

# Standard Operating Procedure

## Title: Tablet Packing - Start-Up and In-Process Testing

10.	Vision System Camera Test .....	10
11.	Summary of Changes .....	10

### Procedure

#### 1. Overview

This SOP explains the procedure for all Start-Up and In-Process Tests required to be conducted by Production Operators in the Tablet areas. You **WILL NOT** use all of these tests for a batch. The MI Sheet will guide you through which needs to be done for a batch.

#### 2. Operators Names in MI Sheet Logbook

At the start of the shift, or at the start of a batch, operators are to enter their initials into the table provided in the MI sheet Logbook. The table format is as follows:

- Time/Date: Time date must be in the format hh.mm/dd.mm.yyyy
- Initial: Initials of all operators come in contact with this BPN.
- Work title: e.g. Operator, Dispenser etc.

If operators are attending the line to cover breaks, it is to be noted they were on the line by entering their name in the table in the MI sheet Logbook.

This applies to **ALL** tablet lines and is required for traceability purposes.

The Maintenance System is utilised to ensure, that if any work by maintenance staff is performed on the line, that the type of work, time and date will be recorded.

#### 3. Tablet Sampling

Please refer to [SOP WAR-080](#) for the procedure on tablet sampling.

#### 4. Machine Line Opening Challenges and In-process Checks

##### 1. Protruding Product Sensor Test (see Part C of topic 1)

This test is performed at the start of every batch.

##### Procedure

Operator will rotate one tablet from its blister pocket so that protrudes from its pocket and start the machine. The tablet should be detected and the machine should stop. Again place on tablet on the web, not in a pocket and start the machine. The tablet should be detected and the machine should stop. If any of these tests fails, operator should readjust the Protruding Product sensor (item18) and repeat the test.

##### 2. Pin Hole Detector Test (Part B of topic 1)

The Pin Hole Detector (item 13) is only used for Aluminum base foil. It is designed to detect if the cold forming of the blister pockets has created a hole or crack greater than 100 microns, which may limit the life of the product to be packed inside the blister. This test should be done at the start of each batch.

##### Procedure

# Standard Operating Procedure

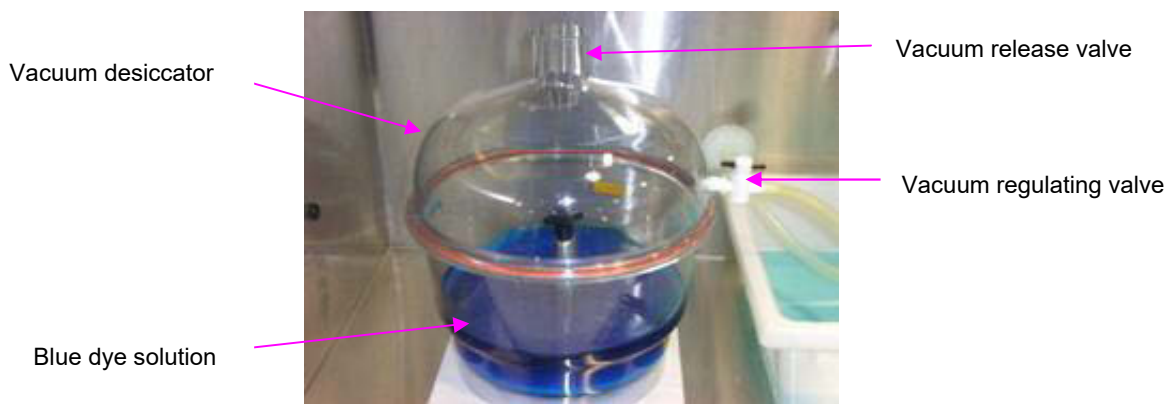
## Title: Tablet Packing - Start-Up and In-Process Testing

### Procedure

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

Turn Vacuum valve “on” of the Leak Tester and ensure Vacuum Regulator valve is fully open. Close the Vacuum Release valve on the Desiccator. Use the Regulating valve to adjust the vacuum until the gauge reads minus 60 KPa by slowly closing the Vacuum Regulator valve.

