

Dissolution Profile Comparison

Compare the dissolution profiles of a test and a reference batch with the f2 similarity factor, for a change, an additional strength or a BCS-based biowaiver.

WRITES

3.2.P.2.2

Report

PRODUCT TYPE

Small molecule

GUIDANCE IT FOLLOWS

FDA SUPAC-IR (1995) Appendix B; FDA Dissolution Testing of Immediate Release Solid Oral Dosage Forms (1997); FDA Bioavailability Studies Submitted in NDAs or INDs (2022); EMA Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401, Rev. 1) Appendix I and Q&A on f2; ICH M9 Biopharmaceutics Classification System-based biowaivers (2019); USP <711>, <1092>

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

You enter the 12 individual results of each batch at each time point in each medium. The tool calculates the means and CVs, applies the rule that both batches at 85% or more in 15 minutes are similar, checks whether f2 can be used and calculates it over the right time points.

For a BCS biowaiver it checks the ICH M9 conditions for class I and class III substances.

What you get

- A Word or PDF report: Dissolution profile comparison, with a profile chart for each medium.

2. Before you start

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

- Test and reference batches and the test conditions.
- Individual results (12 units) at each time point in each medium.
- For a biowaiver: the BCS class and the excipient comparison.

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/dissolution-comparison.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 comparison

Choose the purpose, enter the batches and the test conditions. For a BCS biowaiver, choose the class.

CMCfy Dissolution Profile Comparison 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.P.2.2 Report Save project Open project Start blank Load example

Compare the dissolution profiles of a test and a reference batch in each medium. The tool checks whether f2 can be used (12 units, at least three points, CV limits, one point after 85%), calculates f2, applies the 15-minute rapid-dissolution rule, and for a BCS biowaiver checks the ICH M9 conditions.

Guidance: FDA SUPAC-IR (1995) Appendix B; FDA Dissolution Testing of Immediate Release Solid Oral Dosage Forms (1997); FDA Bioavailability Studies Submitted in NDAs or INDs (2022); EMA Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1) Appendix I and Q&A on f2; ICH M9 Biopharmaceutics Classification System-based biowaivers (2019); USP <711> / Ph. Eur. 2.9.3, <1092>

1 - COMPARISON

Product
CMX-101 tablets 50 mg

Regulations Purpose
Both US and EU Support a post-approval change

Report number Test batch
DC-R-012 B2510 (post-change, new g)

Reference batch
B2401 (pre-change, biobatch)

RESULT

Similar in all 3 media

pH 1.2: f2 61.7; pH 4.5: ≥85% in 15 min for both; pH 6.8: ≥85% in 15 min for both.

