MesaLabs

# QS-507 Validation Summary
# MesaStrip Product Line

## Executive Summary

The MesaStrip manufacturing process is validated according to QS-501 *Validation Master Plan for the Mesa Labs, Inc., Bozeman Manufacturing Facility 625 Zoot Way.*

The MesaStrip manufacturing process, under anticipated conditions, will consistently produce product that meets pre-determined specification requirements.

## Process Performance Qualification

Process Performance Qualification (PPQ) conducted under Protocol #PQ180105P *Performance Qualification for the Manufacture of MesaStrip.* This PPQ qualifies manufacturing of all MesaStrip catalog numbers at 625 Zoot Way, Bozeman MT 59718. A list of catalog numbers validated under protocol #PQ180105P is attached to this summary document.

*Validation Lots*

SGMG/6; log 6 100/bag, Lot BATR-455
SGMG/6; log 6 100/bag, Lot BATR-456
SGMG/6; log 6 100/bag, Lot BATR-457
A2X10/6; log 6 100/bag, Lot CBATR-196
SGMS/6; log 6 100/bag; Lot GST-483
SGMS/6; log 6 100/bag; Lot GST-484
SGMS/6; log 6 100/bag, Lot GST-485

*Rationale for selection of products*

MesaStrip manufacturing is a three-phase process: inoculation of paper carrier, packaging of spore strip in glassine and qualification. The inoculation phase consists of distributing a known quantity of bacteria onto rolled paper using a rollstrip inoculation system. The inoculated paper is packaged into glassine envelopes using a spore strip packaging machine. Once packaged, the strips are subjected to qualification testing consisting of population and steam, ethylene oxide and dry heat resistance testing (where applicable). The results are used to generate the label claim for each lot of MesaStrip. Satisfactory completion of the qualification testing results in release of MesaStrip for distribution.

A matrix approach was chosen for validation of the manufacturing process:

- The components used to manufacture these items are representative of the components used to manufacture all variants of MesaStrip.
- All variants of MesaStrip utilize the same inoculation process. The lots of product included in this PQ utilize both widths of paper used to make MesaStrip.
- The variants of MesaStrip utilized for the PQ are evaluated in the three major sterilization modalities; steam, EO and dry heat.
- The SGMG/6 and SGMS/6 products serve to evaluate the packaging of spore strips into glassine. The A2X10/6 product serves to evaluate bulk packaging of naked BIs.

- The 7 runs were considered sufficient to simulate conditions that will be encountered during routine manufacturing, such as start-up, shut-downs, breaks, and manufacturing over multiple days.

As compared to the manufacturing process prior to transfer to the new facility, there were no changes to the manufacturing process, no changes to specifications, and no changes to components or component suppliers. Procedures were renumbered to align with the quality system, and a number of minor changes occurred to allow for slightly different workflow in the new facility; they otherwise remained unchanged.

*Acceptance criteria and results*

Seven consecutively manufactured lots meeting the criteria provided below were required to confirm that the MesaStrip manufacturing process, under anticipated conditions, will consistently produce product that meets pre-determined specification requirements.

For the QA final inspection per QSWI-103, the Acceptable Quality Level (AQL) for acceptability of a particular lot's inclusion in this qualification was based on criticality and frequency of the defect. If the lot in question fell within these established limits it was deemed acceptable for use as a validation lot. The defects were divided into two tiers. Defects considered *Critical to Performance* were assigned an AQL of 99%. Defects considered as having *No Impact to Performance* were assigned an AQL of 95%. Results are reported below for each validation lot.

| SGMG/6, Lot BATR-455 | | |
|---|---|---|
| **Critical to Performance** | **Results** | **Pass/Fail** |
| Population on assayed strip must be the targeted population log: BATR log6 | $2.3x10^6$ | PASS |
| Steam D-value must be within the range of 1.5-3.0minutes (if applicable) | Not Applicable | NA |
| EO D-value must be $\geq$ 2.0minutes when tested in 100% EO | 3.0minutes | PASS |
| Dry Heat D-value must be $\geq$ 2.0minutes | 2.0minutes | PASS |
| Labeling, specific to product traceability (species, lot number and expiration) | 0 labeling errors | PASS |
| **No Impact to Performance** | **Results** | **Pass/Fail** |
| Position of print on glassine or bag/box label | 0 printing errors | PASS |
| Inclusion of C of A in package | 0 packages without a C of A | PASS |

