PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	**SOP No.:**
Title: Bio-burden test of Washed Vials	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. **Purpose:**

   The purpose of this SOP is to lay down the procedure for sampling of vials for testing of Bio-burden after washing in the formulation plant.

2. **Scope:**

   This SOP is applicable for sampling of all types of washed vials for testing of bio-burden in the sterile formulation area.

3. **Responsibility:** Microbiologist

4. **Accountability:** Head of Quality Control

5. **Material and Equipments**: Washed vials

6. **Procedure:**

   6.1. Enter the sterile area of the respective plant where the washed vials are to be sampled as per the controlled area entry and exit procedure SOP.

   6.2. After reaching the sampling site decontaminate the hands with sterile 70 % IPA.

   6.3. Wear sterile gloves and with the help of sterile forceps sample the vials after it is washed, by holding the neck of the vial in sterile glass beaker.

   6.4. Sample 10 number of vials.

   6.5. Close the beaker and transfer the vials to the microbiology controlled area in closed conditions.

   6.6. Add 1.0 ml of the sterile water for injection to all the vials.

   6.7. Gently rotate the sterile water for injection and pool all the sample in to the sterile cup.

   6.8. Apply vacuum and allow the sample to pass through the membrane.

   6.9. After filtration place the membrane on the m (HPC) agar.

   6.10. Incubate the plates at 30 – 35°C for 48 hrs followed by 20 – 25°C for 72 hrs.

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7. Distribution and control:

7.1. *Master copy*:

Master copy should keep in lock and key in QA department

7.2. Controlled copy:

Controlled copy should keep with HOD of Quality control department.

7.3. Reference copy :

Reference copy should be present in departmental file.