

Analytical Study Report

Write the report of any analytical study run under a protocol (characterisation, in-use, compatibility, comparative or investigational testing), with every result checked against its criterion and the run validity, methods, standards and OOS results checked.

WRITES

Report

PRODUCT TYPE

Small molecule and biologics

**GUIDANCE IT
FOLLOWS**

ICH Q2(R2); ICH Q14; 21 CFR 211.194 (laboratory records); EU GMP Part I Chapter 6; FDA Investigating OOS Test Results (2022); FDA Data Integrity and Compliance with CGMP (2018); USP <1058>; MHRA GxP Data Integrity Guidance (2018)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You give the study, the samples, the methods with their status, the reference standards, the results with their acceptance criteria, the system suitability results and any OOS results or deviations.

The tool compares each result with its criterion (a range, a limit or a statement), sets aside the results of a run whose system suitability failed, checks the methods are fit for the purpose of the study, checks the reference standards were in date and needs an investigation reference for each result outside its criterion.

What you get

- A Word or PDF report: analytical study report.

2. Before you start

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

- The approved protocol number and objective.
- The results with their acceptance criteria.
- System suitability results and the raw data location.

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/analytical-study-report.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

Enter the report and protocol numbers, the title, the objective and whether the study supports a GMP or regulatory decision.

CMCfy Analytical Study Report Projects All modules Training Security Runs entirely on this device [Training guide](#)

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.

Report [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the report of an analytical study (characterisation, in-use, compatibility, comparative or investigational testing) from the protocol, samples, methods and results. Every result is checked against its criterion, system suitability failures invalidate the results of that method, methods are checked as fit for the purpose of the study, reference standards are checked as in date on the day of analysis, and each out-of-specification result needs an investigation.

Guidance: ICH Q2(R2); ICH Q14; 21 CFR 211.194 (laboratory records); EU GMP Part I Chapter 6; FDA Investigating OOS Test Results (2022); FDA Data Integrity and Compliance with CGMP (2018); USP <1058>; MHRA GxP Data Integrity Guidance (2018)

1 · STUDY

Product or material

CMX-101 tablets 50 mg

Regulations

Both US and EU

Report number

ASR-2026-014

Protocol number

ASP-2026-014

Study title

In-use stability of CMX-101 tablets after first opening of the l

RESULT

All 13 results meet their criteria

3 samples, 4 methods, 13 results; 3 system suitability checks; 0 OOS or deviation records.

RESULTS	MEET CRITERIA	OUT OF CRITERIA
13	13/13	0
SST FAILURES		
0		

RESULTS AGAINST CRITERIA

SAMPLE	TEST	METHOD	RESULT	CRITERION	OUTCOME
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2 Enter samples, methods and results

One row per sample, method and result. Use the same sample and method IDs in each table so the tool can link them.

3 Read the result

The headline gives the outcome: "All 13 results meet their criteria".

RESULTS AGAINST CRITERIA

SAMPLE	TEST	METHOD	RESULT	CRITERION	OUTCOME
S-01	Assay (%)	AM-0143	99.6	95.0-105.0	meets
S-01	Total impurities (%)	AM-0143	0.21	NMT 1.0	meets
S-01	Dissolution at 30 min (% Q)	AM-0150	94	NLT 80	meets
S-01	Water (%)	USP <921>	2.1	NMT 4.0	meets
S-02	Assay (%)	AM-0143	99.1	95.0-105.0	meets
S-02	Total impurities (%)	AM-0143	0.26	NMT 1.0	meets
S-02	Dissolution at 30 min (% Q)	AM-0150	92	NLT 80	meets
S-02	Water (%)	USP <921>	2.9	NMT 4.0	meets
S-03	Assay (%)	AM-0143	98.7	95.0-105.0	meets
S-03	Total impurities (%)	AM-0143	0.31	NMT 1.0	meets
S-03	Dissolution at 30 min (% Q)	AM-0150	91	NLT 80	meets
S-03	Water (%)	USP <921>	3.6	NMT 4.0	meets
S-03	TAMC (cfu/g)	AM-0160	<10	NMT 1000	meets

Results against criteria and system suitability.

