

Biologics Stability Studio

Write the stability sections for a protein product: each stability-indicating attribute trended by ICH Q1E regression, the shelf life limited to the real-time data as ICH Q5C expects, and the supporting studies checked.

WRITES

3.2.S.7.1

3.2.S.7.2

3.2.S.7.3

3.2.P.8.1

3.2.P.8.2

3.2.P.8.3

PRODUCT TYPE

Biologics
(biotechnology
products)

GUIDANCE IT FOLLOWS

ICH Q5C, ICH
Q1A(R2), ICH Q1B,
ICH Q1E; FDA
Points to Consider
in the Manufacture
and Testing of
Monoclonal
Antibody Products
(1997)

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

The module writes 3.2.S.7 or 3.2.P.8 for a protein. You enter the stability-indicating attributes with their limits and the long-term results; the tool fits each attribute and reports the time at which it would meet its limit.

Unlike small molecules, ICH Q5C does not allow extrapolation beyond real-time data, so the supported shelf life is capped at the longest real-time time point even when the statistics would allow more.

What you get

- Word or PDF files for 3.2.P.8.1 (or 3.2.S.7.1) summary and conclusions, 8.2 post-approval protocol and commitment, and 8.3 stability data.
- A summary file for the QOS Composer & Dossier Assembler, which checks the shelf life and storage statement 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.

- Long-term condition, proposed shelf life and the container used in the study.
- Each stability-indicating attribute with its lower and/or upper limit and units.
- Long-term results: one row per batch, attribute, month and result (an Excel export works).
- Summaries of accelerated, stress, photostability, freeze-thaw, in-use and shipping studies, and the post-approval commitment.

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/biologics-stability.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

1 Enter product and study design

Choose drug product or drug substance, the long-term condition (5 ± 3 °C in the example) and the proposed shelf life (24 months). Tick that batches are at least pilot scale and made by the commercial process.

CMCfy | **Biologics 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 never leaves this device.
- Works offline**
Everything the tool needs is inside this page.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked.

3.2.S.7.1 | 3.2.S.7.2 | 3.2.S.7.3 | 3.2.P.8.1 | 3.2.P.8.2 | 3.2.P.8.3

Save project Open project Start blank Load example

Write the stability sections for a protein product. Each stability-indicating attribute is trended by ICH Q1E regression, and the supported shelf life is limited to the real-time data as ICH Q5C expects. Accelerated, stress, freeze-thaw, light and in-use studies are checked too.

Guidance: ICH Q5C, ICH Q1A(R2), ICH Q1B, ICH Q1E; FDA Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products (1997)

1 · PRODUCT AND STUDY

Product

CMB-201 Injection, 100 mg/mL in single-dose vials

Submission region

US: FDA (NDA, ANDA, BL)

Stability of

Drug product (3.2.P.8)

Long-term condition

5 ± 3 °C

Proposed shelf life (months)

24

Container used in the study

2R Type I glass vial, fluoropolymer-coated bromobutyl stopper

Batches are at least pilot scale and made by the commercial

RESULT

24 months supported at 5 ± 3 °C

3 batches with real-time data to 24 months. Limiting attribute: HMW species by SEC. Proposed shelf life: 24 months. Statistics alone would allow 31 months, but ICH Q5C limits the claim to the real-time data.

BATCHES	REAL-TIME DATA	ATTRIBUTES TRENDED
3	24 months	6

PROPOSED
24 months

SHELF LIFE BY ATTRIBUTE

2 Enter attributes and results

Enter the limits table and the results table. Load an Excel or CSV file with the same columns if you have one.

3 Read the shelf life

The headline reads "24 months supported at 5 ± 3 °C": 3 batches with real-time data to 24 months, limiting attribute HMW species by SEC. Statistics alone would allow 31 months, but Q5C limits the claim to the real-time data.

RESULT

24 months supported at 5 ± 3 °C

3 batches with real-time data to 24 months. Limiting attribute: HMW species by SEC. Proposed shelf life: 24 months. Statistics alone would allow 31 months, but ICH Q5C limits the claim to the real-time data.

BATCHES	REAL-TIME DATA	ATTRIBUTES TRENDED
3	24 months	6

PROPOSED
24 months

4 Check each attribute

The table shows each attribute with its trend and the month it would meet its limit, and the stability-indicating profile checks that potency, purity, aggregates and charge variants are all covered.

