

# Standard Operating Procedure

## Title: Environmental and Plant Hygiene Monitoring Procedure

- 3.1.3. When exiting the Sterile Scrub Preparation Room fill in **Form 635** the Daily Personnel Monitoring Log for Sterile Areas.
- 3.1.4. Collect the Lethen Agar plates from the factory after checking them against **Form 635** and incubate in the Microbiology Laboratory.
- 3.1.5. Incubate plates, inverted, at 32°C (± 1.5°C) for 48 hours (+24 hours). After incubation, examine the plates and count the number of colonies present.
- 3.1.6. Record the details of the number of colonies graphically in the Personnel Monitoring Reports files. Prepare separate graphs for each Operator. Record the total count as well as number of moulds present on the histogram graphs shading them in with a Green pen. For the purpose of determining if the count is over the specified limit, moulds are included in the final result.
- Record the details of the Microlab Technician results on the Monitoring results for sterility test sessions Finger, Fallout, Environmental and Personnel Results forms.

- 3.1.7. Limits  
Sterile Manufacturing.  
Microlab Technician each sterility session.

Limits for Microbial contamination (average values) refer GMP guide lines		
Grade	<b>Glove Print 5 fingers</b> cfu/glove Alert Limit	<b>Glove Print 5 fingers</b> cfu/glove Action Limit
Sterile Filling	<1	<1
Sterile Preparation	3	5
Packing	-	-

On the Manufacturing graphs the Alert limit will be shown as 6 and Action limit will be 10 to account for both hands. In the event that the result from the Finger dab monitoring equals or exceeds either the ALERT or ACTION levels, follow the actions as listed under 'Micro Organisms on Personnel', see Section 9.

### 3.2. Operator's Clothing

The number of viable microorganisms on the clothing of Sterile Area Operators is to be enumerated daily for every batch using contact plates.  
At the completion of Sterility Testing the Microlab technician is to perform testing of their clothing.

**Note:** If a double consecutive session is being tested, glove print impressions should be taken after the first session with gloves then changed before the second session. Personnel uniform monitoring should be performed after the second session only.

The method to be used is as follows:

- 3.2.1. Prepared irradiated Count-Tact plates are purchased from an approved supplier. If plates are not available prepare contact plates with approximately 18mL/plate of **Nutrient Agar + 3% w/v Tween 80**. Ensure plates are sufficiently full to allow a convex agar surface above the level of the plastic base.
- 3.3. Prepared Count-Tact plates will have an Expiry date printed on the surface of the lid. All other plates prepared within the Micro Lab have an Expiry date of 1 month from date of pouring. Store plates on compactor shelves.
- 3.3.1. Procedure for Sampling
- Record details of the Operator's name, clothing sampled, work area, BPN and date on the contact plate. **It is VERY important that all this information is written on the plates as they correspond to the batch and can affect batch release.**
  - Decontaminate the plates by spraying with 70% IPA and place on the dividing bench in the **Sterile Scrub Preparation Room**.