| SGMG/6, Lot BATR-456 | | |
|---|---|---|
| **Critical to Performance** | **Results** | **Pass/Fail** |
| Population on assayed strip must be the targeted population log: BATR log6 | $1.7x10^6$ | PASS |
| Steam D-value must be within the range of 1.5-3.0minutes (if applicable) | Not Applicable | NA |
| EO D-value must be $\geq$ 2.0minutes when tested in 100% EO | 3.1minutes | PASS |
| Dry Heat D-value must be $\geq$ 2.0minutes | 2.3minutes | PASS |
| Labeling, specific to product traceability (species, lot number and expiration) | 0 labeling errors | PASS |
| **No Impact to Performance** | **Results** | **Pass/Fail** |
| Position of print on glassine or bag/box label | 0 printing errors | PASS |
| Inclusion of C of A in package | 0 packages without a C of A | PASS |

| SGMG/6, Lot BATR-457 | | |
|---|---|---|
| **Critical to Performance** | **Results** | **Pass/Fail** |
| Population on assayed strip must be the targeted population log: BATR log6 | $3.1x10^6$ | PASS |
| Steam D-value must be within the range of 1.5-3.0minutes (if applicable) | Not Applicable | NA |
| EO D-value must be $\geq$ 2.0minutes when tested in 100% EO | 3.0minutes | PASS |
| Dry Heat D-value must be $\geq$ 2.0minutes | 2.4minutes | PASS |
| Labeling, specific to product traceability (species, lot number and expiration) | 0 labeling errors | PASS |
| **No Impact to Performance** | **Results** | **Pass/Fail** |
| Position of print on glassine or bag/box label | 0 printing errors | PASS |
| Inclusion of C of A in package | 0 packages without a C of A | PASS |

| A2X10/6, Lot CBATR-196 | | |
|---|---|---|
| **Critical to Performance** | **Results** | **Pass/Fail** |
| Population on assayed strip must be the targeted population log: BATR log6 | $2.0x10^6$ | PASS |
| Steam D-value must be within the range of 1.5-3.0minutes (if applicable) | Not Applicable | NA |
| EO D-value must be $\geq$ 2.0minutes when tested in 100% EO | 3.1minutes | PASS |
| Dry Heat D-value must be $\geq$ 2.0minutes | Not Applicable | NA |
| Labeling, specific to product traceability (species, lot number and expiration) | 0 labeling errors | PASS |
| **No Impact to Performance** | **Results** | **Pass/Fail** |
| Position of print on glassine or bag/box label | 0 printing errors | PASS |
| Inclusion of C of A in package | 0 packages without a C of A | PASS |

| SGMS/6, Lot GST-483 | | |
|---|---|---|
| **Critical to Performance** | **Results** | **Pass/Fail** |
| Population on assayed strip must be the targeted population log: GST log6 | $1.1x10^6$ | PASS |
| Steam D-value must be within the range of 1.5-3.0minutes (if applicable) | 2.3minutes | NA |
| EO D-value must be $\geq$ 2.0minutes when tested in 100% EO | Not Applicable | NA |
| Dry Heat D-value must be $\geq$ 2.0minutes | Not Applicable | NA |
| Labeling, specific to product traceability (species, lot number and expiration) | 0 labeling errors | PASS |
| **No Impact to Performance** | **Results** | **Pass/Fail** |
| Position of print on glassine or bag/box label | 0 printing errors | PASS |
| Inclusion of C of A in package | 0 packages without a C of A | PASS |

| SGMS/6, Lot GST-484 | | |
|---|---|---|
| **Critical to Performance** | **Results** | **Pass/Fail** |
| Population on assayed strip must be the targeted population log: GST log6 | $1.4x10^6$ | PASS |
| Steam D-value must be within the range of 1.5-3.0minutes (if applicable) | 2.5minutes | NA |
| EO D-value must be $\geq$ 2.0minutes when tested in 100% EO | Not Applicable | NA |
| Dry Heat D-value must be $\geq$ 2.0minutes | Not Applicable | NA |
| Labeling, specific to product traceability (species, lot number and expiration) | 0 labeling errors | PASS |
| **No Impact to Performance** | **Results** | **Pass/Fail** |
| Position of print on glassine or bag/box label | 0 printing errors | PASS |
| Inclusion of C of A in package | 0 packages without a C of A | PASS |

| SGMS/6, Lot GST-485 | | |
|---|---|---|
| **Critical to Performance** | **Results** | **Pass/Fail** |
| Population on assayed strip must be the targeted population log: GST log6 | $1.4x10^6$ | PASS |
| Steam D-value must be within the range of 1.5-3.0minutes (if applicable) | 2.3minutes | NA |
| EO D-value must be $\geq$ 2.0minutes when tested in 100% EO | Not Applicable | NA |
| Dry Heat D-value must be $\geq$ 2.0minutes | Not Applicable | NA |
| Labeling, specific to product traceability (species, lot number and expiration) | 0 labeling errors | PASS |
| **No Impact to Performance** | **Results** | **Pass/Fail** |
| Position of print on glassine or bag/box label | 0 printing errors | PASS |
| Inclusion of C of A in package | 0 packages without a C of A | PASS |

*Deviations to protocol*
There were no deviations encountered during the execution of protocol PQ180105P.