### Figure: 2 Vacuum Leak Test Apparatus



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

Turn “OFF” Vacuum valve and fully open the Vacuum Regulator. Release the vacuum on the Desiccator. Turn “OFF” the Vacuum pump. Wait for another 60 seconds as recovery time to allow dye to enter into faulty blisters/packs.

Takes samples out and rinse with water. Visually inspect each blister and check that none contains dye.

If there is a Leak Test failure, re-sample and re-test. If further failures occur, stop filling and investigate.

### 5. Barcode Sensor Test for Cartons and Leaflets (Part G of topic 1)

The Code Sensor (item 36) operates by using optical scanning heads that translate a printed signal (a bar code) into a series of electronic signals. These signals are compared with the Reference Code or commonly called “Pharmacode” loaded into the Code Reader. If an incorrect bar code is encountered, the carton will be rejected.

# Standard Operating Procedure

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This is an in-process check and should be carried out by the packing process operators in every half an hour. The purpose of this check is to make sure that all cartons have correctly embossed data and printed information.

### Procedure

Collect one bundle of cartons from the stretch bender as shown in the picture **Part I**.

Batch number and expiry date embossed in here



Check selected bundle for:

Correct and legible batch number and expiry date embossed on the carton.

Cartons folder neatly with no creases or dents and facing the same way

Correct number of cartons in bundle

Possible damage may be pinholes in foil side of blister.

Crushed blisters

### Some Examples of Opening Components for Tablet Packing Line



1. An IBC bin filled with bulk tablets



2. Empty carton to be packed



3. Leaflet to be packed



4. Corrugated carton or shippers

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Which lines conduct this test?	All tablet packing line
How often is the test conducted?	Every half hour. <b>NOTE: Operators should check Appearance/Quality every 5 minutes</b> but only record results every half hour.
Where are the results recorded?	Relevant batch documentation (MI sheet).
How do I do it?	<ol style="list-style-type: none"> <li>Select one blister from each of the three or four lanes and 2 packs from after the End of Process.</li> <li>Check selected blisters for: <ul style="list-style-type: none"> <li>Correct print registration</li> <li>Correct BPN</li> <li>Correct Expiry date</li> <li>General appearance</li> <li>Perforation (if applicable) Tear test.</li> </ul> </li> </ol>
What do I do if appearance of information is incorrect?	<u>Immediately stop the line.</u> Contact Fitter to rectify problem and inspect finished goods to make sure no reject blisters have been packed. Refer to relevant QA personnel to decide if a rework is necessary.
What Do I do with all In-Process Samples after testing	All empty cartons are to be rejected. Blisters are to be De-blistered.

### 8. Carton Coding Appearance and Correct Information

Which lines conduct this test?	All tablet packing line
How often is the test conducted?	Every half hour. <b>NOTE: Operators should check Appearance/Quality every 5 minutes</b> but only record results every half hour.
Where are the results recorded?	In the relevant batch documentation (MI sheet).
How do I do it?	<ol style="list-style-type: none"> <li>Select one bundle of cartons.</li> <li>Check selected bundle for: <ul style="list-style-type: none"> <li>Correct BPN and expiry date</li> <li>Cartons folder neatly with no creases or dents and facing the same way</li> <li>Correct number of cartons in bundle</li> <li>Possible damage may be pinholes in foil side of blister.</li> <li>Crushed blisters.</li> </ul> </li> </ol> <p><b>Vacuum Leak Test Samples:</b> Take the top two (2) cartons from a carton bundle. These must be checked for damage during cartoning.</p>
What do I do if appearance or information is incorrect?	<u>Immediately stop the line.</u> Contact Fitter to rectify problem and <b>inspect</b> finished goods to <b>make sure no reject cartons are packed.</b> Refer to relevant QA personnel to decide if a rework is necessary
What do I do with all In-Process Samples after testing?	All empty cartons are to be rejected. Blisters are to be De-blistered.