



Cleaning Validation Kit (MACO / HBEL)

HBEL-based MACO calculator, swab limit, worst-case matrix, protocol and report.

What's inside

File	What it is / how to use it
01_Cleaning_Validation_Workbook.xlsx	MACO and swab-limit calculator, worst-case matrix and results log.
02_Cleaning_Validation_Protocol.docx	Protocol template.
03_Cleaning_Validation_Report.docx	Report template.

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GMP decisions (batch release, validation acceptance, OOS conclusions) belong to your quality unit. Confirm requirements against current 21 CFR 210/211, Part 11 and FDA/ICH guidance for your products.

About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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Cleaning Validation Protocol

Cleaning Validation Kit (MACO / HBEL) - Document 02 - Rev A (2026-10)

Equipment train		Worst-case product	
Cleaning SOP / rev		Protocol no.	

1. Scope and rationale

Products, equipment, grouping and worst-case rationale

2. Acceptance criteria

- Chemical: swab/rinse below the HBEL-based limit (MACO calculator).
- Visual: visually clean.
- Microbial and endotoxin: per your limits (if applicable).
- Detergent residue: per your limit.

3. Sampling plan

Site	Method (swab/rinse)	Analyte	Limit	Recovery %

4. Runs

[Number of consecutive successful runs per your master plan, commonly three.]