

Batch Analysis & CoA

Check every batch result against the specification, write the batch analysis and reference standard sections, and produce a certificate of analysis for any batch.

WRITES

3.2.S.4.4

3.2.P.5.4

3.2.S.5

3.2.P.6

PRODUCT TYPE

Small molecule

GUIDANCE IT FOLLOWS

ICH M4Q(R1), ICH
Q6A, USP General
Notices 7.20
(rounding), ICH Q7
11.1 (reference
standards)

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

Enter the specification, the batches and their results; the tool checks every result against its criterion, finds missing results, checks reference standard retest dates, and writes 3.2.P.5.4 or 3.2.S.4.4 with the results tables, plus 3.2.P.6 or 3.2.S.5 for reference standards.

It can also produce a certificate of analysis for any batch in the table.

What you get

- Word or PDF files for batch analyses, reference standards and the certificate of analysis.
- A summary file for the QOS Composer & Dossier Assembler, which compares the batches here with the specification and stability sections.

2. Before you start

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

- The specification (test and acceptance criterion), or the summary file from the Specification Builder.
- The batches: number, size, site, date of manufacture, use (clinical, stability, registration) and drug substance lot.
- Results for each test and batch, as reported on the certificates.

- Reference standards: type, lot, source, purity or potency and retest date.

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/batch-analysis.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 specification

Choose drug product or drug substance and the region. Paste the specification, or add the Specification Builder summary (its tests replace the table).

1 - PRODUCT

Batch analysis for: **Drug product (3.2.P.5.4)** Submission region: **US: FDA (NDA, ANDA, BL)**

Product or substance name: **CMX-101 Tablets, 50 mg**

Specification from Specification Builder (optional) Its tests replace the table below.

No files added.

Add files **Remove all**

Specification

Columns: Test, Acceptance criterion

Test	Acceptance criterion
Description, "White, round, biconvex film-coated tablet"	
Identification (HPLC), Retention time matches the reference standard	
Assay (HPLC), 95.0–105.0% of label claim	
CMX-101 N-oxide, NMT 0.5%	
Any unspecified degradation product, NMT 0.20%	

RESULT

All 26 results meet the specification

3 batches against 9 tests.

SECTIONS	BATCHES	REFERENCE STANDARDS
3.2.P.5.4, 3.2.P.6	3	3

COA: **CMX-26-0102**

RESULTS AGAINST SPECIFICATION

TEST	ACCEPTANCE CRITERION	CMX-26-0101	CMX-26-0102	CMX-26-0103
Description	White, round, biconvex film-coated tablet	Conforms	Conforms	Conforms
Identification (HPLC)	Retention time matches the reference standard	Conforms	Conforms	Conforms

2 Enter batches and results

The results table has the test in the first column, then one column per batch in the same order as the batches table. Test names must match the specification exactly. Write "< 0.05" for results below the reporting limit.

3 Read the result

The example headline reads "All 26 results meet the specification: 3 batches against 9 tests".
The results table shows each value against its criterion.

RESULTS AGAINST SPECIFICATION				
TEST	ACCEPTANCE CRITERION	CMX-26-0101	CMX-26-0102	CMX-26-0103
Description	White, round, biconvex film-coated tablet	Conforms	Conforms	Conforms
Identification (HPLC)	Retention time matches the reference standard	Conforms	Conforms	Conforms
Assay (HPLC)	95.0–105.0% of label claim	99.6	101.2	98.1
CMX-101 N-oxide	NMT 0.5%	0.18	0.21	0.15
Any unspecified degradation product	NMT 0.20%	0.07	0.06	< 0.05
Total degradation products	NMT 1.5%	0.42	0.38	0.31
Dissolution	Q = 80% in 30 minutes	94 (91–97)	96 (93–98)	95 (92–98)
Uniformity of dosage units (AV)	NMT 15.0	3.1	4.8	2.1
Water (KF)	NMT 3.0%	1.8	2.1	missing

Each result checked against the criterion.

4 Resolve alerts

Two major alerts: water (KF) has no result for CMX-26-0103, and the working standard passed its retest date (2026-09-30). Enter the missing result or state "not tested" with the reason; requalify the standard or say which lot was used.

ALERTS TO RESOLVE

2 alerts to fix, justify, or proceed without before export. It is your call: "Proceed without it" lets you continue when the information is not available.

MAJOR Water (KF): no result for CMX-26-0103.

Results · ICH M4Q

Enter the result, or state "not tested" with the reason.

MAJOR CMX-101 working standard (WS-CMX-004) passed its retest date (2026-09-30).

Reference standards · ICH Q7 11.1

Requalify the standard or use a current lot, and say which lot was used for the batch tests.

5 Write the certificate of analysis

In panel 4, enter a batch number (the example uses CMX-26-0102) and the QA releaser. A CoA for that batch is added to the documents list.

6 Preview and download

Preview 3.2.P.5.4, 3.2.P.6 and the CoA, read the review and download.

2026-01-14 and 2026-02-03, and were used for clinical, stability, registration purposes.

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.

