

Forced Degradation & Photostability

Write the forced degradation (stress testing) report and the ICH Q1B confirmatory photostability report, and conclude whether the procedure is stability-indicating and whether the product needs protection from light.

WRITES

3.2.S.3.2

3.2.S.7

3.2.P.5.5

3.2.P.8

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

ICH Q1A(R2) 2.1.2 Stress testing; ICH Q1B Photostability Testing (1996); ICH Q2(R2) specificity; ICH Q14; ICH Q5C (biologics); ICH Q3A(R2), Q3B(R2); FDA Analytical Procedures and Methods Validation (2015); EMA Guideline on stability testing (CPMP/QWP/122/02 Rev 1); CPMP/QWP/609/96 Rev 2 (storage statements)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

For each stress condition you enter the assay (as % of the unstressed control), the total degradation products, the main degradant, the peak purity and the lowest resolution. The tool calculates the degradation and mass balance, checks the 5–20% target, and checks that the required stresses are covered.

For photostability you enter the exposure achieved and the initial, exposed and dark control results for each presentation. The tool checks the ICH Q1B minimum exposure and finds the presentations that protect the product.

What you get

- Forced degradation report (3.2.S.3.2 or 3.2.P.5.5) with a degradation chart.
- Photostability report (3.2.S.7.3 or 3.2.P.8.3) with the labelling conclusion.

2. Before you start

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

- Stress conditions and results for one representative batch.
- Peak purity and resolution from the stability-indicating procedure.
- Degradation pathways and structures.
- Photostability exposure and results for each presentation.

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/forced-degradation.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

Describe the study

Choose the product type (small molecule or biological), the material, and name the procedure being shown to be stability-indicating.

CMCfy Forced Degradation & Photostability 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.3.2 3.2.S.7 3.2.P.5.5 3.2.P.8 Save project Open project Start blank Load example

Write the forced degradation (stress testing) report and the ICH Q1B confirmatory photostability report. For each stress the tool calculates the degradation and mass balance, checks the target range, peak purity and resolution, and checks the required stresses are covered. For photostability it checks the exposure and compares exposed samples with the dark control in each presentation.

Guidance: ICH Q1A(R2) 2.1.2 Stress testing; ICH Q1B Photostability Testing (1996); ICH Q2(R2) specificity; ICH Q14; ICH Q5C (biologics); ICH Q3A(R2), Q3B(R2); FDA Analytical Procedures and Methods Validation (2015); EMA Guideline on stability testing (CPMP/QWP/122/02 Rev 1); CPMP/QWP/609/96 Rev 2 (storage statements)

1 • STUDY

Product
CMX-101 drug substance

Regulations Both US and EU Product type Small molecule

Material Drug substance Report number FD-R-007

Batch used
API lot DS-2310

RESULT

6 stress conditions · stability-indicating · light protection needed

3 of 6 conditions reached the 5–20% target. Light causes unacceptable change when directly exposed; amber glass vial protects the product.

CONDITIONS	MASS BALANCE	LOWEST RESOLUTION
6	98.9–99.9%	1.7

LIGHT EXPOSURE
1.25 M lux h · 215 W h/m²

2 Enter stress and photostability results

One row per stress testing condition. For photostability, one row per presentation and test, with the maximum change allowed.

3 Read the result

The headline sums it up: "6 stress conditions · stability-indicating · light protection needed". The chart shows the degradation of each condition against the 5–20% band.



Degradation by condition.

4 Resolve alerts and download

A peak purity failure is critical. Missing stresses, low resolution, mass balance outside 95–105%, over-stressing, too little light exposure, no dark control and labelling are flagged. Then preview and download both reports.

balance of 99.9%, Base hydrolysis (0.1 M NaOH 60 °C, 24 h) gave 16.9% degradation, mainly

Preview and review before download

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

1 recommended

DATA AND INPUTS (1)

Light changes the product when directly exposed.
Use the protective pack and propose a storage statement such as "Protect from light" or "Store in the original package".
recommended · Labelling · CPMP/QWP/609/96 Rev 2; ICH Q1B

Ignore

Compare with the protocol
Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in 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

3.2.5.3.2 Forced degradation (stress testing) report
CMX-101 drug substance · FD-R-007 · US (FDA) and EU (EMA)

Product	CMX-101 drug substance
Batch	API lot D5-2310
Procedure	AM-0143 Related substances by HPLC (UV 254 nm, PDA)
Report number	FD-R-007
Regulations	US (FDA) and EU (EMA)

1. Objective
To identify the degradation products and pathways of CMX-101 drug substance and to show that AM-0143 Related substances by HPLC (UV 254 nm, PDA) is stability-indicating.

2. Results

Figure 1. Degradation by stress condition.

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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 · Study

FIELD	WHAT TO ENTER
Product	Type it in.
Regulations	Choose one: US: FDA guidance; EU: EMA stability guideline; Both US and EU.
Product type	Choose one: Small molecule; Biological product.
Material	Choose one: Drug substance; Drug product.

FIELD	WHAT TO ENTER
Report number	Type it in.
Batch used	Type it in.
Procedure shown to be stability-indicating	Type it in.
Peak purity and identification technique	Type it in.

2 · Stress results

One row per condition. Assay as % of the unstressed control; total degradation products in % area. Peak purity: pass or fail. Resolution: lowest between the main peak and any degradant.

FIELD	WHAT TO ENTER
Conditions	Peak purity: pass or fail. Leave resolution empty when no degradant forms. A table. Columns: Stress Condition Duration Assay (% of control) Total degradants (%) Main degradant Peak purity Lowest resolution. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Target degradation from (%)	Type a number.
Target degradation to (%)	Type a number.
Mass balance from (%)	Type a number.
Mass balance to (%)	Type a number.
Degradation pathways and structures	Type or paste text.

3 · Photostability (ICH Q1B)

FIELD	WHAT TO ENTER
Confirmatory photostability study done	Tick the box if it applies.

FIELD	WHAT TO ENTER
Light source	Choose one: Option 2: cool white fluorescent and near-UV lamps; Option 1: D65/ID65 daylight source.
Overall illumination achieved (million lux h)	Type a number.
Near-UV energy achieved (W h/m ²)	Type a number.
Dark control included	Tick the box if it applies.
Photostability results	Maximum change allowed is in the unit of the test. A table. Columns: Presentation Test Initial Exposed Dark control Maximum change allowed. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

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

- Small molecules: acid, base, oxidation, heat and light. Biologics: high temperature, oxidation, light, agitation, freeze–thaw and pH.
- Peak purity (critical) and resolution of at least 1.5.
- Mass balance and degradation targets.
- ICH Q1B: 1.2 million lux h, 200 W h/m², dark control, presentations.

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: Stress testing discussion; Photostability conclusion. 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

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.
2. 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).
3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. 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.
5. 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
Forced degradation report	Results, chart, pathways, stability-indicating conclusion
Photostability report	Exposure, results by presentation, labelling conclusion

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

Both regions follow ICH Q1A(R2), Q1B and Q2(R2) (Q5C for biologics). EU storage statements follow CPMP/QWP/609/96 Rev 2.

8. Working with other modules

- Degradants feed the impurity assessment in the Impurity & Risk Studio.
- The specificity result supports the Method Validation Studio.
- Long-term data go in the Stability Studio.

9. Common pitfalls

- Over-stressing until secondary degradants appear.
- Concluding stability-indicating without peak purity.

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. **Fail peak purity under oxidation**

Change the peak purity of the oxidation condition to fail.

EXPECTED RESULT

The headline says specificity is not shown.

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.