MesaLabs

Validating & Maintaining Sterility for Aseptic Fill

Rev. 09JUL2020

An introduction to pharmaceutical aseptic fill sterilization validation.

Mesa offers a variety of product lines to assure sterility of the manufacturing and filling of vaccines, ophthalmology products, infusion treatments, injectable medicines, and IV fluid solutions.

In the pharmaceutical setting, all aseptic filling workflows must be sterile. These spaces include process fluid distribution, water for injection, API filling, terminal sterilization of product or packaging components or equipment parts prior to filling, and VHP for depyrogenation tunnels, clean rooms, filling rooms, isolators.

Table of Contents

Introduction

Sterilization Synergy: Equipment, Environment, Products 4
Overcoming Validation Challenges 5
Common Sterilization Pitfalls 6

Equipment and Sterilization Validation Solutions

Piping 7
Bioreactors, Holding Tanks, Freeze Dryers 8
Tubes, Needles, Autoclaves, Pumps, Pass-Through Ovens 8

Environment and Sterilization Validation Solutions

Clean Rooms, Isolators, RABS, Filling Rooms, Tunnels 9

Products and Sterilization Validation Solutions

Liquid Products 9
Stoppers, Vials, Syringes 10

Contact Mesa 12

MesaLabs

Equipment, environment, and product sterilization work synergistically to provide a clean pharmaceutical product.

EQUIPMENT

- Bioreactors / fermenters
- Tanks and carts
- Wide variety of piping
- Decontamination autoclaves
- Pass-through dry heat ovens
- Lyophilizers

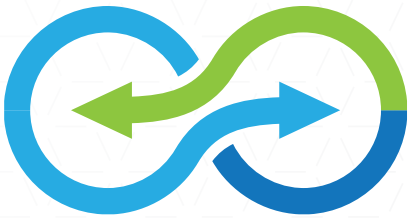
ENVIRONMENT

- Clean room environments
- Filling rooms
- Isolators / RABS
- Depyrogenation tunnels

PRODUCTS

- Liquid products
- Water for injection
- Stoppers, vials, syringes

Aseptic Process Interrelationships



We have solutions to overcome the challenges of validation cycles.

OUR PRODUCTS OFFER PHARMACEUTICAL MANUFACTURERS CONSISTENCY IN THEIR PROCESS.

- Between validation cycles and validation time periods.

WE PROVIDE A ROBUST PORTFOLIO OF VALIDATION STERILIZATION PRODUCTS TO MEET YOUR NEEDS.

- Verify the most challenging to sterilize locations like placing biological indicators in piping installations or other hard to access places.
- Biological indicators are the USP standard and most accurate measure of sterility. (USP 1229)
- We have a dedicated technical support team and contract studies laboratory to assist you selecting and utilizing biological indicators with proper resistance that are appropriate for your application.

IMPROVE ACCURACY AND SAFETY IN YOUR VALIDATION PROCESS.

- Eliminating failed validation cycles, uncertainty of reading or validation results, system damage when placing biological indicators and measuring devices, and influence of validation components on the process.

Avoid These Sterilization Downfalls

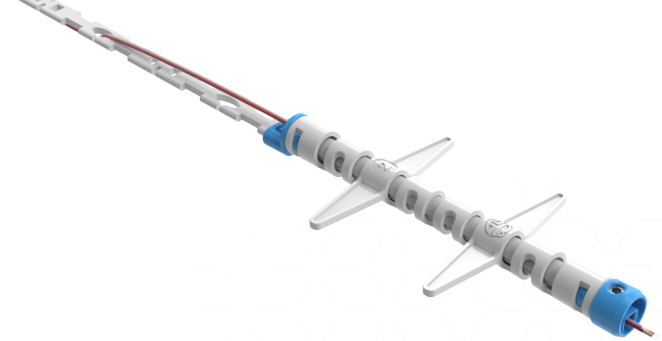
INCONSISTENT PLACEMENT CAN CREATE PROBLEMS.
To avoid inconsistency, place biological indicators in the same spot to create reproducibility from cycle to cycle. Place thermocouples along side biological indicators.

INACCESSIBLE AND HARD TO REACH PLACES.
Access hard to reach places by positioning biological indicators in conditions that represent the most difficult to sterilize location as required by the standards. (EP 9.2, ISO 17665-1 Annex D, ISO 11138-7)

AVOID FALSE POSITIVE AND NON-CONVENTIONAL METHODS WHICH MAY PRODUCE THE FOLLOWING RESULTS:

- Shredding/Loss of BI
- Metal holder or homemade holders' scratch/damage equipment
- Homemade holders unknown influence on BI resistance "D-Value"
- Ink left behind in vessel
- Kapton tape – influence of D-Value, remnants of adhesive remain in system after validation cycle
- Impeding process flow
- Temperature deviations due to contact with surfaces or condensates
- "False positive results" due to condensates coming in contact with BI

There are cost associated risks with improper sterilization. Failed validation cycles, production downtimes, audits, and recalls can occur when proper sterilization is not in place.



