

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Leak Test of Filled and Sealed Respules in FFS Section						
SOP No.:		Department:	Production			
SOF NO.:		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 respoules 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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Revision No.:	00	Revision Date:				
Supersede Revision No.:	Nil	Page No.:	2 of 4			

^{6.10} Loose the clamp of Chamber door & open it.

- **6.11** Take out all the Trays and Inspect for leakages/Empty respules, clean the respules externally with a mopping pad if any dirty.
- **6.12** Collect the rejected respules in a container labeled as "Non Recoverable" and send the Rejection to scrap yard for destruction.
- **6.13** Keep the good resputes in a clean container/carets/trays and affix a Status Label, bearing the Batch Details and quantity, indicating **"Ready for visual Inspection"**.
- 6.14 Record the activity details in BMR and Leak Test Record of filled and sealed Respules in Annexure-I.
- 6.15 Keep the respoules in a clean container/carets/trays and affix a Status Label, bearing the Batch Details and quantity, indicating "**Ready for visual Inspection**".
- 6.16 Clean the Leak Test Machine Chamber and record in respective log book/format.
- 6.17 Before loading of new Batch, proper Line clearance should be taken from QA Officer / Executive.

6.18 CHALLENGE TEST: (In first cycle of the batch)

- **6.18.1** Take 5 respules (one cassette) and make one micro hole in each with 22 gauge needle and mark them with Permanent Marker.
- **6.18.2** Place these micro holed resputes in the third no. SS tray, located in the middle of the Chamber.

6.18.3 Record the challenge test in Annexure-I, as star marking.

7.0 ANNEXURES:

TITLE OF ANNEXURE	FORMAT No.
Fest Record of filled and sealed Respules	
]	Test Record of filled and sealed Respules

ENCLOSURES: SOP Training Record.

8.0 **DISTRIBUTION:**

• Controlled Copy No. 01	Quality Assurance
• Controlled Copy No. 02	Production
Master Copy	Quality Assurance



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SOP No .	DP No.: Department:	Production				
SOF No.:		Effective Date:				
Revision No.:	00	Revision Date:				
Supersede Revision No.:	Nil	Page No.:	3 of 4			

9.0 **REFERENCES**:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

	Revision	Change Control	Details of Changes	Reason for	Effective	Updated			
	No.	No.		Change	Date	By			
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ANNEXURE-I LEAK TEST RECORD OF FILLED AND SEALED RESPULES

PRODUCT NAME: BATCH SIZE:

BATCH No.:

	Date	Time	ne	Vacuum	No. of Loaded Respules	No. of Rejected Respules	Good Respules	Done By Sign	Checked By Sign	Verified By (QA) Sign
Lot No.		From	То	observed (500-550 mm of Hg.)						
Tota	l I									

*Challenge test