



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Leak Test of Filled and Sealed Respules in FFS Section

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 4

1.0 OBJECTIVE:

To lay down a Procedure for Leak Test of Filled and Sealed Respules in FFS section.

2.0 SCOPE:

This SOP is applicable for Leak Test of Filled and Sealed Respules in FFS section.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

Hg	Mercury
Ltd.	Limited
mm	Millimeter
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
SS	Stainless Steel

6.0 PROCEDURE:

- 6.1 Clean the vacuum chamber Internally and Externally before start and after completion of a batch, make ensure for absence of respules of Previous Load.
- 6.2 Check the oil level in the Vacuum Pump, It should be optimum level.
- 6.3 Load the chamber with filled respules in perforated Trays (06 Trays at a time, each tray with 2750, total 16500 in a LOT). The respules should be in upright position in the Tray.
- 6.4 Close the chamber door & tighten the clamps. Close the outlet valve below the Chamber.
- 6.5 Identify the lot by Identity Card, which should have Product details.
- 6.6 Start the Vacuum Pump by pressing the start switch on at the panel board/HMI.
- 6.7 Check the printer, it should be on condition, Vacuum between -500 mm Hg to -550 mm Hg Will reach & hold for minimum 15 minutes in straight position. There after Vacuum is released and chamber is moved in upright position & again Vacuum hold for minimum 15 minutes for above mentioned range.
- 6.8 The Chamber will come back to its original position after release of Vacuum.
- 6.9 After complete release of Vacuum, open the Drain Valve at the bottom of the Chamber, to drain of any contents of the Leak respules.



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9.0 REFERENCES:
Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE-I

LEAK TEST RECORD OF FILLED AND SEALED RESPULES

PRODUCT NAME:

BATCH No.:

BATCH SIZE:

Lot No.	Date	Time		Vacuum observed (500-550 mm of Hg.)	No. of Loaded Respules	No. of Rejected Respules	Good Respules	Done By Sign	Checked By Sign	Verified By (QA) Sign
		From	To							
Total										

*Challenge test