PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Handling of Sterile Raw Materials in Production	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for the Receipt and Storage of Sterile Raw Materials in Production Department.

2.0 SCOPE:

This SOP is applicable in injectable department for the Receipt and Storage of Sterile Raw Materials in Production Department.

3.0 RESPONSIBILITY:

Production Supervisor.

4.0 ACCOUNTABILITY:

Asst. Production Manager/Production Manager.

5.0 PROCEDURE:

5.1 On receipt of sterile raw material from stores**,** Production Supervisor checks the quantity, Batch No., A.R. No. And identification label of each container and bag as per BPR.

5.2 Production Supervisor ensures that the physical condition of each container and bag is satisfactory.

5.3 Production Supervisor arranges to clean outer surface of each container with vacuum cleaner.

5.4 Production Supervisor transfers such containers to Air Lock –I of sterile area and cleans the outer surface of each container with sterile cloth soaked with 70% IPA (200 # mesh filtered).

5.5 Production Supervisor transfers containers to buffer zone for storage after sterile cleaning but before fumigating the area (One day in advance before filling).

6.0 ABBREVIATION: NIL

7.0 ANNEXURES: NIL

CHANGE HISTORY		
Supersedes SOP No.	**Change Control No.**	**Changes made**
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