



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Aseptic Area Practices	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 Objective**

To lay down a procedure for defining aseptic area practices.

**2.0 Scope**

This SOP is applicable for the persons working in the aseptic area and for following the aseptic area practices while working in the aseptic areas.

**3.0 Responsibility**

Officer and Above Production/IPQA Officer: Implementation of Procedure.

**4.0 Accountability**

Production Head.

**5.0 Procedure**

**5.1 Do's**

**5.1.1** While entering in aseptic area person should enter one by one at a time.

**5.1.2** Only one door of the area should be opened at a time.

**5.1.3** Wash the hand in first air lock with disinfectant solution using sterillium.

**5.1.4** Maintain proper gown control.

**5.1.5** Movement in aseptic area should be minimum and talking should be minimum and when required.

**5.1.6** Man & material movement of the area should be followed as per Sop's.

**5.1.7** Keep the LAF unit operational during operation/storage.

**5.1.8** Place the sterile component under LAF in closed condition.

**5.1.9** Disinfect hand in aseptic area with freshly prepared 70% IPA (use before 72 hrs) before touching any sterile item.



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**5.1.10** Contact sterile materials only with sterile instruments.

**5.1.11** Keep the entire body out of the path of unidirectional airflow.

**5.1.12** Area should be cleaned daily as per SOP using filtered disinfectant solution as per schedule.

**5.1.13** Remove the remaining materials after batch completion.

### **5.2 Don't**

**5.2.1** Do not move fast in the aseptic area.

**5.2.2** Do not gather in one room of the aseptic area.

**6.2.3** Do not open two door of the area at a time.

**6.2.4** Do not enter in area through 1<sup>st</sup> air lock to 4<sup>th</sup> air lock.

**6.2.5** Do not expose the component outside the LAF.

**6.2.6** Do not carry out production operations when temperature and humidity condition are beyond the specified limits. (Temperature NMT 28°C and RH NMT 40%)

### **7.0 Annexure (S)**

NA

### **8.0 Reference (S)**

### **9.0 Glossary**

SOP : Standard Operating Procedure.

LAF : Laminar air flow.

HEPA : High efficiency particulate air filter.

RH : Relative humidity

NMT : Not More Than