4

Resolve alerts and download

A result outside its criterion with no investigation and a failed system suitability are critical. Methods that are not validated for a GMP decision, expired standards and a missing raw data location 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.

1 recommended

MISSING INFORMATION (1)

"OOS, OOT and deviations" is empty.

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

recommended · Results 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 changed.

Analytical study report

CMX-101 tablets 50 mg · ASR-2026-014 · In-use stability of CMX-101 tablets after first opening of the HDPE bottle · US (FDA) and EU (EMA)

Report	ASR-2026-014
Protocol	ASP-2026-014
Product	CMX-101 tablets 50 mg
Laboratory	CMX Analytical Laboratories, Raleigh NC
Testing period	2026-07-06 to 2026-09-07
Raw data	Empower 3 project CMX101_INUSE; LIMS study ASR-2026-014; notebooks NB-0412, NB-0417

Objective

Show that the tablets remain within the shelf-life specification for 60 days after the bottle is first opened and stored at 25 °C/60% RH with daily opening, to support the in-use period in the labelling.

Samples

Sample ID	Batch	Description	Condition or time point
S-01	CL-2601	Bottle opened day 0	Initial
S-02	CL-2601	Bottle opened daily	Day 30
S-03	CL-2601	Bottle opened daily	Day 60

Methods

Method ID	Method	Status
AM-0143	Assay and related substances (HPLC)	Validated

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 · Study

FIELD	WHAT TO ENTER
Product or material	Type it in.
Regulations	Choose one: US: 21 CFR 211 and FDA guidance; EU: EU GMP Part I Chapter 6; Both US and EU.
Report number	Type it in.
Protocol number	Type it in.
Study title	Type it in.
Purpose of the study	Choose one: Supports a GMP or regulatory decision; Development or information only.

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FIELD	WHAT TO ENTER
Objective	Type or paste text.
Laboratory	Type it in.
Testing started	Type it in.
Testing completed	Type it in.

2 · Samples, methods and standards

Method status: validated, compendial (verified), transferred, qualified or not validated.

FIELD	WHAT TO ENTER
Samples	A table. Columns: Sample ID Batch Description Condition or time point. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Methods	A table. Columns: Method ID Method Status. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Reference standards	A table. Columns: Standard Lot Valid until. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Instruments qualified and in calibration on the days of analysis (USP <1058>)	Tick the box if it applies.
Raw data location (audit-trailed system and notebook references)	Type it in.

3 · Results

One row per sample and test. Write the criterion as a range, a limit or a statement; leave it empty for report-only tests.

FIELD	WHAT TO ENTER
Results	Write the criterion as 95.0–105.0, NMT 1.0, NLT 80 or a statement such as "conforms". A table. Columns: Sample ID Test Method ID Result Acceptance criterion. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
System suitability	A table. Columns: Method ID Run date Parameter Result Criterion. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
OOS, OOT and deviations	A table. Columns: Reference Sample ID Description Investigation closed (yes/no). 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:

- Each result against its criterion.
- System suitability, method status and reference standard dates.
- OOS investigations, instruments and raw data.

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: 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
Report	Analytical study 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: 21 CFR 211.194 and the FDA OOS guidance. EU: EU GMP Part I Chapter 6. ICH Q2(R2) applies to both.

8. Working with other modules

- Validate a method first in Method Validation Studio; investigate an OOS result in Investigation Studio (OOS, deviation, CAPA).

9. Common pitfalls

- Reporting the results of a run whose system suitability failed.
 - Using a development method for a GMP decision without saying why it is fit for purpose.
-

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. Report an out-of-specification result

Change the day-60 water result from 3.6 to 4.4.

EXPECTED RESULT

The headline shows a critical issue: the result has no investigation.

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.