3 to fix 1 recommended

MISSING INFORMATION (1)

"Released by (QA)" is empty.
Enter it in the tool, or confirm it does not apply. Empty inputs show as placeholders or gaps in the report.

recommended · Certificate of analysis Ignore

DATA AND INPUTS (2)

Water (KF): no result for CMX-26-0103.
Enter the result, or state "not tested" with the reason.

major · Results · ICH M4Q Ignore

CMX-101 working standard (WS-CMX-004) passed its retest date (2026-09-30).
Requalify the standard or use a current lot, and say which lot was used for the batch tests.

major · Reference standards · ICH Q7 11.1 Ignore

REPORT CONTENT (1)

Placeholder left in the report: [Explain the tests not performed.]
Replace the placeholder with the real information, or delete the sentence if it does not apply.

3.2.P.5.4 Batch analyses
CMX-101 Tablets, 50 mg · US (FDA)

Table 1. Batch information

Batch	Batch size	Site	Date of manufacture	Use	Drug substance lot
CMX-26-0101	150,000 tablets	Raleigh NC	2026-01-14	clinical; stability	DS-25-011
CMX-26-0102	150,000 tablets	Raleigh NC	2026-01-20	stability; registration	DS-25-012
CMX-26-0103	150,000 tablets	Raleigh NC	2026-02-03	registration	DS-25-012

Table 2. Batch results

Test	Acceptance criterion	CMX-26-0101	CMX-26-0102	CMX-26-0103
Description	White, round, biconvex film-coated tablet	Conforms	Conforms	Conforms
Identification (HPLC)	Retention time matches the reference standard	Conforms	Conforms	Conforms
Assay (HPLC)	95.0–105.0% of label claim	99.6	101.2	98.1
CMX-101 N-oxide	NMT 0.5%	0.18	0.21	0.15
Any unspecified degradation product	NMT 0.20%	0.07	0.06	< 0.05
Total degradation products	NMT 1.5%	0.42	0.38	0.31
Dissolution	Q = 80% in 30 minutes	94 (91–97)	96 (93–98)	95 (92–98)
Uniformity of dosage units (AV)	NMT 15.0	3.1	4.8	2.1
Water (KF)	NMT 3.0%	1.8	2.1	not tested

Fix or justify the 2 blocking alerts before downloading. Or choose "Download anyway".

Download anyway Download Word (.docx) Download PDF

3.2.P.5.4 Batch analyses US: FDA (NDA, ANDA, BLA, IND)

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

FIELD	WHAT TO ENTER
Batch analysis for	Choose one: Drug product (3.2.P.5.4); Drug substance (3.2.S.4.4).
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Product or substance name	Type it in.
Specification from Specification Builder (optional)	Press Add files and pick summary files (.cmcfy.json) saved by other modules.
Specification	A table. Columns: Test Acceptance criterion. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

2 · Batches

FIELD	WHAT TO ENTER
Batches	A table. Columns: Batch Batch size Site Date of manufacture Use Drug substance lot. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Results	First column is the test name exactly as in the specification, then one column per batch in the order of the batches table. A table. Columns: Test Batch 1 Batch 2 Batch 3. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Reference standards

FIELD	WHAT TO ENTER
Reference standards	A table. Columns: Standard Type (primary / working) Lot Source Purity or potency Retest date. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

4 · Certificate of analysis

FIELD	WHAT TO ENTER
Write a certificate of analysis for batch	Leave blank if you do not need a CoA. Type it in.
Released by (QA)	Type it in.

5. Checks and alerts

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

- Every numeric result against its criterion (NMT, NLT, ranges, Q values). A failing result is critical: link it to the investigation with its reference and outcome.
- Every test in the specification has results, and every batch has a value; results rows that match no test are flagged.
- Results reported to the same number of decimals as the criterion.

- At least three batches; batch size, site, date and use given; drug substance lot for each drug product batch; at least one stability batch.
- Assay spread over more than half the specification range is flagged for discussion.
- Reference standards in date, with purity or potency, and a primary standard listed.

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 of batch results; Reference standards. 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.5.4 / 3.2.S.4.4	Batch analyses
3.2.P.6 / 3.2.S.5	Reference standards or materials
CoA	Certificate of analysis for the chosen batch

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

The sections are the same in both regions. In EU mode, results for batches tested outside the EU are noted for EU retesting on import, and USP-only method references are flagged. A failing result refers to the FDA OOS guidance in US mode and EU GMP Chapter 6 in EU mode.

8. Working with other modules

- Add the Specification Builder summary to keep tests identical.
- Record a failing result as an investigation in the Investigation Studio (OOS, deviation, CAPA), then enter its reference here.
- The QOS Composer & Dossier Assembler checks that stability batches named here have stability data and that the criteria match the specification.

9. Common pitfalls

- Test names that differ slightly ("Assay" against "Assay (HPLC)"): the row is not matched and both a missing-results and an extra-row alert appear.
- Putting batches in a different column order from the batches table.
- Leaving a blank where a test was not done; write "not tested" and why.
- Forgetting that reference standards have retest dates too.

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. Enter a failing result

In the results table, change the assay of the first batch from 99.6 to 94.6.

EXPECTED RESULT

A critical alert says the assay result for CMX-26-0101 does not meet the criterion, with a box to record the investigation.

2. Ask for a CoA of a batch that is not in the table

Change [Write a certificate of analysis for batch](#) to CMX-99.

EXPECTED RESULT

A minor alert says batch CMX-99 is not in the batch table.

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.