



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leak Test Apparatus for Filled and Sealed Bottle	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down the procedure for the Cleaning and Operation of leak test apparatus.

2.0 SCOPE:

2.1 This procedure is applicable to cleaning and operation of leak test apparatus, which is used for Leak test of filled and sealed bottles in liquid department.

3.0 RESPONSIBILITY:

3.1 Technical associate Production: For Cleaning and Operation of leak test apparatus for filled and sealed bottles.

3.2 Officer/Executive Production: For operation and execution of SOP "Cleaning and operation of leak test apparatus for filled and sealed bottles".

3.3 Officer/Executive QA department: For operation, verification and implementation of SOP "Cleaning and operation of leak test apparatus for filled and sealed bottles".

3.4 Head Production Department: Compliance of the SOP cleaning and operation of leak test apparatus for filled and sealed bottles.

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 Cleaning

Affix "UNDER CLEANING" label as per reference SOP No. ("Status labeling") during cleaning activity.

5.1.1 Carry out the following procedure whenever required.

5.1.2 Ensure the instrument is switched off.

5.1.3 Remove the clear top lid, gasket of the leak test apparatus and vacuum pipe.



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- 5.1.4 Remove the bottles from the perforated disc open the bottles and put the liquid into the Non recoverable rejection (NRR) container and keep the bottles in the waste bin.
- 5.1.5 Remove the plain paper from perforated disc and carry out the moping with lint free cloth if there is any stains on the perforated disc use wet lint free cloth.
- 5.1.6 Dry it with dry lint free cloth.
- 5.1.7 Fix the gasket, assemble the desiccators with lid and connect the vacuum connection.
- 5.1.8 After completion of cleaning activity affix "CLEANED" label as per reference SOP ("status labeling")

5.2 Set up and Operation

Affix "EQUIPMENT STATUS" label as per reference SOP ("Status labeling") during operation.

5.2.1 Vacuum and Time set up

- 5.2.2 Ensure the cleanliness of leak test apparatus.
- 5.2.3 Switch 'ON' the main power supply by switching the 'ON/OFF' button.
- 5.2.4 Switch 'ON' the instrument by button provide on the back side of the instrument.
- 5.2.5 Ensure the preset value of vacuum that should be 300mmHg by pressing the SET button, if required to set the vacuum to 300 mm Hg by pressing the ►,▲,▼ button and by pressing key. ◀

5.2.5.1 Ensure the preset value of Hold time that should be 01:00 by pressing SET button twice.

5.2.5.2 If preset value of vacuum and hold time is ok then press ◀ button

5.2.5.3 If required, set the parameters by pressing the ►, ▲, ▼ and ◀ buttons.

5.2.6 Checking the bottles for leakage.

- 5.2.6.1 Collect the sealed bottles from each sealing head of bottle sealing machine as per frequency mentioned in respective Batch Packing Record.
- 5.2.6.2 Identify each head by putting number on each sealed bottles with marker.
- 5.2.6.3 Open the lid and put plain paper to cover perforated disc of desiccators and Place each bottle in inverted position on plain paper.
- 5.2.6.4 Cover the bowl properly and ensure that vacuum pipe is connected properly.
- 5.2.6.5 Apply vacuum by pressing the Run/Stop key.
- 5.2.6.6 The vacuum pump will start and watch the vacuum building up on display.



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- 5.2.6.7 Once the “Set Vacuum” is reached, the pump will stop automatically and the timer will start (Hold time).
- 5.2.6.8 When the timer comes to ‘Zero’, vacuum releases automatically. Open the lid removes the bottles one by one from bowl and check the plain paper for presence of stains (if any).
- 5.2.6.9 If no stains are observed on plain paper, bottles are leak proof and sealing is satisfactory.
- 5.2.6.10 If leakage is observed from any head rectify the particular head or heads and re-perform the leak test, if leakage is not observed, continue filling process.
- 5.2.6.11 Record the observation in the respective BPR.
- 5.2.6.12 Leak test to be performed as per instruction given in the Batch Packing Record.
- 5.2.6.13 After completion of batch switch off the instrument by ‘OFF’ button provided on the back of the instrument, switch ‘OFF’ the main supply and affix “TO BE CLEANED” label as per SOP (“Status labeling”).

5.3 Precaution

- 5.3.1 Ensure that there is adequate lightening while carrying out the leak test.

6.0 ABBREVIATION(S):

- 6.1 SOP : Standard Operation Procedure
- 6.2 No. : Number
- 6.3 Q.A : Quality Assurance
- 6.4 BPR : Batch Packing Record
- 6.5 Mg : Milligram
- 6.6 Ml : Milliliter
- 6.7 Hg : Mercury
- 6.8 Mm : Millimeter
- 6.9 NRR : Non recoverable rejection

7.0 REFERENCE(S):

- 7.1 SOP: Status labeling

8.0 ANNEXURE(S):



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8.1 NA

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department (01) , Quality Assurance (01)

9.3 **Reference copy (s)** : Production department (01)

10.0 REVISION HISTORY:

S.No.	Revision No.	Change Control No.	Reason (s) for revision	Details of revision	Effective Date
01	00	NA	New SOP	NA	