Piping Installations (SIP, WFI)

Conventional issues with sterilizing piping include placing the biological indicator and thermocouple near the elbow of the piping or near potential air pockets and/or cold spots. Avoid condensation or places where there could be an impedance in the piping. Make sure the sterilizer validator is placed in the same spot. With our solution, the biological indicator (BI) can easily be placed and removed, with no visible adhesive or ink left in your piping system.

MESA SOLUTIONS:

Item	Part Number
MeCo™ Round 2”	MC-RND2.00
MeCo Round 1.5”	MC-RND1.50
MeCo Round 1”	MC-RND1.00
MeCo Round 0.75”	MC-RND0.75
Mesa Spore Strip	SGMS/6

MesaLabs

Bioreactors, Holding Tanks, Freeze Dryers, Autoclaves

Secure without Kapton tape. No risk of loss or damage to biological indicator. Consistent placement. Easy removal / aseptic removal of the biological indicator.

MESA SOLUTIONS:

Item	Part Number
MeCo Flat holder	MC-FLT
Mesa Spore Strip	SGMS/6 & SGMG/6

Terminal sterilization of equipment components: tubing, filling needles, filter assemblies, decontamination autoclaves, pumps, pass-through ovens.

MESA SOLUTIONS:

Item	Part Number
ProLine	PL-3-6-15
EZTest®	EZS/6
DriAmp®	DH/50
Mesa Spore Strip	SGMS/6 SGMG/6
Microstrip	S1X25/6

ENVIRONMENT VALIDATION SOLUTIONS

Clean Rooms, Filling Rooms, Isolators, RABS, Depyrogenation Tunnels

Identifying areas where vapor hydrogen peroxide has difficulty penetrating. Monitoring disinfection of all surfaces. Consistent biological indicator performance. Proper biological indicator selection: carrier, strain, resistance, packaging.

MESA SOLUTIONS:

Item	Part Number
Apex® Discs in Tyvek	HMV-091
Apex Bare SS Ribbon	SBC-327
Releasat® Media for Culturing	PM/100

PRODUCT VALIDATION SOLUTIONS

Liquid Products

Minimal processing of sensitive products. Identifying bioburden resistance. Certainty of successful terminally sterilization. Selection of appropriate biological indicators. Avoiding off-label use of biological indicators. Easy aseptic removal of a biological indicator.

MESA SOLUTIONS:

Item	Part Number
MagnaAmp®	MA/6
SterilAmp II®	SA/6
SterilAmp II 5230	SASU/6
Contract Studies	Bioburden studies, D-value studies, Direct inoculation for custom biological indicators

MesaLabs

Stoppers, Vials, Syringes

Identifying bioburden resistance. Small and difficult to reach locations. Confidence in successful terminal sterilization of components. Monitoring terminally sterilized packaged product. Selecting appropriate biological indicator.

MESA SOLUTIONS:

Item	Part Number
EZTest Steam	EZS/6
Liquid Self-Contained Biological Indicators MagnaAmp SterilAmp II	 MA/6 SA/6
Contract Studies	Bioburden Resistance Testing, D-value Analysis Custom Biological Indicators
Process Challenge Device® (PCDs) to simulate packaged product challenge during routine use	PCDV.13
Microstrip Mesa Spore Strips DriAmp	S1X25/6 SGMS/6 & SGMG/6 DH/50
Unique Biological Indicators (wires, ribbons, coupons, etc to simulate product challenge for validation studies)	

We're committed to **protecting the vulnerable.**

At Mesa, we fulfill our purpose by providing innovative, reliable monitoring and quality assurance products and services. With over 35 years of experience in material compatibility, sterilization science, validation approaches and cycle optimization, we help ensure the safety and efficacy of your products.

Why Mesa?

- Technical expertise and consultative services
- FDA-registered facility, which is ISO 13485:2016 certified.
- Performance testing, standards development, AAMI, ISO and PDA members

MesaLabs

For European Orders: mesafrance@mesalabs.com | Ph: +33 (0)4 78 90 56 88

All Other Orders: bicustomerservice@mesalabs.com | Ph: 406.585.9535 or 877.746.8883 X10040

Technical Support: bi-support@mesalabs.com | Ph: 406.585.9535 or 877.746.8883 X10042

Contract Studies: info.mesalabs.com/contract-studies

All products manufactured by Mesa Labs are done so in accordance with current Quality System Regulations of the United States Food and Drug Administration and meet the standards established by USP and ISO 11138. Mesa Labs' Quality System is registered to ISO 13485:2016 Standards. See Mesa Labs Standard Terms and Conditions at www.mesalabs.com/terms-conditions