

Preservative Efficacy Test Report

Write the antimicrobial effectiveness test report: log reductions for each organism checked against USP <51> for the product category and Ph. Eur. 5.1.3 criterion A or B.

WRITES

3.2.P.2.5

Report

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

USP <51>
Antimicrobial Effectiveness Testing; Ph. Eur. 5.1.3 Efficacy of antimicrobial preservation; ICH Q8(R2) 3.2.P.2.5; EMA Guideline on excipients in the dossier (EMA/CHMP/QWP/396 CPMP/QWP/159/96 (in-use stability)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You enter the inoculum and the counts at each time point for each organism. The tool calculates the log reductions and checks them against the criteria for the product category in each region you choose.

It also checks the organisms tested, the inoculum level, that the test was done at the lowest preservative level in the specification, and method suitability.

What you get

- A Word or PDF report: Preservative efficacy test report (3.2.P.2.5).

2. Before you start

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

- The product category, preservative system and level tested.
- Inoculum and counts for each organism at each time point.
- Method suitability and in-use or end-of-shelf-life results.

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/preservative-efficacy.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 test

Choose the regions and product category, and enter the preservative level tested and the specification lower limit.

CMCfy Preservative Efficacy Test Report [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.2.5 [Report](#) [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the antimicrobial effectiveness (preservative efficacy) test report. Enter the inoculum and counts for each organism; the tool calculates the log reductions and checks them against USP <51> for the product category and against Ph. Eur. 5.1.3 criteria A and B, at the lowest preservative level in the specification.

Guidance: USP <51> Antimicrobial Effectiveness Testing; Ph. Eur. 5.1.3 Efficacy of antimicrobial preservation; ICH Q8(R2) 3.2.P.2.5; EMA Guideline on excipients in the dossier (EMA/CHMP/QWP/396951/2006); CPMP/QWP/159/96 (in-use stability)

1 · STUDY

Product

CMX-101 oral solution 10 mg/mL

Regulations

Both USP and Ph. Eur. ▼

Product category

Oral ▼

Report number

PET-R-003

Batch and time point

B2401 at release (preservative at 80% of label claim, made f

RESULT

Meets USP <51> and Ph. Eur. criterion A

USP <51> category 3 (oral): met. Ph. Eur. 5.1.3 oral criterion A: met.

CATEGORY	ORGANISMS	LEVEL TESTED
Oral	5	80% of label

SPEC LOWER LIMIT

80%

LOG REDUCTIONS

≥ means the count was below the detection limit.

2 Enter the counts

One row per organism with the inoculum and the counts at 6 h, 24 h, 2, 7, 14 and 28 days. Write counts below the detection limit as "<10".

3 Read the result

The headline gives the outcome: "Meets USP <51> and Ph. Eur. criterion A".

LOG REDUCTIONS

≥ means the count was below the detection limit.

ORGANISM	INOCULUM (CFU/ML)	6 H	24 H	2 D	7 D	14 D	28 D
S. aureus ATCC 6538	5.2e+5	–	–	–	2.1	≥ 4.7	≥ 4.
P. aeruginosa ATCC 9027	6.0e+5	–	–	–	3.7	≥ 4.8	≥ 4.
E. coli ATCC 8739	4.8e+5	–	–	–	2.3	≥ 4.7	≥ 4.
C. albicans ATCC 10231	3.9e+5	–	–	–	0.8	1.3	1.6
A. brasiliensis ATCC 16404	2.7e+5	–	–	–	0.4	1.1	1.3

Log reductions and criteria.

4 Resolve alerts and download

A failed criterion is critical. Missing organisms or time points, inoculum outside 10^5 – 10^6 , testing above the lowest level and missing method suitability 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 review 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.2.5 Preservative efficacy test report
 CMX-101 oral solution 10 mg/mL · PET-R-003 · US (FDA) and EU (EMA)

Product	CMX-101 oral solution 10 mg/mL
Category	Oral
Preservative	Methylparaben 0.15% / propylparaben 0.02% (label claim)
Batch	B2401 at release (preservative at 80% of label claim, made for the test)
Level tested	80% of label claim
Report number	PET-R-003
Regulations	US (FDA) and EU (EMA)

1. Objective
 To show that the antimicrobial preservative system of CMX-101 oral solution 10 mg/mL is effective at the lowest concentration allowed by the specification.

2. Log reductions

Organism	Inoculum	6 h	24 h	2 d	7 d	14 d	28 d
S. aureus ATCC 6538	5.2e+5	-	-	-	2.1	≥ 4.7	≥ 4.7
P. aeruginosa ATCC 9027	6.0e+5	-	-	-	3.7	≥ 4.8	≥ 4.8
E. coli ATCC 8739	4.8e+5	-	-	-	2.3	≥ 4.7	≥ 4.7
C. albicans ATCC 10231	3.9e+5	-	-	-	0.8	1.3	1.6
A. brasiliensis ATCC 16404	2.7e+5	-	-	-	0.4	1.1	1.3

USP <51> category 3 (oral)

Organism	Time	Requirement	Result	Outcome
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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: USP <51>; EU: Ph. Eur. 5.1.3; Both USP and Ph. Eur..
Product category	Choose one: Parenteral, ophthalmic, otic; Topical, nasal, mucosal; Oral; Antacid (USP category 4).
Report number	Type it in.
Batch and time point	Type it in.
Preservative system	Type it in.

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FIELD	WHAT TO ENTER
Preservative level tested (% of label claim)	Type a number.
Lower limit of the preservative specification (% of label claim)	Type a number.
Method suitability (neutralisation and recovery) shown	Tick the box if it applies.
In-use or end-of-shelf-life testing	Type or paste text.

2 - Counts

One row per organism. Inoculum and counts in cfu/mL (or per g). Write a count below the detection limit as "<10". Leave a time point empty if not tested.

FIELD	WHAT TO ENTER
Counts	Counts can be written as 4.1E3 or 4100. A table. Columns: Organism Inoculum 6 h 24 h 2 d 7 d 14 d 28 d. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Ph. Eur. criterion claimed when it applies	Choose one: A (recommended); B (justified where A cannot be met).
Justification for criterion B when it applies	Type or paste text.

5. Checks and alerts

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

- USP <51> category criteria and Ph. Eur. 5.1.3 criterion A or B.
- S. aureus, P. aeruginosa, C. albicans and A. brasiliensis (and E. coli where required).
- Inoculum level, lowest preservative level, method suitability, in-use 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
3.2.P.2.5	Preservative efficacy test 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 USP <51>: "no increase" allows 0.5 log₁₀. EU follows Ph. Eur. 5.1.3: criterion A is expected, B only where justified.

8. Working with other modules

- Preservative content is in the specification (Specification Builder) and its development in the Development Studio.
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9. Common pitfalls

- Testing at the label claim rather than the lowest specified level.
 - Missing the 6 h and 24 h counts needed for Ph. Eur. parenteral products.
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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. **Let *C. albicans* grow back**

Change the 28-day count of *C. albicans* from 9.0E3 to 9.0E4.

EXPECTED RESULT

The headline says Ph. Eur. criterion A is not met.

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.