## Method Verification

The following Compendial Method Verifications were completed as part of this protocol:

- Population assay testing of paper carrier biological indicators per ISO 11138-1
- EO resistance testing on paper carrier biological indicators per ISO 11138-2
- Steam resistance testing on paper carrier biological indicators per ISO 11138-3
- Dry heat resistance testing on paper carrier biological indicators per ISO 11138-4

## Equipment Qualification

The following equipment qualifications were completed in order to execute this protocol:

| Equipment Number | Equipment | Qualification document(s) | Protocol Deviations | Conclusion |
|---|---|---|---|---|
| INO-102 | Strip Inoculation System | INO102-IOQ-001 | None | The inoculator has been installed successfully. The installation and operation qualification criteria have been met. |
| STZ-101 | Steam Autoclave | STZ101-IOQ-001 | None | The Steam Autoclave has been installed successfully. The installation, operation, and performance criteria have been met. |
| | | STZ101-PQ-003 | None | |
| SSP-103 | Spore Strip Packaging Machine | SSP103-IOQ-001 | None | The Spore Strip Packaging machine has been installed successfully. The installation and operation qualification criteria have been met. |
| RES-101 | Steam Resistometer | RES101-IOQ-001 | None | The steam resistometer has been installed successfully. The installation and operation qualification criteria have been met. |

| Equipment Number | Equipment | Qualification document(s) | Protocol Deviations | Conclusion |
|---|---|---|---|---|
| RES-102 | EO Resistometer | RES102-IOQ-001 | D-001: The original protocol referenced a form from the Evergreen Facility QS. No impact to the PPQ protocol or the product | The EO resistometer has been installed successfully. The installation and operation qualification criteria have been met. |
| RES-103 | Steam Resistometer | RES103-IOQ-001 | D-001: the resistometer was only qualified up to 132°C instead of 135°C. No impact to PPQ protocol or product | The steam resistometer has been installed successfully. The installation and operation qualification criteria have been met. |
| RES-104 | Dry Heat Resistometer | RES104-IOQ-001 | None | The Dry Heat resistometer has been installed successfully. The installation and operation qualification criteria have been met. |
| RES-106 | EO Resistometer | RES106-IOQ-001 | None | The EO resistometer has been installed successfully. The installation and operation qualification criteria have been met. |
| RES-107 | Dry Heat Resistometer | RES107-IOQ-001 | None | The Dry Heat resistometer has been installed successfully. The installation and operation qualification criteria have been met. |
| INC-101 | 30-35°C Incubator | INC101-IOQ-001 | None | The 30-35°C incubator has been installed successfully. The installation and operation qualification criteria have been met. |

| Equipment Number | Equipment | Qualification document(s) | Protocol Deviations | Conclusion |
|---|---|---|---|---|
| INC-103 | 30-35°C Incubator | INC103-IOQ-001 | None | The 30-35°C incubator has been installed successfully. The installation and operation qualification criteria have been met. |
| INC-105 | 55-60°C Incubator | INC105-IOQ-001 | None | The 55-60°C incubator has been installed successfully. The installation and operation qualification criteria have been met. |

**Utility Qualification**

The following utility qualifications were completed in order to execute this protocol:

| System Number | Utility | Qualification document(s) | Protocol Deviations | Conclusion |
|---|---|---|---|---|
| AIR-101 | Compressed Air System | AIR101-IOQ-001 | None | The Compressed Air System has been installed successfully. The installation and operation qualification criteria have been met. |
| STM-101 | Steam System | STM101-IOQ-001 | None | The Steam System has been installed successfully. The installation and operation qualification criteria have been met. |
| WPU-101 | RO/DI Water System | WPU101-IOQ-001 | None | The RO/DI Water System has been installed successfully. The installation and operation qualification criteria have been met. |
| | | WPU101-PQ-002 | Six deviations, described below. No impact to protocol | The RO/DI water system meets acceptance criteria. Data confirmed that the system generates water that meets or exceeds Type II RO/DI water specifications |

Deviations to WPU101-PQ-001:

