

Standard Operating Procedure

Title: Manufacturing Instruction For Tablet Packing

Form-560	Test and Retention Sample Log Book
QMS-020	Documentation Rule for GMP Documents
QMS-035	Deviation Report System
QMS-090	Example-Evaluation of Batch Documentation for Tablet Packing
WAR-075	Example-Tablet Dispensary Procedure
WAR-080	Example-Raw Material Tablet Sampling by Dispensary
WAR-040	Finished Goods Transfer to Quarantine and Distribution Warehouse
MAN-055	Procedures for Line Clearance, Line Opening and Line Cleaning
MAN-075	Example-Tablet Packing Machine and Cartoner-construction, operation and cleaning
QMS-040	Shelf Life of Product
MAN-065	Example-Operation of Barcode Reader
MAN-110	Example-Operation of Checkweigher
MAN-095	Vacuum Leak Testing Procedure
MAN-035	Packaging Configuration for Production Line
MAN-115	Example-Tablet Packing-Start up and In-process Testing
MAN-060	Reconciliation of Component and Product
MAN-120	Example-Packed Tablet Sampling by Production Personnel for Testing

EHS Statement

No EHS impact is justified.

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1. General Instruction

1.1. Phases

Manufacturing Instruction for tablet packing consists of three main phases. Each phase number is a four digits numerical number starting with a single digit e.g. 1, 2, 3 for each separate phase. Therefore each phase can be identified with a whole number like 1000, 2000 or 3000.

1.2. Sub-phases

Each phase can be split into several sub-phases depending on the nature of the phase and ease of identification. The difference between one sub-phase to another is kept 50. Since there could be more than one sub-phases in a phase, the first instruction of a phase is the first instruction of a sub-phase. For example, the first instruction of phase 1000 starts with the sub-phase 1050.

1.3. Instruction number



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- In process check – Shippers
- Complete the phase

Sub-Phase 2300

- Reconciliation of products and components

2.3. Phase 3000: MI sheet logbook

Sub-Phase 3050

- Sign all people working in the MI sheet log book
- Complete the phase

3. Protocol: Manufacturing Instruction for Tablet Packing

PROTOCOL

MI SHEET FOR TABLET PACKING - PRODUCTION

Batch Production Number:

Product Name:

Product Code:

Issued By: (Quality Assurance)	Checked By: (Production)	Authorized by: (Quality Assurance)
Date:	Date:	Date

Purpose and Reason for the protocol

This Protocol contains step by step instruction for the operators to follow during tablet dispensing, tablet blister packing and final packing.

Special Instructions

1. To ensure compliance please remember to **sign and date all entries**.
2. The shaded areas needed a **Second Independent check, Signature and Date** above the highlighter.
3. To ensure complete documentation of this process please include all additional forms used during the manufacture of this batch and utilize the checklist on next page of this protocol.
4. All entries are to be clearly written directly onto the MI sheet, signed and dated.
5. If additional pages of forms are required staple them with this document.
6. If you need a **Deviation Report** to rise use **Form-450** and follow **SOP QMS-035** for understanding.

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BPN:			Issue Date:			
Product Code:			Packing Line			
Product Name:			Page:			
Phase: 2000			Operating group : Blister Packing			
Sub-Phase 2050/Instruction no. 0010 Operator to sign that the batch has started			Sign batch started:			
Sub-Phase 2050/Instruction no. 0015 If any deviation occur during the process, raise a deviation report, follow SOP QMS-035			Follow QMS-035			
Sub-Phase 2050/Instruction no. 0020 At the start of each shift record in the log book MI sheet the surname of all people working on this BPN on your line including technicians and trainees. Also record new people on the line as they arrive.						
Sub-Phase 2050/Instruction no. 0025 Perform Line clearance according to SOP MAN-055. Fill in the form Form-160			Sign Line clearance completed:			
Sub-Phase 2050/Instruction no. 0030 Set up the blistering machine, the cartoner, and perform the line opening according to SOP MAN-075			Follow SOP MAN-075			
Sub-Phase 2050/Instruction no. 0035 Enter the Batch Production number and the product code as appeared on the information board.			This BPN: This product code:			
Sub-Phase 2050/Instruction no. 0040 From the warehouse: Enter the material and batch numbers of the materials requisitioned from the ware house for this BPN. Enter the full material number. Attach samples to a sample sheet Form-120 for each batch number of each printed material.						
TO #	Material code	Description	Lab. B/N	Confirmed qty.	Sign	Date
Sub-Phase 2050/Instruction no. 0045 Enter the material and batch number of printed carton.			Carton material no: Carton batch no:			
Sub-Phase 2050/Instruction no. 0050 Enter the material and batch number of PVC film.			PVC material no: PVC batch no:			

