Standard Operating Procedure

Title: Microbiological Data Recording Procedure

Department	Micro Lab		Document no	MICLAB 015	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Document Owner

Microbiology Manager

Affected Parties

All Manufacturing Colleagues

Purpose

To describe procedures for the recording of Microbiological data using the in-house hard copy and computerised recording system. All documents containing test results are legal documents and therefore it is imperative that all the information required is recorded accurately. **Any changes/corrections to be made must be signed with that person's initials and dated**.

Scope

This SOP is to be followed by all Microbiology Lab Staff in execution of the recording of Microbiological Data.

Definition

N/A	

Related Documents

MICLAB 045	Environmental and Plant Hygene Monitoring Procedure
MICLAB 035	Aseptic Media Filling and Micro. Integrity Leak (Soup) Testing Procedure
MICLAB 060	Micro Laboratory Procedure for Sterility Testing
MICLAB 075	Micro Evaluation on Bioburden, Non sterile and Raw Materials
MICLAB 080	Bacterial Endo Toxin Testing (LAL) - Gel Clot Method
MICLAB 095	Sterile Sampling Procedure for Microbiology Laboratory
MICLAB 085	Bacterial Endo Toxin Testing kCA Method
Form 650	Checklist for Procedure for Entry into Sterile
Form 670	Aseptic Media Fill Information Sheet
Form 655	Validation Record For Sterile Gowning Procedure
Form 685	Lal Gel-Clot Test Session Results
Form 645	Sterile Chart Log For Microbiology Laboratory
Form 635	Daily Personnel Monitoring Logs for Sterile Areas

EHS Statement

There is no EHS impact as this is a documentation procedure only.

3. Sterilisation Logbooks

- **Steaming Charts logbook**, keeps a log of all the results of steaming of the machines.

4. Comment Books

- **Environmental Monitoring - Comments Book**

Any relevant information concerning Environmental Areas such as leaks, spills or other incidents plus any additional testing conducted, and why, is recorded with the full date and initials of the operator at the conclusion of the comment.

5. Files

- **Environmental Results (Surfaces) Sterile Areas** – Surface sample results from Glass & sterile areas.
- **Environmental Results (Air File) Sterile Areas –** Air sample results from Glass & serile areas.
- **Environmental Results (Surfaces) Non-sterile –** Surface sample results from sterile production and Microlab areas.
- **Environmental Results (Air File) Non-sterile –** Air sample results from sterile and Microlab areas.
- **Environmental Tracking Forms –** is used to keep track of when and who conducts the testing and recording of an environmental area. All entries must be initialled and dated.
- **Personnel Monitoring Log Sheets - Sterile areas** – Files used to store the forms that log personnel monitoring conducted by sterile operators.
- **Environmental Recovery Forms** – Forms used by production to document steps taken after an environmental breach.
- **Recommissioning of Environmental Areas –** Information to be filled out to recommission a graded room.
- **Fridge Monitoring & Store Room Temperature file** – All microlab fridges and media store areas.
- **Water Testing Reports file** - Water sampling summaries and Water graph summary reports.
- **Bioburden Reports file** -Microbiological status of batches before filtration or sterilisation and Bioburden analysis of filled containers.
- **Personnel Monitoring Reports Glove Print Plates file** - Sterile Area personnel – finger dab results.
- **Personnel Monitoring Reports Uniform Plates file** - Sterile Area personnel – uniform plate results.
- **LAL-GEL Clot Test Session Results file** - Results of Gel-Clot test session using **form.** Information to be recorded includes, the batch number, date tested, tested by, product, container & size, dilution, results, passed, standards, controls and reagent details.
- **Microlab Minutes and General file –** Contains the Minutes to Monthly Microlab Meetings and any other information relevant to the Microlab.
- **Monitoring Results for Sterility Test Session file** – Results of fallout plates exposed during sterility test session, results of finger print impressions by the Operator, the Operator's name, the Laminar air results (1000L), the Laminar bench surface result from a contact plate and the Sterility room number to be recorded plus personnel monitoring.
- Environmental Monitoring **Investigations file.**
- **Compressed Air and Nitrogen Testing file.**
- **Summary Review of Environmental Monitoring file.**
- **In-Process Media Run file –** that details all relevant information to a media run **(MICLAB 035)**

Sterile Chart Log for Microbiology Laboratory

(Ref. MICLAB 095)

Year:

Product Description	BPN	Load No.	Machine/Autoclave Name	Operator Sign In	Date	Micro Sign Out

Validation Record for Sterile Gowning Procedure

(Ref. MICLAB 010)

Validated Microbiology Technician	Print	Sign

Complete the following section upon recording validation results

Actions in the Event of Failure		Validation Successful (Y/N)	

Follow up checklist	Tick appropriate
Email/Notification of validation result sent to participant:	YES ☐ NO ☐
Sterile Entry Master List updated with successful validation date:	YES ☐ NO ☐ N/A ☐
Validation record photocopy sent to Manufacturing Learning:	YES ☐ NO ☐ N/A ☐

Recorded by:	Print	Sign
Approved by:		

Aseptic Media Fill Information Sheet

(Ref. MICLAB 035)

Counter reading: Number of Rejects: Number of Filled units:			

Intervention List:

The following routine interventions are to be included into the running of a media fills.
The number and types of interventions will vary depending on the process line, however we need to cover off normal daily interventions that take place during the manufacturing of our production batches.

Type of Intervention	Shift	Time	Person responsible
Weight and fill volume adjustments			
Component replenishment			
Filter Change			
Filling needle change			
Operator breaks Personnel leaving the room.			
Component change			
Operator Changes (Need to note maximum number of persons in room)			
Sterilisation/Product Filter change			
Major Stoppage			

Aseptic Media Fill Information Sheet

(Ref. MICLAB 035)

15 days			

Environmental Monitoring Results:

Fallout Plates: Include times and shift		**Gram-Stain and Identification**
Air sample: Include times and shift **Contact Plates:** Include locations.		

Personnel Monitoring Results:

Operator name and Sample Date	**Finger Dabs:**	**Hood:**	**Chest:**	**Sleeve:**	**Name of Person Recording Results and Date**	**Gram-Stain and Identification**

LAL Gel-Clot Test Session Results

(Ref. MICLAB 080, MICLAB 015)

Assay Date: _____

Analyst: _____

TEST SESSION STANDARDS - RESULTS

Key: (+) firm gel, (-) no gel or viscous gel.

Replicate Assay No.	Positive Endotoxin Controls Concentration (EU/ml)						Endpoint (EU/ml)
	0.5	0.25	0.125	0.06	0.03	0.015	
1							
2							
3							
4							

NEGATIVE CONTROLS

Key: (+) firm gel, (-) no gel or viscous gel.

Replicate Assay No.	Control Results
1	
2	

TEST REAGENTS

Reagents	Lot No.	Reconstitution Date	Expiry date	
Pyrogent				EU/mL sensitivity
Endotoxin				EU/mL potency
Pyrosperse		NA		2% working concentration
Test kit		NA		

L.A.L, Endotoxin & Endotoxin Working Standards diluent.

W.F.I. (Tested to be L.A.L. negative) Batch No.: _____

Comments about Session: _____

_____

SIGNATURE _____