PURPOSE	MEDIA	LOWEST F2
Support a post-approval change	3	61.7

UNITS PER BATCH
12

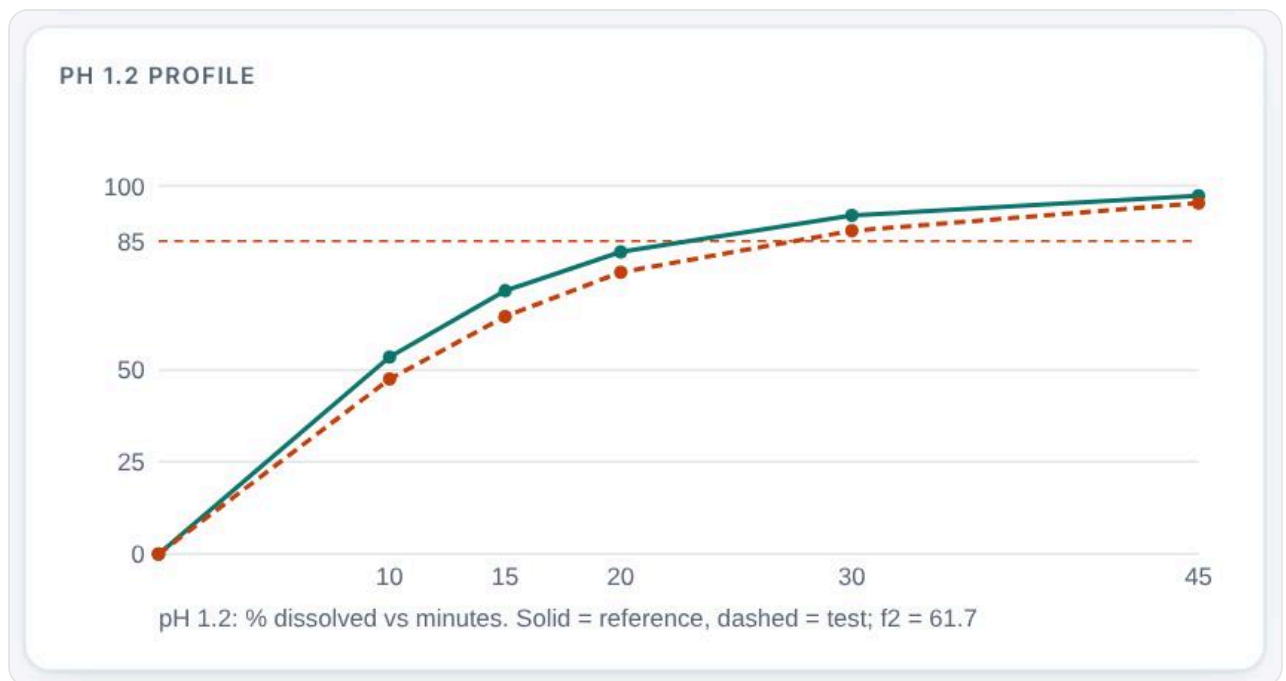
PH 1.2 PROFILE

2 Enter the profiles

One row per medium and time point, with the 12 results of each batch separated by ";".

3 Read the result

The headline gives the conclusion: "Similar in all 3 media". The note gives f2 or the rapid-dissolution rule for each medium.



Profiles and f2.

4

Resolve alerts and download

f2 below 50 is critical. Fewer than 12 units, fewer than three points, CVs above the limits and missing biowaiver conditions are flagged. Then preview 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.

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 preview before you sign.

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 changed.

Run AI review

3.2.P.2.2 Dissolution profile comparison report
CMX-101 tablets 50 mg · DC-R-012 · US (FDA) and EU (EMA)

Product	CMX-101 tablets 50 mg
Purpose	Support a post-approval change
Test batch	B2510 (post-change, new granulation equipment)
Reference batch	B2401 (pre-change, biobatch)
Conditions	USP apparatus 2 (paddle), 50 rpm, 900 mL, 37 ± 0.5 °C
QC specification	Q = 80% at 30 min
Regulations	US (FDA) and EU (EMA)

1. Objective
To compare the dissolution profiles of B2510 (post-change, new granulation equipment) and B2401 (pre-change, biobatch) and decide whether they are similar.

2. Profiles

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 • Comparison

FIELD	WHAT TO ENTER
Product	Type it in.
Regulations	Choose one: US: FDA guidance; EU: EMA bioequivalence guideline; Both US and EU.
Purpose	Choose one: Support a post-approval change; Biowaiver for an additional strength; BCS-based biowaiver (ICH M9); Development comparison.
Report number	Type it in.
Test batch	Type it in.
Reference batch	Type it in.
Apparatus, speed, volume and temperature	Type it in.
BCS class of the drug substance when it applies	Choose one: Class I (high solubility, high permeability); Class III (high solubility, low permeability); Class II or IV (not eligible).
Excipient differences between test and reference when it applies	Type or paste text.

2 • Profiles

One row per medium and time point, with the 12 individual results (% dissolved) of each batch separated by “,”.

FIELD	WHAT TO ENTER
Dissolution results	Use the same time points for both batches. Zero is not entered. A table. Columns: Medium Time (min) Reference units (%) Test units (%). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
QC dissolution specification	Type it in.

5. Checks and alerts

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

- f2 over the points up to the first at which either batch reaches 85%.
- $CV \leq 20\%$ at points up to 10 minutes and $\leq 10\%$ after; 12 units; at least three points.
- ICH M9: class I $\geq 85\%$ in 30 min, class III $\geq 85\%$ in 15 min, pH 1.2, 4.5 and 6.8, excipients assessed.

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: Discussion and 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
3.2.P.2.2	Dissolution profile comparison report

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

US follows SUPAC-IR Appendix B and the FDA dissolution guidance. EU follows Appendix I of the EMA bioequivalence guideline and its Q&A on f2. Both follow ICH M9 for BCS biowaivers.

8. Working with other modules

- Development data go in the Development Studio.
- For the change itself, see the Post-approval Change Classifier module.

9. Common pitfalls

- Including several points after 85% dissolution, which inflates f2.
- Using f2 when the CV is too high.

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. **Ask for a biowaiver for a class II substance**

Set the purpose to BCS-based biowaiver and the class to Class II or IV.

EXPECTED RESULT

A critical alert says class II or IV substances are not eligible.

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.