- WPU-101-PQ-001-D-01 was opened to document that microbial data gathered before 11Jul2017 were determined to be invalid, as it was discovered that the filters used for testing were not sterile. No impact to the protocol; the required 30 business days of testing was completed.
- WPU101-PQ-001-D-02 was opened for using expired test strips to record the ozone levels. Data were invalidated. No impact to the protocol; the required 30 business days of testing were completed.
- WPU101-PQ-001-D-03 was opened for having a detectable level of ozone present in the water when ozone wasn't being generated. Data was invalidated. No impact to protocol; the reason ozone was detected was that Facilities had run the ozone cycle less than 90 minutes before the testing was performed.
- WPU101-PQ-001-D-04 was opened to document that the form used to record data for this study included an action limit for a sampling point before the RO tanks. No action limit should have been set, as this data was being gathered for information only, is not part of the RO system, and was not included in the performance qualification. No impact to the protocol, as all data required for the protocol were gathered and are reported.
- WPU101-PQ-001-D05 was opened to document that all microbial testing was performed at 10 Evergreen Drive instead of at 625 Zoot Way. No impact to protocol; testing was performed and documented according to procedures and forms identified in the protocol.
- WPU101-PQ-001-D-06 was opened to document that microbial samples were incubated at room temperature instead of in a 20-25°C incubator as specified in the protocol. No impact to protocol; room temperatures were confirmed to have remained within 20-25°C for the period of the study.

## Standard Operating Procedures

The protocol was executed under the following standard operating procedures:

| Document Number | Revision | Title |
|---|---|---|
| LP-205 | 3 | Preparation of Spore Dilutions for Production |
| LP-302 | 3 | Resistance Determination of Biological Indicators |
| LP-305 | 3 | Population Assay of Biological Indicator Products |
| LP-404 | 1 | Operation of Steam BIERs |
| LP-417 | 1 | Operation of EO BIERs |
| LP-418 | 2 | Operation of Dry Heat Ovens |
| LP-428 | 3 | Machine Inoculating Strips |
| AP-102 | 1 | Printing Labels with Brady Printer |
| AP-201 | 4 | Packaging of Product |
| AP-202 | 3 | Inspection of Biological Indicators and Releasat Media Tubes |
| AP-203 | 1 | Hand Assembly of Biological Indicators |
| AP-301 | 3 | Spore Strip Packager Operation |
| QSWI-103 | 1 | QA Release of Finished Product Inventory |

## Training

The operators in the table below completed qualification training on the SOPs identified above during the PPQ.

| Operator | Procedure(s) | Status of read-and-understand training on SOPs | Status of qualification training on SOPs |
|---|---|---|---|
| CV | LP-205, LP-302, LP-305, LP-404, LP-417, LP-418, LP-428 | Complete | Complete |
| EA | LP-205, LP-302, LP-404, LP-418, LP-428 | Complete | Complete |
| NA | LP-302, LP-305 | Complete | Complete |
| DS | LP-302, LP-305 | Complete | Complete |
| RM* | LP-302, LP-418 | Complete | In Process |
| EN | LP-305 | Complete | Complete |
| BRS | LP-305 | Complete | Complete |
| PS | LP-305 | Complete | Complete |
| AS | LP-205, LP-305 | Complete | Complete |
| NF | AP-102, AP-301 | Complete | Complete |
| KN | AP-201 | Complete | Complete |
| JS | AP-102, AP-301 | Complete | Complete |
| LG | AP-202 | Complete | Complete |
| AT | AP-102, AP-301 | Complete | Complete |
| DG | AP-201, AP-202, AP-203 | Complete | Complete |
| KT | AP-202 | Complete | Complete |
| BT | AP-201 | Complete | Complete |
| DF | AP-202 | Complete | Complete |
| GS | AP-301 | Complete | Complete |
| EF | AP-202 | Complete | Complete |
| TB** | AP-201 | See Below** | Complete |

*RM was in training during the execution of the protocol. All activities were performed alongside of a qualified trainer.

**TB is a temp-to-hire resource that is not set up in Ensur. Understanding of the procedure and process is documented via the Employee Qualification Form.

**Attachments**

List of catalog numbers validated under PQ180105

**Approvals:**

Validation: _____ Date: 18 JUN 2018

Kurt McCauley - Director of Manufacturing

Production: _____ Date: 18 Jun 2018

Robert Bradley - Director of Manufacturing

QA: Janis E Smoke Date: 18 Jun 2018

Janis Smoke - Director of QA/RA

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List of Catalog Numbers Validated Under PQ180105

SGMS/3
SGMS/5
SGMS/6
SGMG/6
SGMG/6R
SGMR/6
SGMR/7
SGMSU/6
RG/100
AOZ/3T
AOZ/6T
A1X25/6
A1X25/6G
S1X25/6
S1X25/6G
SU1X25/6
A2X10/6
A2X10/6G
S2X10/6
S2X10/6G
SU2X10/6

BD 14 JUN 2018