SHELF LIFE BY ATTRIBUTE					
Supported time is the earlier of the regression estimate and the latest real-time point.					
ATTRIBUTE	LIMITS	MODEL	SLOPE PER MONTH	REGRESSION ESTIMATE	SUPPORT
Potency (cell-based)	$\geq 70, \leq 130$ % of reference	common slope	-0.330	80.7 mo	24 mo
Monomer by SEC	≥ 97 %	common slope	-0.045	47.6 mo	24 mo
HMW species by SEC	≤ 2 %	pooled	0.040	31.8 mo	24 mo
Main peak by icIEF	$\geq 60, \leq 75$ %	common slope	-0.176	43.2 mo	24 mo
Protein concentration	$\geq 90, \leq 110$ mg/mL	pooled	-0.020	> 120 mo	24 mo
Subvisible particles $\geq 10 \mu\text{m}$	≤ 6000 per container	pooled	14.003	> 120 mo	24 mo

Shelf life by attribute.

5 Resolve alerts

The example has four minor alerts: two attributes not in the programme, in-use times without a microbiological statement, and no shipping study.

ALERTS TO RESOLVE

All blocking alerts are fixed, justified or accepted. Minor alerts are listed in the Word files.

MINOR Appearance is not in the stability programme.

Profile · ICH Q5C 6

Include appearance as a stability-indicating attribute, or justify leaving it out.

 Justification

MINOR pH is not in the stability programme.

Profile · ICH Q5C 6

Include pH as a stability-indicating attribute, or justify leaving it out.

 Justification

MINOR In-use times are given without a microbiological statement.

Supporting studies · EMA CPMP/QWP/159/96

Add that, from a microbiological point of view, the product should be used immediately unless prepared under controlled aseptic conditions.

 Justification

MINOR No shipping study.

Supporting studies · ICH Q5C; USP <1079>

Show that shipping conditions (temperature, vibration) do not affect quality, or reference the shipping validation.

 Justification

6

Preview and download

Preview the three stability sections, read the review and download.

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.

5 recommended

MISSING INFORMATION (1)

"Shipping study" is empty.

Enter it in the tool, or confirm it does not apply. Empty inputs show as placeholders or gaps in the report.

recommended · Supporting studies

DATA AND INPUTS (4)

Appearance is not in the stability programme.

Include appearance as a stability-indicating attribute, or justify leaving it out.

recommended · Profile · ICH Q5C 6

pH is not in the stability programme.

Include pH as a stability-indicating attribute, or justify leaving it out.

recommended · Profile · ICH Q5C 6

In-use times are given without a microbiological statement.

Add that, from a microbiological point of view, the product should be used immediately unless prepared under controlled aseptic conditions.

recommended · Supporting studies · EMA CPMP/QWP/159/96

3.2.P.8.1 Stability summary and conclusions

CMB-201 Injection, 100 mg/mL in single-dose vials · US (FDA)

Attribute	Limits	Regression estimate	Supported
Potency (cell-based)	≥ 70 , ≤ 130 % of reference	80.7 months	24 months
Monomer by SEC	≥ 97 %	47.6 months	24 months
HMW species by SEC	≤ 2 %	31.8 months	24 months
Main peak by icIEF	≥ 60 , ≤ 75 %	43.2 months	24 months
Protein concentration	≥ 90 , ≤ 110 mg/mL	> 120 months	24 months
Subvisible particles $\geq 10 \mu\text{m}$	≤ 6000 per container	> 120 months	24 months

The stability of CMB-201 Injection, 100 mg/mL in single-dose vials was studied on 3 batches (DP-201-01, DP-201-02, DP-201-03) stored at $5 \pm 3^\circ\text{C}$ in 2R Type I glass vial, fluoropolymer-coated bromobutyl stopper (commercial), with real-time data to 24 months.

The stability-indicating attributes were potency (cell-based), monomer by SEC, HMW species by SEC, main peak by icIEF, protein concentration, subvisible particles $\geq 10 \mu\text{m}$. Results were evaluated by linear regression with 95% confidence bounds (ICH Q1E). The limiting attribute is HMW species by SEC, with a slope of 0.040 per month.

Accelerated conditions: $25 \pm 2^\circ\text{C}$ / 60% RH for 6 months: HMW +1.1%, potency -6%; trends consistent with long-term degradation pathways.

