MesaLabs

QS-508 Validation Summary
DriAmp Product Line

Executive Summary

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

The DriAmp 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 #PQ180206P *Performance Qualification for the Manufacture of DriAmp*. This PPQ qualifies manufacturing of catalog number DH/50 at 625 Zoot Way, Bozeman MT 59718.

Validation Lots

DH/50; log 6 50ct/box, Lot DH-162
DH/50; log 6 50ct/box, Lot DH-163
DH/50; log 6 50ct/box, Lot DH-164

Rationale for selection of products

DriAmp manufacturing is a multi-phase process: dispensing of sand into ampoules, inoculation of sand filled ampoules, sealing the filled ampoules and qualification testing. The sand filling phase consists of dispensing a known volume of sand into glass ampoules. The inoculation phase consists of distributing a known quantity of bacteria into the sand filled ampoules. Then the filled ampoules are flame sealed using a Cozzoli sealing machine. Once sealed, the ampoules are subjected to qualification testing consisting of population and dry heat resistance testing. The results are used to generate the label claim for each lot of DriAmp. Satisfactory completion of the qualification testing results in release of DriAmp for distribution.

- The components used to manufacture these lots are representative of the components used to manufacture all lots of DriAmp.
- The 3 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

Three consecutively manufactured lots meeting the criteria provided below were required to confirm that the DriAmp 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.

DH/50, Lot DH-162		
Critical to Performance	**Results**	**Pass/Fail**
Population on assayed ampoule must be the targeted population log: Log6	$2.9x10^6$	PASS
Dry heat resistance must be greater than 2.0minutes.	6.2minutes	PASS
Labeling, specific to product traceability (species, lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
Inclusion of C of A in package	0 packages without a C of A	PASS
Quantity per box: 50pk box	Confirmed to be within acceptable range	PASS
No breakage visible inside the package	No visible breakage was identified during final inspection	PASS

DH/50, Lot DH-163		
Critical to Performance	**Results**	**Pass/Fail**
Population on assayed ampoule must be the targeted population log: Log6	$2.8x10^6$	PASS
Dry heat resistance must be greater than 2.0minutes.	5.2minutes	PASS
Labeling, specific to product traceability (species, lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
Inclusion of C of A in package	0 packages without a C of A	PASS
Quantity per box: 50pk box	Confirmed to be within acceptable range	PASS
No breakage visible inside the package	No visible breakage was identified during final inspection	PASS

DH/50, Lot DH-164		
Critical to Performance	**Results**	**Pass/Fail**
Population on assayed ampoule must be the targeted population log: Log6	$2.5x10^6$	PASS
Dry heat resistance must be greater than 2.0minutes.	6.6minutes	PASS
Labeling, specific to product traceability (species, lot number and expiration)	0 labeling errors	PASS
No Impact to Performance	**Results**	**Pass/Fail**
Inclusion of C of A in package	0 packages without a C of A	PASS
Quantity per box: 50pk box	Confirmed to be within acceptable range	PASS
No breakage visible inside the package	No visible breakage was identified during final inspection	PASS

Deviations to protocol

There were no deviations encountered during the execution of protocol PQ180206P.

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
- 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
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	
LFM-104	Cozzoli Liquid Filling Machine	LFM104-IOQ-001	None	The Cozzoli liquid filling machine has been installed successfully. The installation and operation qualification criteria have been met.

Equipment Number	Equipment	Qualification document(s)	Protocol Deviations	Conclusion
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-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-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.
INC-115	52-56°C Incubator	INC115-IOQ-001	None	The 52-56°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-203	4	Preparation of Proprietary Media for Product
LP-205	3	Preparation of Spore Dilutions for Production
LP-211	1	Manufacture of DriAmp
LP-302	3	Resistance Determination of Biological Indicators
LP-305	3	Population Assay of Biological Indicator Products
LP-306	1	Population Assay on Non-Cellulose Carriers
LP-418	2	Operation of Dry Heat Ovens
LP-434	1	DriAmp Filling Machine
AP-201	4	Packaging of Product
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
CBr	LP-203, LP-434	Complete	Complete
NA	LP-205, LP-211, LP-302, LP-305, LP-306, LP-418, LP-434	Complete	Complete
DS	LP-302, LP-306, LP-418	Complete	Complete
EA	LP-306	Complete	Complete
AS	LP-302, LP-306, LP-418	Complete	Complete
JK	LP-203	Complete	Complete
KG	LP-203	Complete	Complete
CBc	LP-203	Complete	Complete
JS	AP-201	Complete	Complete
EA	AP-201	Complete	Complete
BT	AP-201	Complete	Complete
AT	AP-201	Complete	Complete
DG	AP-201	Complete	Complete
DF	AP-201	Complete	Complete
KN	AP-201	Complete	Complete
GS	AP-201	Complete	Complete
HR	AP-201	Complete	Complete
KR	AP-201	Complete	Complete
JW	AP-201	Complete	Complete
VK	AP-201	Complete	Complete
KM	AP-201	Complete	Complete
ED	AP-201	Complete	Complete

Approvals:

Validation: _____ Date: 09 JUL 2018

Kurt McCauley - Director of Manufacturing

Production: _____ Date: 09 Jul 2018

Robert Bradley - Director of Manufacturing

QA: _____ Date: 09 JUL 2018

Jole Wilson – QA Manager