



# PHARMA DEVILS

## PRODUCTION DEPARTMENT

### STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> SOP for Operation of Leak Test Apparatus	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Purpose:** To lay down operating procedure for the operation of Leak test apparatus

**Scope:** This procedure is applicable for .....

**Responsibility:** Production Chemist  
To supervise the activity

**Pre-operating Check:** Check no packing material or residue of previous product should be there.

**Equipment used:** Leak test apparatus

**Operating procedure:**

1. Take the strips in such a way that they will cover the entire area of the sealing roller in all respect.
2. Take the strips and observe them for the manufacturing defects especially like pocket damage so that such sets can be rejected for the leak test.
3. Ensure that the desecrator is cleaned and filled with water up to the mark
4. Remove the rubber tube and clean both the tubes and the groove with the help of dry clean cloth so
5. Place the strips or blisters under examination on resting plate into the desicator and close the jar tightly.
6. Switch on the main supply
7. Apply gentle force on the top of the jar so that the vacuum will start developing with in 30 to 45 sec the indication the pressure developed by the vacuum will be indicated on the pressure gauge provided.
8. When the desired reading appears on the gauge close the isolation valve so as to maintain the pressure in side the chamber.
9. Keep those strips and blisters for about 2 min. and then take out from the chamber.
10. Observe the strips minutely and check weather the water in penetrated inside the strips or not. Not any strips should fail the leak test. If any strips fail the leak test than change the setting of pressure and temperature and other setting so that the strips produced should comply the leak test