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Challenge the machine for running in foil	
Sub-Phase 2050/Instruction no. 0155 Challenge the carton bar code reader according to SOP MAN-065	Sign carton bar code reader OK:
Sub-Phase 2050/Instruction no. 0160 Challenge the leaflet bar code reader according to SOP MAN-065	Sign leaflet bar code reader OK:
Sub-Phase 2050/Instruction no. 0165 Set and challenge the checkweigher according to SOP MAN-110. If the nominal weight is changed during the process refer to the same SOP.	Follow SOP MAN-110 Sign checkweigher set correct:
Sub-Phase 2050/Instruction no. 0170 Check set-up cartons removed off line according to SOP MAN-075.	Sign setup cartons removed:
Sub-Phase 2050/Instruction no. 0175 Check guide roll on the cartonner infeed has been adjusted to suit blister height according to SOP MAN-075	Sign guide rail adjusted:
Sub-Phase 2050/Instruction no. 0180 Check the recipe in compaker, packliner and scanware checkweigher has been reloaded according to SOP MAN-075	Sign comp/pack liner reloaded: Sign scanware c/w reloaded:
Sub-Phase 2050/Instruction no. 0185 For the following tests failures must be recorded in the batch comment to ensure a complete record of event.	
Sub-Phase 2050/Instruction no. 0190 Perform the vacuum leak test at the beginning of the batch, after maintenance of the thermo-former, after the change of foil or film and one hourly, on four consecutive blisters according to SOP MAN-095. Record the result of the Vacuum Leak Test in the vacuum Leak Test phase.	Follow SOP MAN-095 Sign start up VLT passed:
Sub-Phase 2050/Instruction no. 0195 Perform the appearance and correct blister and carton coding checks half hourly and record in the "in process checks" phase.	
Sub-Phase 2050/Instruction no. 0200 Check that all entries have been made for this phase.	Check phase completed:
Sub-Phase 2100/Instruction no. 0010 Packing The operator must constantly check the quality of the print on the foil during the entire run.	
Sub-Phase 2100/Instruction no. 0015 Record the time and date that packing has started.	Time/Date packing started:
Sub-Phase 2100/Instruction no. 0020 Pack two blisters of fifteen tablets into each coded carton. Place individual carton into shipper.	



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In process checks are to be performed every half hour at the start up and the end of the batch. Follow SOP MAN-115					Follow SOP MAN-115.			
Sub-Phase 2250/Instruction no. 0020 In-process checks table Blister and Cartons. Time format is HHMM. Enter the signatures. For additional spaces use "In Process Check-Blister and Carton" Form (Form-200).					Form-200			
Time	App Blstr	Blstr BPN	Blstr Exp	App carton	Carton BPN	Carton Exp	Shipp #	Sign
Sign all blister and carton inspection passed:								
Sub-Phase 2250/Instruction no. 0025 In process check table for shipper For additional spaces use "In Process Check-Shipper" Form (Form-195).					Form-195			
Time	App. Ship.	BPN Ship Label	Exp Ship Label	Shipper #	Sign			
Sign all shipper inspection passed:								
Sub-Phase 2250/Instruction no. 0030 Sign once all in process checks have been completed					Sign all in process checks complete:			
Sub-Phase 2250/Instruction no. 0035 Retention and Test Samples Take retention and test samples for QA evaluation and laboratory analytical testing according to SOP MAN-120. Log into "Test and Retention Samples Logbook" Form-560.					Follow SOP MAN-120 Form-560			
Sub-Phase 2250/Instruction no. 0040 If any additional issue of component is made enter the data from the re-issued Material Transfer Orders into the following table. Take all printed material samples from the additional issues and					Follow SOP MAN-055 Form-120			

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	No. of rejected tablet: No. of returned leaflet: Tablet % yield:
Sub-Phase 2300/Instruction no. 0045 Place all rejected tablets and cartons in the security reject bins. Sign packing completed.	Sign packing completed:
Sub-Phase 2300/Instruction no. 0050 Check all entries have been made for this phase. Check all DR are completed. Sign the blister packing MI sheet off and send all MI sheets to QA for evaluation	Check & Sign phase completed: Sign MI sheet off:
Sub-Phase 2350/Instruction no. 0010 Collect all the batch documents (MI Sheets), records and forms together and logged into Form-150 according to SOP MAN-120. Send the batch document for QA evaluation and release for sale.	Follow SOP MAN-120 Form-150

BPN:	Issue Date:			
Product Code:	Packing Line:			
Product Name:	Page:			
Phase: 3000		Operating group : Logbook		
Sub-Phase 3050/Instruction no. 0010 At the start of each shift record in the log book MI sheet the surname of all people working on this BPN on your line including technicians and trainees. Also record new people on the line as they arrive. For additional spaces use "People Working In Tablet Packing Line" Form (Form-205).		Form-205		
Shift #	Date	Time	Initial	Work title
Sub-Phase 3050/Instruction no. 0015 Check all entries have been made for this phase		Check phase completed:		