



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Leak Test Apparatus (Model: LT-101P)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down the procedure for Cleaning and Operation of Leak Test Apparatus.

2.0 SCOPE:

2.1 This procedure is applicable for Cleaning and Operation of Leak Test Apparatus in Production Department.

3.0 RESPONSIBILITY:

3.1 Technical associate Production : Cleaning and Operation of Leak Test Apparatus

3.2 Officer/ Executive Production : Supervision of Cleaning and Operation

3.3 Head Production : SOP Compliance

3.4 IPQA : SOP Compliance

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 CLEANING:

5.1.1 Ensure that leak test apparatus is switched "OFF".

5.1.2 Drain the dye solution from desiccator of leak test apparatus in a double poly bag and seal the poly bag with cable tie and kept it into container with under process status label having status as "water to be discard".

5.1.3 Transfer the container to washing area for disposal.

5.1.4 Clean the outer and inner surface of leak test apparatus with a wet lint free cloth followed by dry lint free cloth.

5.1.5 Dry the apparatus with a clean dry lint free cloth.

5.1.6 Clean the tubing and body with a dry lint free cloth.

5.1.7 After cleaning of apparatus, fill the desiccator with purified water upto the separator and add ten to twelve drops of methylene blue indicator solution and close the desiccator.

5.1.8 Finally wipe out the surface of the apparatus with dry lint free cloth.

Frequency of Cleaning: Daily at the start of shift.

5.2 OPERATION OF LEAK TEST APPARATUS FOR BLISTER/STRIPS:










PHARMA DEVILS

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- 5.2.1 Collect the blisters / strips continuously equivalent to one full rotation / no. of pack forms by one stroke of the forming roller / plate for leak test with product.
- 5.2.2 Carry the collected blisters / strips for leak test in sample polybag labeled with “sample for in-process”.
- 5.2.3 Ensure that power supply of leak test apparatus is on.
- 5.2.4 Place the blister/strips by lifting the separator and placing it back, close the desiccator
- 5.2.5 Set the VAC SET (vacuum) as 380 mm of Hg for blister/strips packing by pressing key SET followed by pressing Key   then press , for moving cursor left and right use .
- 5.2.6 Set the timer for hold time after pressing SET key again. Change the value by pressing Key   then press .
- 5.2.7 Set the HOLD TIME as one minute for blisters and two minutes for strips packing.
- 5.2.8 Press the RUN/STOP switch to start the vacuum.
- 5.2.9 Leak test apparatus will run automatically and achieve the set vacuum pressure and run up to set HOLD TIME and will release the vacuum automatically.
- 5.2.10 Open the desiccator and take out the blisters/strips.
- 5.2.11 Completely dry the blisters/strips using a lint free cloth or tissue paper.
- 5.2.12 Visually inspect the blisters/strips for any leakage or presence of blue stains before de-foiling.
- 5.2.13 Wear the gloves and de-foil the blisters/strips and check for any physical deformation or presence of moisture/blue stain on tablets/capsules.
- 5.2.14 Discard the product into container kept for in-process rejects.
- 5.2.15 Discard de-foiled blisters/strips into waste bin.
- 5.2.16 Record the observation in batch packing record.
- 5.2.17 In-case of leak test failure, stopped the packing activity. Failure shall be reported as event and investigated as per SOP (“Event management”). The fate of batch shall be decided based on the event outcome.
- 5.3 **OPERATION OF LEAK TEST APPARATUS FOR HDPE BOTTLES ON BULK LINES:**
- 5.3.1 In bulk packing, leak test for bottles shall be done with polyester coil (Without Product).
- 5.3.2 Polyester coil will be dispensed as per issuances of additional raw/Packing material (Refer to SOP titled as Issuance of Additional Raw / Packing Material) and to be kept in primary packing material room.
- 5.3.3 Take polyester coil in sample polybag labeled with “sample for in-process” from primary packing material room and carry it to filling area.
- 5.3.4 Take empty HDPE bottle from line conveyor before bulk counter machine and apply challenge test label on it.



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- 5.3.5 Fill sufficient quantity of polyester coil into empty HDPE bottle up to the neck of bottle and ensure that polyester coil do not touch the bottle sealing area.
- 5.3.6 Place the bottle on conveyor belt before inline capper machine.
- 5.3.7 Collect the sealed bottle after induction sealing machine.
- 5.3.8 Carry the sealed bottle for leak test in sample polybag labeled with “sample for in-process”.
- 5.3.9 Ensure that power supply of leak test apparatus is on.
- 5.3.10 Place that sealed bottle in leak test apparatus by lifting separator and placing back it and then close the desiccator.
- 5.3.11 Set the VAC SET (vacuum) as 380 mm of Hg for HDPE bottle packing by pressing key SET followed by pressing Key \triangle ∇ then press \leftarrow , for moving cursor left and right use \rightarrow .
- 5.3.12 Set the timer for hold time after pressing SET key again.
- 5.3.13 Set hold time as two minute for HDPE bottle by pressing Key \triangle ∇ then press \leftarrow .
- 5.3.14 Push the RUN/STOP switch to start the vacuum.
- 5.3.15 Leak test apparatus will run automatically and achieve the set vacuum pressure and run up to set HOLD TIME and will release the vacuum automatically.
- 5.3.16 Open the desiccator and take out the bottle.
- 5.3.17 Completely dry the bottle using lint free cloth or tissue paper.
- 5.3.18 Visually inspect the bottle for any leakage.
- 5.3.19 De-foil the bottle and check for any presence of moisture or blue stain by placing polyester coil on white lint free cloth or white tissue paper.
- 5.3.20 Discard bottle, closure and polyester coil after examine into waste bin.
- 5.3.21 Record the observation in batch packing record.
- 5.3.22 In-case of leak test failure, stopped the packing activity. It shall be reported as event and investigated as per SOP (“Event management”). The fate of batch shall be decided based on the event outcome.
- NOTE: Leak test shall not be feasible for HDPE bottles of 850 CC and more than 850 CC. Only physical verification of filled bottle (with product) sealing shall be done.**

