

Standard Operating Procedure

Title: Vacuum Leak Testing Procedure (Blue Dye Test)

1.1. For Blister Pack Tablets

Vacuum Leak test of tablet blister packs are to be done at the time of start-up and after maintenance, after changing either lidding or base foil or PVC. VLT to be done on every hour while the machine is running unless otherwise directed by the area Manager to increase the amount of Blister Leak tests. See **Form-175 and Form-180**.

8 blisters should be leak tested from the shipper which is being packed. These must be the top 4 packs of a bundle to ensure consecutive blisters are taken. The blisters are taken to check that no damage has been done to them during carton loading or while packing in the shipper. Test pressure will be -60 Kpa for 60 seconds.

2. Leak Test procedure

2.1. Using Desiccator

2.1.1. Place the packs or blisters to be leak tested into the Desiccator containing a Blue Dye solution. Place a wire mesh and a weight on top of the packs ensuring the Blue Dye solution covers the packs. Slide the lid onto the Desiccator.

2.1.2. Turn Vacuum valve "on" of the Leak Tester and ensure Vacuum Regulator valve is fully open.

2.1.3. Close the Vacuum Release valve on the Desiccator.

2.1.4. Use the Regulating valve to adjust the vacuum until the gauge reads minus 60 kPa by slowly closing the Vacuum Regulator valve.

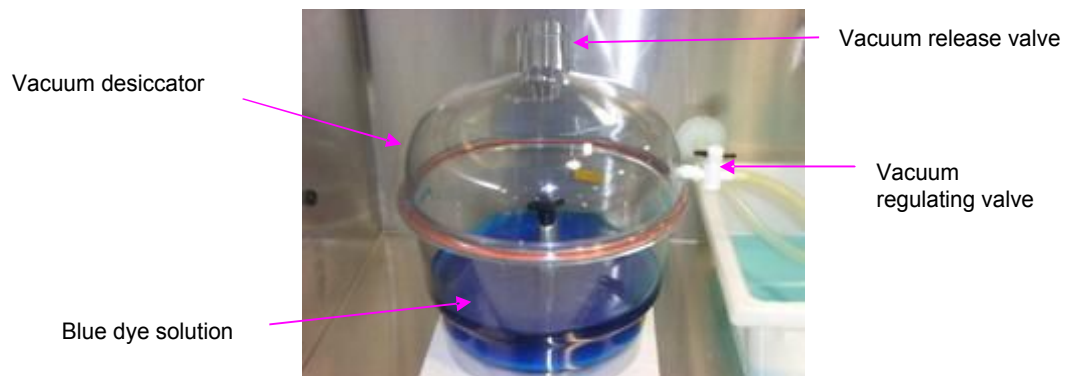
2.1.5. When the correct pressure is reached, maintain for exposure time for 60 seconds, look for telltale bubble flows in the Desiccator, which may indicate leakers.

Turn "OFF" Vacuum valve and fully open the Vacuum Regulator. Release the vacuum on the Desiccator. Turn "OFF" the Vacuum pump.

DO NOT REMOVE SAMPLES YET.

Wait for another 60 seconds as recovery time to allow Blue Dye to enter faulty containers.

Figure: 1 Vacuum Leak Test Apparatus



2.2. Takes samples out and rinse with water.

2.3. Visually inspect each blister and check that none contains Blue dye.

For non-clear tablet blisters, thoroughly dry the external face of the blister with an absorbent cloth, then pop each tablet out and inspect both the tablet and the pocket.

2.4. If there is a Leak Test failure, re-sample and re-test. If further failures occur, stop filling and immediately notify the Fitter and Manager. The product that has gone through up to the point of the last check should be reworked to check for other possible failures.

Note: Blistered products produced with bad blisters are reworked.