Sterility Test Failure Investigation

(Ref. MICLAB 060)

Table Contents DR_____

1 Purpose of report

The purpose of this document is to provide a summary report of the incident investigation conducted into:

2 Batch Details

Product Name		Batch #	
Date of Manufacturing		Filling Room #	
Product Code		Filling Machine	
Container and size			
Terminally sterilized Y/N		Autoclave Cycle	

Sterility Test Details

Date		Technician	
Test room		Number of products tested	
Time of test session		Session number that day	
Validated test method		Tested to Specification	
Date of results		Test session results	
Contaminant/s type		Negative control result	

Sterility Test Failure Investigation

(Ref. MICLAB 060)

3 Batch review from manufacturing and testing.

Product Manufacturing Review

REVIEW AREA	DETAILS & Results	REVIEWED BY

Dispensing results:

Review of raw materials used for the manufacture	Batch # Materials code Validated test method Results of tests	Sign: Date: Review Attached: Yes/No
Dispensing of the raw materials		Sign: Date: Review Attached: Yes/No
Sterilization cycles for components	Autoclave Cycle# Date Result	Sign: Date: Review Attached: Yes/No

Solution Preparation results:

Distilled water used for manufacturing	Time of collection Sample port results	Sign: Date: Review Attached: Yes/No
Review Bulk solution Bioburden	Time of collection Validated test method Results of tests	Sign: Date: Review Attached: Yes/No
Review of Filled Container Bioburden	Validated test method Results of tests	Sign: Date: Review Attached: Yes/No
Review of Bacterial Endotoxin results	Finished product Water used for manufacture of batch	Sign: Date: Review Attached: Yes/No
Line steaming results	Line # Date Result	Sign: Date: Review Attached: Yes/No
Vessel steaming results	Vessel # Date Result	Sign: Date: Review Attached: Yes/No
Holding tank results	Holding Tank # Date Result	Sign: Date: Review Attached: Yes/No
Filtering review	Bioburden reduction filter # Exacta # Date Results	Sign: Date: Review Attached: Yes/No

Filling Machine results:

Environmental monitoring results

Filling machine Viable	Surface plates machine	Sign: Date: Review Attached: Yes/No

Sterility Test Failure Investigation

(Ref. MICLAB 060)

Filling Machine non viable particulates	Sterile filling zone, date when last conducted	Sign: Date: Review Attached: Yes/No
Manufacturing room Viable Air	Air L/F Air Filling Room Air Corridor	Sign: Date: Review Attached: Yes/No
Manufacturing room Viable Surface	Surface floor Surface wall	Sign: Date: Review Attached: Yes/No
Manufacturing room Non- Viable particulates	Filling room, date when last conducted	Sign: Date: Review Attached: Yes/No
Fallout Plates for Batch	Date Start time of exposure End time of exposure Shift Result	Sign: Date: Review Attached: Yes/No
Review of Prepared plate media	Type of Media Batch # Expiry Date	Sign: Date: Review Attached: Yes/No

Filling Machine results:

Setting up Procedures		Sign: Date: Review Attached: Yes/No
Machine steaming results	Machine # Date Result	Sign: Date: Review Attached: Yes/No
Error log report	Report Date Result	Sign: Date: Review Attached: Yes/No
Filtering review	Sterilisation filter # Date Results	Sign: Date: Review Attached: Yes/No
Manufacturing instruction sheet review Interventions Stoppages Reject rate		Sign: Date: Review Attached: Yes/No
Maintenance log review		Sign: Date: Review Attached: Yes/No
Product values		Sign: Date: Review Attached: Yes/No
Pressure testing calibrations		Sign: Date: Review Attached: Yes/No
Differential pressure excursion review		Sign: Date: Review Attached: Yes/No
Air shower system		Sign: Date: Review Attached: Yes/No
Waste tanks		Sign: Date: Review Attached: Yes/No

Sterility Test Failure Investigation

(Ref. MICLAB 060)

Filling Process		Sign: Date: Review Attached: Yes/No
All shifts		Sign: Date: Review Attached: Yes/No
Cleaning review		Sign: Date: Review Attached: Yes/No
Disinfectants		Sign: Date: Review Attached: Yes/No
Chilled water review		Sign: Date: Review Attached: Yes/No
Product line integrity		Sign: Date: Review Attached: Yes/No
Work orders		Sign: Date: Review Attached: Yes/No
Run Sheet		Sign: Date: Review Attached: Yes/No
Sterile Log Book		Sign: Date: Review Attached: Yes/No

