



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Operation and Calibration of Leak Test Apparatus	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

To lay down a procedure for Operation and Calibration of Leak Test Apparatus.

**2.0 SCOPE:**

This procedure is applicable to operation and calibration of Leak Test Apparatus in the Quality control department.

**3.0 RESPONSIBILITY:**

Officer, Executive – Quality Control Department.

Head – Quality Control Department

**4.0 DEFINITION(S):**

NA

**5.0 PROCEDURE:**

**Make: Electrolab , Model: LT-101P**

**5.1 Operating Procedure:**

- 5.1.1 Place the test sample in the desiccator, which is filled with water to the desired level. Connect the vacuum tubing between desiccator and the “Vacuum Inlet” Nozzle provided on the back panel of the instrument.
- 5.1.2 Switch “ON” the Power switch. The LCD Module displays “LEAK TEST APPARATUS” followed by “SERIAL NUMBER “ of the instrument then changes over to “ Vacuum in Hg and Time”
- 5.1.3 Press the “SET” key and display shows “USER ID” Give the user ID by press UP or DOWN key to set the required alphabet or number. User ID can hold a maximum of six numbers or letters.
- 5.1.4 Press the “SET” key and the display to “SAMPLE ID” and the required data is entered by using up, down and shift key. “SAMPLE ID” can hold a maximum of eight number or letters.



### STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Operation and Calibration of Leak Test Apparatus	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

5.1.5 Press the “SET” key to “No. of Samples” and required data is entered by using UP, DOWN and SHIFT keys. “No. of samples” can hold a maximum of two numbers.

5.1.6 Press the “SET” key to “Batch No” and required data is entered by using UP, DOWN and SHIFT keys. “Batch No” can hold a maximum of eight numbers or letters.

5.1.7 Press the “SET” key to “VAC SET” and required data is entered by using UP, DOWN and SHIFT keys. “VAC SET” can hold a maximum of three numbers. (Maximum vacuum set is 699 mmHg).

5.1.8 Press the “SET” key to “HOLD TIME” and required data is entered by using UP,DOWN and SHIFT keys. “HOLD TIME” can hold a maximum of two numbers.

5.1.9 After all the data is entered then press the ENTER key. Now the press the run key to run the program which is set for required test. Now vacuum release takes place for 3 seconds and pump starts and vacuum built up which is displayed on the LCD module. If no vacuum builds up then press the dessicator top for a few seconds.

5.1.10 After complete the analysis instrument release vacuum automatically.

5.1.11 Press the print key to get full details of the test.

#### **5.2 Calibration:**

##### **5.2.1 Calibration of Vacuum Gauges :**

5.2.1.1 Calibration of vacuum Gauges is done by External Party.

Frequency - Six Monthly

5.2.1.2 If instrument is out of calibration, affix “UNDER MAINTENANCE” and call for service engineer.

5.2.1.3 Note calibration activity in the Instrument log book.

#### **5.3 Cleaning:**

5.3.1 Clean the Instrument properly with cotton cloth.

5.3.2 Clean the Desiccator properly with cotton cloth.

#### **5.4 Precaution:**

5.4.1 Instrument should be placed on stable and leveled support.



**PHARMA DEVILS**  
QUALITY CONTROL DEPARTMENT

**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Operation and Calibration of Leak Test Apparatus	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**6.0 ABBREVIATION (S):**

QCD – Quality Control Department  
SOP – Standard Operating Procedure

**7.0 REFERENCE(S):**

NA

**8.0 ANNEXURE (S):**

--NIL--

**9.0 REVISION CARD:**

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION