submission region	US, EU or both; sets references and the storage statement wording.
Production-scale batches in these data	Says whether the batches are production scale; affects the commitment text.
Accelerated, intermediate and photostability results	A short summary; needed when the shelf life extrapolates beyond real-time data.
Storage statement	Type it or press Suggest storage statement for the region .

5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- Poolability by ANCOVA at the 0.25 level: common slope and intercept, common slope with separate intercepts, or separate lines. The batch that meets the limit first sets the shelf life.
- Shelf life where the one-sided 95% confidence bound of the mean (two-sided for two limits) meets the criterion, capped by the ICH Q1E extrapolation limits.
- In the preview review: fewer than three batches; less than 12 months of long-term data; accelerated data shorter than 6 months; time points or batches without results; results outside the criterion (critical); significant change at accelerated conditions with extrapolation; no accelerated summary; no storage statement; no unit; data that support no shelf life (critical).

6. Preview, gap review and download

1. Press [Preview](#) next to a section, or [Preview and download all](#). The document opens in a preview window, exactly as the Word file will read.

- The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under **Compare with the protocol**, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
- Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
- Optional **AI review**: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
- Press **Download Word (.docx)** or **Download PDF**. With several documents open, **All as Word (.zip)** and **All as PDF (.zip)** download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

Documents this module produces

SECTION	DOCUMENT
Stability report	Report for one attribute, with chart, tables, conclusion, storage statement and the post-approval commitment (3.2.S.7.2 / 3.2.P.8.2)

7. US and EU submissions

The statistics are the same in both regions (ICH Q1E). The region changes the references in the report (FDA OOS guidance and 21 CFR 211.166 in the US; EU GMP Chapter 6 and EMA guidance in the EU) and the storage statement wording, for example "Store below 25 °C" in the EU against "Store at 20–25 °C (68–77 °F)" in USP terms.

8. Working with other modules

- For proteins, where Q5C does not allow extrapolation, use the Biologics Stability Studio module.
- A result outside the criterion should be investigated in the Investigation Studio (OOS, deviation, CAPA).
- The QOS Composer & Dossier Assembler checks that the stability batches appear in the Batch Analysis & CoA and that the shelf life matches the label.

9. Common pitfalls

- Choosing "lower and upper limits" for assay when only the lower limit matters: the bound becomes two-sided and the shelf life shorter.

- Mixing units (months and weeks) in the time column.
- Expecting the full statistical estimate: the extrapolation limits apply, and need accelerated data to support any extrapolation.
- One report covers one attribute; run the tool once per stability-indicating attribute.

10. Practice exercises

Each exercise starts from the example (press [Load example](#) to reset). We run these on every update of this guide, so the result you see should match.

1. Tighten the limit

Change [Lower limit](#) from 95 to 97.

EXPECTED RESULT

The proposed shelf life drops to 18 months.

2. Set a limit the data cannot meet

Change [Lower limit](#) to 101.

EXPECTED RESULT

The shelf-life estimate shows "None".

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.