Stress studies: 40°C for 1 month, 0.01% H₂O₂, agitation 24 h: oxidation at HC M255 and aggregation identified; SEC, peptide map and icIEF shown to be stability-indicating.

Photostability: Unprotected vials degrade (HMW +4%); product in the carton is protected. Label: keep in the outer carton to protect from light.

In-use: Diluted in 0.9% sodium chloride to 2–20 mg/mL: physically and chemically stable for 24 h at $2-8^\circ\text{C}$ and 8 h at room temperature.

Based on the real-time data, a shelf life of 24 months at $5 \pm 3^\circ\text{C}$ is proposed.

Storage conditions: $5 \pm 3^\circ\text{C}$

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.

1 • Product and study

FIELD	WHAT TO ENTER
Product	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Stability of	Choose one: Drug product (3.2.P.8); Drug substance (3.2.S.7).
Long-term condition	Type it in.
Proposed shelf life (months)	Type a number.
Container used in the study	Type it in.
Batches are at least pilot scale and made by the commercial process	Tick the box if it applies.

2 • Long-term results

One row per batch, attribute and time point. Load an Excel or CSV export with the same columns.

FIELD	WHAT TO ENTER
Stability-indicating attributes and limits	A table. Columns: Attribute Lower limit Upper limit Units. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Results	One row per batch, attribute and time point. Attribute names must match the limits table. A table. Columns: Batch Attribute Month Result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Supporting studies

FIELD	WHAT TO ENTER
Accelerated condition and outcome	Type it in.
Stress studies (temperature, pH, oxidation, agitation)	Type it in.
Photostability (ICH Q1B)	Type it in.
Freeze-thaw (drug substance) or temperature excursion	Type it in.
In-use stability after dilution	Type it in.
Shipping study	Type it in.
Post-approval commitment	Type it in.

5. Checks and alerts

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

- At least three batches on long-term stability, of at least pilot scale and the commercial process; the container stated; enough months of real-time data.
- Proposed shelf life not beyond the real-time data; no attribute predicted to meet its limit before the proposed shelf life (critical).
- Results outside the limits are critical; attributes with limits need results; results need limits.
- Accelerated, stress, photostability, freeze-thaw (drug substance), in-use (with a microbiological statement) and shipping studies.
- A post-approval stability commitment.

How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press **Record**.
- **Major** alerts block the download until you fix them or type a justification and press **Accept justification**.
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.

- Some alerts have an **Apply fix** button that makes the change for you. **Reopen** undoes a justification.

Narratives

This module writes: Stability summary and conclusions. Each narrative is written by fixed rules from your data. You can edit it in the box. **Rewrite with AI** (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. **Reset to rule-based text** brings back the original.

6. Preview, gap review and download

- 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
3.2.P.8.1 / 3.2.S.7.1	Stability summary and conclusions
3.2.P.8.2 / 3.2.S.7.2	Post-approval stability protocol and stability commitment
3.2.P.8.3 / 3.2.S.7.3	Stability data

Use **Save project** to keep your work as a file on your computer, and **Open project** to continue later. **Start blank** clears every field; **Load example** brings the example back. Nothing is stored on CMCfy servers.

7. US and EU submissions

ICH Q5C and Q1E apply in both regions. US mode writes the storage statement in USP terms (for example "Store refrigerated at 2–8 °C"); EU mode uses the EU wording ("Store in a refrigerator (2 °C – 8 °C)") from the EMA guideline on declaration of storage conditions.

8. Working with other modules

- Small-molecule stability is the Stability Studio.
- Limits come from Biologics Characterisation & Specification.
- In-use compatibility links to the Biologics Drug Product Writer.

9. Common pitfalls

- Proposing a shelf life longer than the real-time data, expecting extrapolation as for small molecules.
- Attribute names that differ between the limits and results tables.
- Leaving the post-approval commitment empty.
- In-use hold times with no statement on microbiological risk.

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. Propose a longer shelf life

Change [Proposed shelf life \(months\)](#) to 36.

EXPECTED RESULT

A major alert says the proposed 36 months is beyond the real-time data (24 months).

2. Remove the commitment

Clear `Post-approval commitment`.

EXPECTED RESULT

A major alert says there is no post-approval stability commitment.

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.