



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Leak Test of Filled and Sealed Bottles

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 3

1.0 OBJECTIVE:

To lay down a Procedure for Leak Test of Filled and Sealed Bottles.

2.0 SCOPE:

This SOP is Applicable for Leak Test of Filled and Sealed Bottles of LVP Products.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

IPA	Isopropyl Alcohol
Ltd.	Limited
LVP	Large Volume Parenteral
NLT	Not Less Than
No.	Number
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 PRECAUTION:

- 6.1.1 Do not create panic on machine and remove the leak bottles if any from running machine to avoid any accident & injury.
- 6.1.2 Clean the machine with the help of IPA & lint free cloth before starting the work and record in concern log book.
- 6.1.3 Thorough line clearance is to be done by production officer & verified by QA officer prior to starting the next batch.
- 6.1.4 Status board shall be updated before startup of any batch.
- 6.1.5 Before starting the machine measure the gap between rotating disc and bottle squeeze rod and it must be 15 cm to 17 cm and pressure shall be 0.75 Kg/cm² to 1.0 Kg/cm².
- 6.1.6 Feed the bottles manually on the moving conveyor belt in each slot provided for the same.



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6.1.7 Check each bottle for leakage while passing through the leak test machine. If the bottle leaks from bottom or tip the solution spreads on the acrylic sheet & such bottle is removed from conveyor belt & rejected and rejected bottle kept in plastic crate / pigeon box with rejection status.

6.1.8 Good bottles are passed on the conveyor belt for visual inspection.

6.1.9 Clean the machine with lint free cloth, when it gets wetted by leak bottle.

6.1.10 Before start the leak test process must be verified the pressure limit by manual pressure gauge and record it same in Annexure-I.

6.2 SETTING CONDITION / PARAMETER:

6.2.1 Set the pressure of machine between 0.75 Kg/cm² to 1.0 Kg/cm². The pressure measurement shall be done at the marked point on the center of squeeze rod by maintaining gap 15 cm to 17 cm between rotating disc and bottle squeeze rod.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Leak Test of Filled and Sealed Bottles Record	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

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

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