Sterile Operator Review

Name and Number of Operators & Location of working	Name Location	Sign: Date: Review Attached: Yes/No
Interview of Operator for any excursion of procedures:	Name: Date	Sign: Date: Review Attached: Yes/No
Training records Gowning validations	Name Training Record	Sign: Date: Review Attached: Yes/No
Operators Finger Dabs	Name Results	Sign: Date: Review Attached: Yes/No
Operators Uniform	Name Results	Sign: Date: Review Attached: Yes/No

Packing Line:

Autoclave cycle finished product	Autoclave # Cycle # Result	Sign: Date: Review Attached: Yes/No
Issues on Inspection / Finishing line		Sign: Date: Review Attached: Yes/No

Sterility Test Failure Investigation

(Ref. MICLAB 060)

QA Review Manufacturing:

Product Review of past 12 months of results		Sign: Date: Review Attached: Yes/No
Deviation Reports Review		Sign: Date: Review Attached: Yes/No
Similar incidents		Sign: Date: Review Attached: Yes/No
Change control history review		Sign: Date: Review Attached: Yes/No
Audit of security card swipe		Sign: Date: Review Attached: Yes/No
Review of Media run reports past 12 months		Sign: Date: Review Attached: Yes/No

Summary

Micro. Lab. to place a **HOLD on adjacent & subsequent batches** until establishing a cause which will eliminate their risk of contamination and also;

Date done:	Notify QA Manager

Batches on HOLD (Q)

Batch #	Code	Product & %	Container Size

Sterility Test Failure Investigation

(Ref. MICLAB 060)

Sterility Testing Review

REVIEW AREA	DETAILS	REVIEWED BY
Results of known sterile controls		Sign: Date: Review Attached: Yes/No
Level of false positives in routine testing (previous 12 months)		Sign: Date: Review Attached: Yes/No
Level false positives in known sterile controls previous 12 months)		Sign: Date: Review Attached: Yes/No
Review of sampling procedures		Sign: Date: Review Attached: Yes/No
Review of handling procedures		Sign: Date: Review Attached: Yes/No
Review of swab method		Sign: Date: Review Attached: Yes/No
Review of certificate for Steritest unit		Sign: Date: Review Attached: Yes/No
Review of autoclave cycle for sterility test equipment		Sign: Date: Review Attached: Yes/No
Media used in sterility test		Sign: Date: Review Attached: Yes/No
Validation of HEPAs		Sign: Date: Review Attached: Yes/No
Validation of Laminar Flow unit		Sign: Date: Review Attached: Yes/No
Review of sterility test session, other batches		Sign: Date: Review Attached: Yes/No
Training records for sterility technician		Sign: Date: Review Attached: Yes/No
EM results for the sterility test room Viable	Air L/F Air Sterility Test room Air Change room	Sign: Date: Review Attached: Yes/No
EM results for the sterility test room Viable	Surface plates LAF Surface floor Sterility test Room Surface floor Change room	Sign: Date: Review Attached: Yes/No
EM results for the sterility test room Non- Viable	Sterility test room Change room	Sign: Date: Review Attached: Yes/No
Review of Prepared plate media	Type of Media Batch # Expiry Date	Sign: Date: Review Attached: Yes/No
LAF Fallout Plate for Session		Sign: Date: Review Attached: Yes/No

Sterility Test Failure Investigation

(Ref. MICLAB 060)

Sterility Technician Finger Dabs		Sign: Date: Review Attached: Yes/No
Sterility Technician Uniform		Sign: Date: Review Attached: Yes/No
Differential pressure excursion review		Sign: Date: Review Attached: Yes/No
Audit of security card swipe		Sign: Date: Review Attached: Yes/No
Cleaning review		Sign: Date: Review Attached: Yes/No
Disinfectants for cleaning		Sign: Date: Review Attached: Yes/No
Interview of Technician		Sign: Date: Review Attached: Yes/No
Sterility Log Book		Sign: Date: Review Attached: Yes/No

Comparison of Isolates

Date of Streaking all Isolates:_____
Technician:_____

Source of Isolate	No. of Colonies	Colony Morphology	Microscopic Appearance
Product	N/A		
Finger Dab Plate			
Uniform Plate			
Laminar Flow Contact plate			
Laminar Flow Air Sample			
Fallout Plate			

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(Ref. MICLAB 060)

IPA Exp. Date: Bucket 1	N/A		
Bucket 2	N/A		

4. Summary of Conclusions found

5. Possible cause/ Root Cause

6. Corrective action

Task	Responsible	Date Completed

7 Disposition of filling room/batch

8. Documentation Approval of Investigation

Prepared by	Signature	Date

Sterility Test Failure Investigation

(Ref. **MICLAB 060**)

Reviewed by 1	Signature	Date
Reviewed by 2	Signature	Date
Approved by Quality Assurance Manager	Signature	Date

Glossary:

EM	Environmental Monitoring
L/F	Laminar Flow
Fallout plates	Also known as Settle Plates