

Hold Time Study Report

Establish the maximum hold times for intermediates, bulk product and process pools from your time-point data, and compare them with the hold times you propose for the batch record.

WRITES

3.2.S.2.5

3.2.P.3.5

Report

PRODUCT TYPE

Small molecule and
biologics

GUIDANCE IT FOLLOWS

WHO TRS 992
Annex 4: General
guidance on hold-
time studies (2015);
EU GMP Annex 15
(hold times, 5.31
and 10.10); 21 CFR
211.111 (time
limitations on
production); ICH Q7
8.2; FDA Process
Validation guidance
(2011); EMA
Guideline on
process validation
for finished
products (2016) and
for biotechnology-
derived active
substances (2016)

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

You list each material held, its container, condition and proposed maximum hold, and enter the results at each time point with their criteria.

The tool finds the longest time at which every result passed (with every earlier time point also passing), compares it with the proposed hold time, shows the change from the initial value and checks

microbiological testing.

What you get

- A Word or PDF report: Hold time study report.

2. Before you start

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

- The materials held, containers, conditions and proposed hold times.
- Results at time 0 and each time point, with criteria.

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/hold-time-study.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 product, the report and protocol numbers and the batches.

Keep in this browser

Save a single file that opens from your own computer with all network access blocked.

[Load example](#)

1 • STUDY

CMX-101 tablets 50 mg

Report number

Both US and EU

HT-R-004

Protocol number

HT-P-004

Batches

PPQ-01 (worst case: longest processing time) and PPQ-02

RESULT

MATERIALS

RESULTS

FAILURES

BATCHES

2

4 Resolve alerts and download

A failing result is critical. Proposed hold times beyond the data, missing time-0 results and missing microbiological tests are flagged. Then preview and download.

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.

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 fileCompare

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

Hold time study report

CMX-101 tablets 50 mg · HT-R-004 · US (FDA) and EU (EMA)

Product	CMX-101 tablets 50 mg
Report number	HT-R-004
Protocol	HT-P-004
Batches	PPQ-01 (worst case: longest processing time) and PPQ-02
Regulations	US (FDA) and EU (EMA)

1. Objective

To establish the maximum hold times for the intermediates and bulk product of CMX-101 tablets 50 mg in their production containers and storage conditions.

2. Materials and hold times

Material and stage	Container	Condition	Proposed	Supported
Wet granules (before drying)	Closed stainless-steel bowl	15–25 °C	24 h	24 h
Final lubricated blend	Double PE bags in closed IBC	15–25 °C ≤ 60% RH	30 days	37 days
Film-coated cores (bulk tablets)	Double PE bags in HDPE drum with desiccant	15–25 °C	90 days	90 days

3. Results

Material	Test	Time	Result	Criterion	Outcome
Wet granules (before drying)	Microbial enumeration TAMC (cfu/g)	0 h	10	≤ 1000	Pass
Wet granules (before drying)	Microbial enumeration TAMC (cfu/g)	12 h	20	≤ 1000	Pass

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	Type it in.
Regulations	Choose one: US: 21 CFR 211.111; EU: EU GMP Annex 15; Both US and EU.
Report number	Type it in.
Protocol number	Type it in.

FIELD	WHAT TO ENTER
Batches	Type it in.

2 · Materials held

One row per material and stage. Unit: h or days.

FIELD	WHAT TO ENTER
Materials	Use exactly the same material name in the results table. A table. Columns: Material and stage Container Storage condition Proposed maximum hold Unit. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Results

One row per material, test and time point (in the unit of that material). Time 0 is the initial result.

FIELD	WHAT TO ENTER
Results	A table. Columns: Material and stage Test Time Result Acceptance criterion. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Deviations and their impact	Type or paste text.

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.
- Proposed hold time not longer than the supported hold time.
- Initial (time 0) results; microbiological testing.

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
Report	Hold time 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 follows 21 CFR 211.111 (time limits on production). EU follows EU GMP Annex 15. WHO TRS 992 Annex 4 gives the general approach.

8. Working with other modules

- The hold times are summarised in the Process & Controls Writer (3.2.P.3.5) and the Process Validation Report.

9. Common pitfalls

- Testing in a container that is not the production container.
- Proposing a hold longer than the last passing time point.

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 blend hold**

Change the proposed hold for the final lubricated blend from 30 to 45 days.

EXPECTED RESULT

The headline shows one proposed hold time not supported.

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.