5.4 OPERATION OF LEAK TEST APPARATUS FOR POUCH PACK:

- 5.4.1 Collect the filled pouch with product from machine for leak test and labeled it with “sample for in-process”.
- 5.4.2 If manual packing of product in pouch to be done then polyester coil will be filled in pouch (without product) and same will be used for leak test and labeled with “sample for in-process”.
- 5.4.3 Polyester coil will be dispensed as per issuances of additional raw / Packing material (Refer to SOP titled as Issuance of Additional Raw / Packing Material) and to be kept in primary packing material room.



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- 5.4.4 Ensure that power supply of leak test apparatus is on.
- 5.4.5 Place the sealed pouch by lifting the separator and placing it back, close the desiccator.
- 5.4.6 Set the VAC SET (vacuum) as 380 mm of Hg for pouch pack by pressing key SET followed by pressing Key \triangle ∇ then press $\left[\leftarrow \downarrow \right]$.
- 5.4.7 Set the timer for hold time after pressing SET key again.
- 5.4.8 Set hold time as two minute for pouch pack by pressing Key \triangle ∇ then press $\left[\leftarrow \downarrow \right]$.
- 5.4.9 Push the RUN/STOP switch to start the vacuum.
- 5.4.10 Leak test apparatus will run automatically and achieve the set vacuum pressure and run up to set HOLD TIME and will release the vacuum automatically.
- 5.4.11 Open the desiccator and remove the pouch pack.
- 5.4.12 Completely dry the pouch pack using lint free cloth or tissue paper.
- 5.4.13 Visually inspect pouch pack for any leakage or presence of blue stains before opening.
- 5.4.14 Wear gloves and open pouch pack to check any presence of moisture or blue stain on white lint free cloth or white tissue paper.
- 5.4.15 Discard pouch and polyester coil after examine into waste bin.
- 5.4.16 Discard the product into container kept for in-process rejects.
- 5.4.17 Record the observation in batch packing record.
- 5.4.18 In-case of leak test failure, stopped the packing activity. It shall be reported as event and investigated as per SOP ("Event management"). The fate of batch shall be decided based on the event outcome.

5.5 FREQUENCY OF LEAK TEST:

- 5.5.1 Leak test to be performed at the start, end of batch, after every one hour of the batch execution and as per frequency given in batch packing record.

5.6 PRECAUTION':

- 5.6.1 Sufficient quantity of polyester coil to be filled in HDPE containers up to neck of bottle.
- 5.6.2 Polyester coil should not interfere with sealing area of HDPE container and pouch pack.
- 5.6.3 Fill desiccator with purified water only up to the separator in leak test apparatus.
- 5.6.4 Ten to twelve drops of methylene blue indicator solution must be added in the leak test apparatus after refilling with purified water only up to the separator of desiccator.
- 5.6.5 Ensure that methylene blue solution container labeled as per SOP titled as "Receipt storage and usage of reagents, solvents and acids".
- 5.6.6 Ensure adequate light while carrying out the leak test.



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5.6.7 If any breakdown observed during operation of leak test apparatus. Breakdown maintenance intimation request will be raised. After rectification of leak test apparatus breakdown, leak test will be re-initiate on fresh sample.

Note: During execution of validation batch (bulk line and pouch line) leak test to be done with product and in other than validation batch leak test to be done with polyester coil (without product).

6.0 ABBREVIATION (S):

- 6.1 BPR : Batch Packing Record
- 6.2 HDPE : High density poly ethylene
- 6.3 ml : Milliliter
- 6.4 Hg : Mercury
- 6.5 Mm : Millimeter
- 6.6 Min. : Minutes
- 6.7 mg : Milligram

7.0 REFERENCES(S):

- 7.1 SOP: Receipt storage and usage of reagents, solvents and acids.
- 7.2 SOP: Issuance of Additional Raw / Packing Material

8.0 ANNEXURE(S):

- 8.1 NA

9.0 DISTRIBUTION:

- 9.1 Master Copy : Quality Assurance
- 9.2 Controlled Copy (S): Production department (2)
- 9.3 Reference Copy (S): Production department (2)

10.0 REVISION HISTORY:

S.No.	Version No.	Change control No.	REASON (S) FOR REVISION	DETAILS OF REVISION	Effective Date
1.	00	NA	New SOP	NA	