

# Standard Operating Procedure

## Title: Microbiological Data Recording Procedure

### 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 & sterile 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)