MesaLabs

QS-506 Validation Summary v1
Media Tube Product Line

Executive Summary

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

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

Process Performance Qualification

The Process Performance Qualification (PPQ) was conducted under Protocol #PQ180102P *Process Performance Qualification for the Manufacture of Media Tubes.* This PPQ qualifies manufacturing of all media tube catalog numbers at 625 Zoot Way, Bozeman MT 59718. Catalog numbers validated under protocol #PQ180102P are:

- PM/100
- RM/100
- TSB-BP16
- RG/100 (media only)
- C-3-6-1080PPA (media only)

Validation Lots

- TSB-BP16; Lot TSBP-001
- PM/100; Lot PM-201
- RM/100; Lot RM-299
- In-House TSB; Lot TSB-012618

Rationale for selection of products

Media tube manufacturing is a multi-phase process: filling/capping tubes, growth promotion/sterility testing, retorquing to ensure caps are tight, and labeling/packaging. The filling/capping phase consists of distributing a known volume of media into the tubes per LP-427 *Operation and Use of the Media Tube Filling and Capping Machine* and applying a screw cap closure using qualified equipment (TFM-101). Once filled the tubes are subjected to growth promotion and sterility testing is performed per QC-102 *Growth Promotion and Purity Testing of Media.* The tubes are labeled per AP-104 *Labeling of BIs and Media Tubes using AXUS Labeler* using qualified equipment (LBR-106). Satisfactory completion of the qualification testing results in release of media tubes for distribution.

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

- The components used to manufacture these items are representative of the components used to manufacture all variants of the media tubes.
- Four 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

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

For the QA final inspection per QSWI-103 *QA Release of Finished Product Inventory*, 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.

77-04-TSB-BP16, Lot TSBP-001		
Critical to Performance	**Results**	**Pass/Fail**
Media must pass growth promotion and sterility testing	Media supported growth as required and negative control tubes were absent of growth	PASS
Primary/Secondary labeling, specific to product traceability (lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
No breakage visible inside the box	0 broken tubes	PASS
Quantity per box: 100pk box	Confirmed to be within acceptable range	PASS

PM/100, Lot PM-201		
Critical to Performance	**Results**	**Pass/Fail**
Media must pass growth promotion and sterility testing	Media supported growth as required and negative control tubes were absent of growth	PASS
Primary/Secondary labeling, specific to product traceability (lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
No breakage visible inside the box	0 broken tubes	PASS
Quantity per box: 100pk box	Confirmed to be within acceptable range	PASS

RM/100, Lot RM-299		
Critical to Performance	**Results**	**Pass/Fail**
Media must pass growth promotion and sterility testing	Media supported growth as required and negative control tubes were absent of growth	PASS
Primary/Secondary labeling, specific to product traceability (lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
No breakage visible inside the box	0 broken tubes	PASS
Quantity per box: 100pk box	Confirmed to be within acceptable range	PASS

In-House TSB, Lot TSB-012618		
Critical to Performance	**Results**	**Pass/Fail**
Media must pass growth promotion and sterility testing	Media supported growth as required and negative control tubes were absent of growth	PASS

Deviations to protocol

There were no deviations encountered during the execution of protocol PQ180102P.

Method Verification

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

- Media preparation per USP General Chapter 1117 and Mesa procedure LP-203 *Preparation of Proprietary Media for Product*
- Growth promotion and sterility testing per USP General Chapter 71 and Mesa procedure QC-102 *Growth Promotion and Purity Testing of Media*
    - USP's growth promotion test is designed for general use media utilized to culture a wide range of organisms. Since Mesa's media is specifically used to culture our biological indicator products, a modified version of that USP growth promotion test was employed that substitutes the organisms utilized for our biological indicator products.

Equipment Qualification

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

Equipment Number	Equipment	Qualification document(s)	Protocol Deviations	Conclusion
KTL-102	Steam Kettle	KTL101-IOQ-102	None	The Steam Kettle 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-005	None	
TFM-101	Tube Filling Machine	TFM101-IOQ-001	None	The Tube Filling machine has been installed successfully. The installation and operation qualification criteria have been met.
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-112	36-38°C Incubator	INC112-IOQ-001	None	The 36-38°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-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.
INC-107	58-62°C Incubator	INC107-IOQ-001	None	The 58-62°C incubator has been installed successfully. The installation and operation qualification criteria have been met.
LBR-106	AXUS Labeler	LBR106-IOQ-001	None	The AXUS labeler 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.

System Number	Utility	Qualification document(s)	Protocol Deviations	Conclusion
		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-203	3	Preparation of Proprietary Media for Product
LP-427	1	Operation and Use of the Media Tube Filling and Capping Machine
QC-102	2	Growth Promotion and Purity Testing of Media
AP-103	1	Printing Labels with SATO Printer
AP-104	1	Labeling of BIs and Media Tubes using AXUS Labeler
AP-202	3	Inspection of Biological Indicators and Releasat Media Tubes
AP-201	3	Packaging of Product
QSWI-103	2	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-203	Complete	Complete
CB	LP-427, LP-203	Complete	Complete
JS	LP-427, AP-102, AP-104, AP-201, AP-202	Complete	Complete
EA	AP-104, AP-201, LP-427	Complete	Complete
DG	AP-104, AP-201, AP-202	Complete	Complete
LA	QC-102	Complete	Complete
EF	AP-201, AP-202	Complete	Complete
NF	AP-102, AP-104, AP-201, AP-202,	Complete	Complete
KT	AP-201, AP-202, LP-427	Complete	Complete
AT	AP-102, AP-201, AP-202	Complete	Complete
DF	AP-104, AP-201	Complete	Complete
OR	AP-201, AP-202	Complete	Complete
GS	AP-201, AP-202	Complete	Complete

Approvals:

Equipment Owner:_____ Date: 19 MAR 2018

Kurt McCauley - Director of Support Services

Process Owner:_____ Date: 19 Mar 2018

Robert Bradley - Director of Production

QA: Janis E Smoke Date: 19 Mar 2018

Janis Smoke - Director of QA/RA