STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Operation and Cleaning of Leak Test Apparatus	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for the operation and cleaning of Leak test apparatus.

2.0 SCOPE:

This procedure is applicable for the operation and cleaning of Leak test apparatus in production department.

3.0 RESPONSIBILITY:

Production: Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Cleaning:

4.1.1 Ensure the instrument is switch off.

4.1.2 Remove the vacuum connection to desiccator and take it to the washing area.

4.1.3 Drain the dye solution.

4.1.4 Clean the gasket, lid & vessel with purified water from inside and outside.

4.1.5 Wipe the body of the apparatus with a cleaned cloth soaked in purified water.

4.1.6 Dry it with a cleaned dry cloth.

4.1.7 Clean the tubing and the outside body with cleaned dry cloth.

4.1.8 Fix the gasket and assemble the desiccators & lid and connect the vacuum connection.

4.2 Operation:

4.2.1 Ensure the cleanliness of Leak test apparatus.

4.2.2 Fill purified water in desiccator of leak test apparatus up to the required quantity. Prepare a dye solution by dissolving 300 mg of methylene blue crystals or adding 4 drops of stock solution of methylene blue dye (0.01% w/v TS USP), in approximately 4000 ml of Purified water.

4.2.3 Put the main switch ‘ON’.

4.2.4 Collect the number of blisters/strips equivalent to one full rotation of the forming

drum/plate/sealing roller for leak test.

4.2.5 Wear hand gloves and immerse the blisters/strips completely in the methylene blue solution.

4.2.6 Place the mesh over the blisters/strips then close in the desiccator.

4.2.7 Set the timer of the leak test apparatus.

4.2.8 Switch on the apparatus and apply vacuum till it reaches 381 mmHg and close the vacuum valve

4.2.9 Set the vacuum parameter at 120 seconds for blisters and 120 seconds for strips then maintain accordingly.

4.2.10 Machine should auto release the vacuum from dessicator after achieving the set parameter.

4.2.11 Open the dessicator and remove the blisters/strips.

4.2.12 Completely dry the blisters/strips using a clean lint free cloth / tissue paper.

4.2.13 Remove the hand gloves and discard it by putting into waste bin.

4.2.14 Keep the collected Blisters/strip on the table and take white A4 size paper.

4.2.15 Defoil the blisters/strips by using cutter/Scissor and remove the tablets/capsules on white paper and check for any physical deformation or presence of moisture / Color.

4.2.16 Check the tablets/capsules for other side by taking one more paper putting on the first one and accurately turn around the same to ensure on reverse side also.

4.2.17 Check any physical deformation or presence of moisture/color in tablets/capsules.

4.2.18 Discard the defoiled samples of tablets by putting into water.

4.2.19 In Case of any failure in Leak test, segregate the packed shipper, packed after last successful leak test performed as per the batch packing record. Also segregate the primary and secondary goods on the line. Inform to Production and QA head for necessary action.

4.2.20 Record the same in the respective BPR.

4.2.21 Leak test to be performed at the start of shift/batch and after every two hour of the batch run alternatively by production and QA. (Or as per frequency mentioned in BPR).

4.3 Precaution:

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

4.3.2 Ensure that the gloves are dry prior to defoiling of blisters/strips.

4.4 Limit:

4.4.1 No tablets/capsules shall be affected during leak test i.e. any penetration of water to observed

in any strip/blister.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S) :

BPR : Batch Packing Record

Q.A. : Quality Assurance

mg : Milligram

ml : milliliter

Mm Hg: millimeter of mercury

w/v :Weight/Volume

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---