

Sterilisation Validation Report

Write the validation report for moist heat sterilisation, sterilising filtration or dry-heat depyrogenation, with every run or batch checked against the acceptance criteria.

WRITES

3.2.P.3.5

3.2.P.2.5

Report

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

EU GMP Annex 1 (2022) 8.33–8.100; FDA Sterile Drug Products Produced by Aseptic Processing (2004); FDA Submission Documentation for Sterilization Process Validation (1994); EMA Guideline on the sterilisation of the medicinal product (EMA/CHMP/CVMP/QW USP <1229> series, <1228.1>; Ph. Eur. 5.1.1; ASTM F838; PDA TR 1, 3 and 26; EN 285

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

Moist heat: the tool calculates the spore log reduction from FO and the D121 of the biological indicator, and the SAL for the bioburden approach, and checks the temperature band and the BIs.

Filtration: it checks the bacterial retention challenge and every pre- and post-use integrity test. **Dry heat:** it checks the endotoxin reduction, temperature and time.

What you get

- A Word or PDF report: Sterilisation validation report.

2. Before you start

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

- Run data: FO at the cold spot, temperatures during the hold and BI results (steam).
- Retention test and integrity test results (filters).
- Endotoxin challenge results (dry heat).

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/sterilisation-validation.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 Choose the method

Choose moist heat, filtration or dry heat, and initial validation or requalification.

Sterilisation Validation Report

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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](#)
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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.

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

[3.2.P.3.5](#)
[3.2.P.2.5](#)
[Report](#)

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

Write the sterilisation validation report for moist heat (steam), sterilising filtration or dry-heat depyrogenation. The tool checks each run against the acceptance criteria: lethality and spore log reduction, temperature band and biological indicators for steam; bacterial retention and integrity tests for filters; endotoxin log reduction and temperature for dry heat.

Guidance: EU GMP Annex 1 (2022) 8.33–8.100; FDA Sterile Drug Products Produced by Aseptic Processing (2004); FDA Submission Documentation for Sterilization Process Validation (1994); EMA Guideline on the sterilisation of the medicinal product (EMA/CHMP/CVMP/QWP/850374/2015); USP <1229> series, <1228.1>; Ph. Eur. 5.1.1; ASTM F838; PDA TR 1, 3 and 26; EN 285

1 - PROCESS

Product or item sterilised
CMX-301 injection 10 mg/mL, 10 mL vials (terminal sterilisation)

Regulations
Both US and EU

Method
Moist heat (steam) sterilisation

Equipment
Steam-air mixture autoclave AC-04, room 1.210

Report number
SV-R-033

Study type
Initial validation (three cc)

RESULT

Moist heat validated · 6 runs pass

Lowest F0 15.5 min; SLR 8.6; log SAL -7.6. Band 121–124 °C.

METHOD	RUNS OR BATCHES	FAILURES
Moist heat	6	0

STUDY
Initial

RUNS

log SAL = log10(bioburden) – F0 ÷ D121; must be ≤ –6.

2

Enter the runs

Moist heat: one row per run with the load, minimum F0, temperatures and BIs. Filtration: one row per batch with the bubble points.

3

Read the result

The headline gives the outcome: "Moist heat validated · 6 runs pass".

RUNS							
log SAL = log10(bioburden) - F0 ÷ D121; must be ≤ -6.							
RUN	LOAD	MIN F0	SLR	LOG SAL	TEMP IN HOLD (°C)	BAND	BIS
PQ-1	Maximum load (2400 vials)	15.8	8.8	-7.8	121.2-123.1	within	0/10 positive
PQ-2	Maximum load (2400 vials)	16.4	9.1	-8.1	121.3-123.0	within	0/10 positive
PQ-3	Maximum load (2400 vials)	15.5	8.6	-7.6	121.1-123.4	within	0/10 positive
PQ-4	Minimum load (200 vials)	21.0	11.7	-10.7	121.6-123.2	within	0/10 positive
PQ-5	Minimum load (200 vials)	20.6	11.4	-10.4	121.5-123.0	within	0/10 positive
PQ-6	Minimum load (200 vials)	21.3	11.8	-10.8	121.7-123.3	within	0/10 positive

Runs and lethality.

4

Resolve alerts and download

Insufficient lethality, a temperature outside the band, a positive BI or a failed integrity test is critical. Fewer than three passing runs per load is 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

Sterilisation validation report: moist heat sterilisation
 CMX-301 injection 10 mg/mL, 10 mL vials (terminal sterilisation) · SV-R-033 · US (FDA) and EU (EMA)

Product or item	CMX-301 injection 10 mg/mL, 10 mL vials (terminal sterilisation)
Method	moist heat sterilisation
Equipment	Steam-air mixture autoclave AC-04, room 1.210
Report number	SV-R-033
Regulations	US (FDA) and EU (EMA)

1. Acceptance criteria
 log SAL ≤ -6 at the coldest point (bioburden ≤ 10 cfu/unit, D121 1.8 min); temperature 121–124 °C during the hold; all BIs negative.

2. Results

Run	Load	Min FO	SLR	Temp (°C)	BIs	Outcome
PQ-1	Maximum load (2400 vials)	15.8	8.8	121.2–123.1	0/10	Pass
PQ-2	Maximum load (2400 vials)	16.4	9.1	121.3–123.0	0/10	Pass
PQ-3	Maximum load (2400 vials)	15.5	8.6	121.1–123.4	0/10	Pass
PQ-4	Minimum load (200 vials)	21.0	11.7	121.6–123.2	0/10	Pass
PQ-5	Minimum load (200 vials)	20.6	11.4	121.5–123.0	0/10	Pass
PQ-6	Minimum load (200 vials)	21.3	11.8	121.7–123.3	0/10	Pass

3. Discussion and conclusion
 CMX-301 injection 10 mg/mL, 10 mL vials (terminal sterilisation) was sterilised in Steam-air mixture autoclave AC-04, room 1.210 at 121 °C for 20 min. Empty chamber distribution in three runs: spread 0.9 °C, cold spot at the drain (probe)

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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 • Process

FIELD	WHAT TO ENTER
Product or item sterilised	Type it in.
Regulations	Choose one: US: FDA; EU: EU GMP Annex 1, EMA; Both US and EU.
Method	Choose one: Moist heat (steam) sterilisation; Sterilising filtration; Dry-heat depyrogenation.
Equipment	Type it in.
Report number	Type it in.
Study type	Choose one: Initial validation (three consecutive runs); Requalification.

2 · Moist heat

One row per run and load. FO at the coldest point; temperatures during the hold.

FIELD	WHAT TO ENTER
Setpoint (°C) <small>when it applies</small>	Type a number.
Hold time (min) <small>when it applies</small>	Type a number.
Approach <small>when it applies</small>	Choose one: Overkill ($SLR \geq 12$); Bioburden-based ($SAL \leq 10^{-6}$).
D121 of the biological indicator (min) <small>when it applies</small>	Type a number.
BI population (log10 per carrier) <small>when it applies</small>	Type a number.
Maximum bioburden (cfu per unit) <small>when it applies</small>	Type a number.
Runs <small>when it applies</small>	Use the same load name for runs of the same load pattern. A table. Columns: Run Load Min FO (min) Min temp in hold (°C) Max temp in hold (°C) BIs positive BIs exposed. Paste rows from Excel, type comma-separated rows, or press <small>Load file</small> (Excel, CSV, Word, PDF or a scan).
Empty chamber heat distribution and cold spot <small>when it applies</small>	Type or paste text.

3 · Sterilising filtration

FIELD	WHAT TO ENTER
Filter <small>when it applies</small>	Type it in.
Bacterial retention challenge (cfu/cm ² , B. diminuta) <small>when it applies</small>	Type a number.

FIELD	WHAT TO ENTER
Filtrate sterile in every retention test (3 membrane lots) when it applies	Tick the box if it applies.
Viability of <i>B. diminuta</i> in the product shown (or surrogate fluid justified) when it applies	Tick the box if it applies.
Chemical compatibility and extractables assessed when it applies	Tick the box if it applies.
Product-specific bubble point specification (psi, minimum) when it applies	Type a number.
Integrity tests when it applies	A table. Columns: Batch Pre-use bubble point (psi) Post-use bubble point (psi). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Pre-use post-sterilisation integrity test (PUPSIT) performed when it applies	Tick the box if it applies.
PUPSIT risk assessment (if not performed) when it applies	Type or paste text.

4 · Dry-heat depyrogenation

FIELD	WHAT TO ENTER
Setpoint (°C) when it applies	Type a number.
Runs when it applies	A table. Columns: Run Load Min temp (°C) Time at or above setpoint (min) Endotoxin log reduction. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

FIELD	WHAT TO ENTER
Minimum exposure time at setpoint (min) when it applies	Type a number.

5 · Deviations

FIELD	WHAT TO ENTER
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:

- $SLR \geq 12$ (overkill) or $SAL \leq 10^{-6}$ (bioburden).
- Temperature band and BIs.
- Retention challenge, integrity tests and PUPSIT; endotoxin reduction.

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	Sterilisation validation 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

EU follows EU GMP Annex 1 (2022) and the EMA sterilisation guideline. US follows the FDA aseptic processing guidance (2004) and USP <1229>.

8. Working with other modules

- Aseptic filling is validated in the Media Fill (APS) Report report; equipment in Equipment Qualification Report.

9. Common pitfalls

- BIs not at the coldest point.
 - No post-use integrity test.
-

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. **Lower the lethality**

Change the minimum FO of run PQ-2 from 16.4 to 9.0 minutes.

EXPECTED RESULT

The headline shows one run failed.

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.