

# Standard Operating Procedure

## Title: Sterile Sampling Procedure for Microbiology Laboratory

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### EHS Statement

- Be careful not to overload and hurt yourself when carrying samples.
- If any samples are dropped, clean up the area and organise for new samples to be taken.

### Procedure

#### General

All samples, charts and Settle plates (Fallout plates) are to be delivered to the Micro. Lab. Sample Cabinets and logged into the relevant logbooks, i.e. Sterility Logbook, Chart Logbook, Non-sterile Raw Material Logbook and Environmental Monitoring logbook.

Each group of samples taken from a Batch Production Number, (BPN) must be accounted for by noting the quantity and signing the BPN document when the samples are taken.

1. All sampling is to be done by Authorised Persons.
2. Samples selected for the Sterility test, the Bacterial Endotoxin test, Bioassay test or the Microbial Limit test are not to include any rejects, i.e. they are to be saleable product. They are to be taken after the Inspection (where possible).
3. Only saleable product is to be sampled for the Micro. Lab., that is, **NO REJECTED** material is to be sent to the Micro. Lab. for testing.
4. Sample security must be maintained by placing the samples of small containers in a clean, NEW plastic bag and adequately labelling it with PRODUCT NAME, MATERIAL CODE Number (include all Material Code numbers if the batch has split codes), BPN and number of samples. If a single BPN samples are unable to be collected into one single bag, ensure that there is a new documentation for the second bag to clearly identify the samples.
5. Samples of large containers of non-sterile products, e.g. Jars of tablets, must be adequately labelled with PRODUCT NAME, MATERIAL CODE Number, BPN Number and date and time of fill where appropriate.
6. When Settle plates (Fallout plates) are being exposed during the manufacturing Filling shift, the Sterile operator is to check the filling machine for any leaks. If breaches to the filling environment take place the sooner they are identified the better, it is the responsibility of all personnel working in the filling room to report any breaches to both the Process Manager and to the Micro. Lab.

#### **NOTE: Environmental Monitoring (see MICLAB 045)**

If Environmental Monitoring is to be conducted due to reasons stated in **MICLAB 020** by production personnel in the place of Micro. Lab Staff, please take Air samples of both the filling machine room and Laminar Flow using the Air Sampling equipment, located inside the Sterile areas, using **TSA** Agar plates. Take surface samples, using contact plates, of the machine surface, wall and floor. Deliver samples to the Micro. Laboratory sample Cabinets.

Air Sampling Position	Air sampling setting
Under Laminar Flow	1000L
Filling Room	200L

### 1. Solution Preparation Area - Details of Specific Responsibilities

**NOTE:** Only saleable product is to be sampled for Micro. Lab., that is, **NO REJECTED** material is to be sent to the Micro. Lab. for testing.

#### **Specific Requirements for sampling:**

Bulk Bioburden samples, i.e. **Solution Prior to Membrane filtration** are to be sampled near the end of filling for all batches manufactured in the Solution Preparation Rooms.

**Samples are to be stored in the Solution Preparation Room fridges immediately after sampling. These samples are to be logged into the appropriate logbooks.**

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### 2.4. Biological Assay Test Samples - (if required)

When collecting Bacterial Endotoxin Samples please record the information on the Sterile Area Sample Identification Checklist (**Form 625**).

### 2.5. Sterilisation Charts

All charts that are generated from the steaming of the sterile preparation machines and transfer lines are to include the following details:

- Machine Number
- Shipper Label to be signed and dated by Operator
- The details of BPN, Material Code, User ID, Product Type are to be entered onto the chart at the header section.

The chart is to be checked before the commencement of filling of product. Once the chart has been checked, it is to be signed and dated by the Operator.

If, for any reason a machine is not steamed (because of filling a product of the same Code and there has been no break in sterility of the line), It is still require the header section of the chart to include all details and a signed and dated Shipper Label. If no Shipper label has been generated for the BPN, or the machine does not require steaming, **the Operator still needs to send a completed copy of Form 630 to the Micro. Lab.**, to enable Micro. Lab. personnel to enter the steaming details into the steaming log. Include the information that the machine has not been steamed, (i.e. N/A for Steaming).

If at the start of filling a batch, the machine does not require steaming, but during the filling of the batch it does require steaming, due to a break in sterility, then a **Deviation Report (DR)** is to be raised. The DR number is to be written onto the chart.

All sterile preparation and transfer machine chart records are to be inspected before delivery to the Micro. Lab. Sample Cabinets. The charts are to be logged into the Chart Logbook (FM 0635).

**Micro. Lab. staff** is responsible for the daily collection of the charts from the Sample Cabinets and the checking of the charts.

### 2.6. Settle Plate (Fallout plate)

2.6.1. Each Filling Machine is required to have exposed at least one Settle plate (Fallout) for 4hours **+ or -** 15minutes/ per shift/ per BPN/ per number of days of filling, (i.e. if filling over 3 shifts then you are required to have at least 3 Settle plates). If for some reason the exposure time is less due to the batch finishing on that shift or due to breaks, major stoppage then indicate this on Settle plate. Settle plates are not to be exposed for longer than 4hours **+ or -** 15minutes due to the possibility of the plates becoming dehydrated. **NOTE:** If a batch has only just started or about to end on a shift and the exposure time is less than 4hours **+ or -** 15minutes, then the plate should be identified with start and end of batch to avoid a deviation being raised for insufficient exposure time on that individual shift of manufacturing.

2.6.2. **Nutrient Agar plates** are exposed to sample the air quality during filling. Written details required on the plate are as follows:

- BPN
- Material Code Number
- Date of Filling
- Sterile Preparation Machine number
- Start time of Exposure
- Finish time of Exposure
- Position on machine, i.e. Left, Right side.

2.6.3. Plates are to be available from the production or Micro Lab. fridges.

**Non-Steaming Machine Record For Micro lab**  
(Ref. MICLAB 095)

**This form is to be used when there is NO Steaming required on the Filling Machine: It is to be delivered with shipper label for the Micro Laboratory. Please complete this Checklist.**

PRODUCT NAME:	BPN.
MATERIAL CODE No.	DATE OF FILLING:
FILLING MACHINE No.	SIGN

# Sterile Chart Log for Microbiology Laboratory

(Ref. MICLAB 095)

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