Form-150	Example-Logbook for Tablet Batch Documents
Form-210	Goods Booking Slip
Form-450	Deviation Report Form
Form-540	Pallet Booking Information
Form-555	Batch Documentation Checklist for Tablet Packing
Form-560	Test and Retention Sample Log Book
Form-565	QA Inspection Sheet
TEM-145	Finished Product Specification and Test Report Template
TEM-150	Packaging Material Specification and Test Report
TEM-155	Bill of Materials Template
QMS-020	Documentation Rule for GMP Documents
MAN-055	Procedures for Line Clearance, Line Opening and Line Cleaning
MAN-080	Example-Manufacturing Instruction for Tablet Packing
MAN-060	Reconciliation of Component and Product
QMS-035	Deviation Report System
QMS-065	Rework Procedure
QMS-085	Example-Checklist for Batch Documentation
MAN-005	Clothing Requirements Inside the Factory Area.
MAN-060	Reconciliation of Component and Product
QMS-075	Determination of Batch Disposition
QMS-070	Authorised Person
QMS-125	Quality Concern Investigation Process
MAN-120	Example-Packed Tablet Sampling by Production Personnel for Testing
LAB-045	Retention Samples - Laboratory
LAB-065	Finished Goods-Laboratory Testing and Documentation

EHS Statement

- Protective eyewear and gloves should be worn when handling 70% IPA.
- Care must be taken to avoid injury to personnel or damage to the sample.
- Product packed in glass requires extra care to be taken.
- QA staffs must observe clothing requirements when collecting samples (see **SOP MAN-005)**

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carton from which the test samples were taken. Then sign on the Sample Logbook (**Form-560**)

3.2.4. Batch documentation should be received within 24 hours of completion of packing.

4. Receiving/Collecting of Batch Documents

4.1. Batch Documents are delivered by production to the designated Batch Document office for each process area and are placed in the incoming tray labelled "Completed Batch Documents". Batch Documents are logged into the Batch Documentation Logbook, (**Form-150**) by production staff and must be signed and dated as logged out by the QA Staff before QA evaluation.

4.2. Batch Documentation is to be evaluated by the authorised QA Staff in the Batch Documentation office. Any Batch Documentation errors found are to be flagged by a Post-it note and placed into the Process Manager's Red incoming tray labelled "Corrections". Process managers are responsible for checking the correction trays daily to ensure prompt resolution of errors.
NOTE: The use of 'Post-it' notes is restricted to the flagging of an error, there is to be no GMP information recorded onto the post-it note. The 'Post-it' note is to be removed only by the QA Staff evaluating the batch documentation.

4.3. Once the Batch Documentation error has been corrected, the Batch Documents are placed by production into the Green incoming tray labelled "Corrected Batch Documents" for collection by the QA Staff. The QA staff will sign and date the Batch Documentation Logbook prior to removal from the office.

5. Evaluation of Batch Documents

5.1. Batch Documents are checked against the appropriate "Batch Documentation Checklist" (**Form-555**) (see **SOP QMS-085**). This checklist is printed by production and delivered with the Batch Documents.
NOTE: Use RED pen to perform all QA checks on the "Batch Documentation Checklist" Form.

5.2. Check that Section 1 of the form is correctly filled up. Each document listed on section 2 of the checklist has been received and that all relevant paperwork is of the same BPN and the same manufacturing Material Code. Write "N/A" on page 1 next to any documents not applicable to the BPN. Check any additional forms are attached with the MI sheet.

5.3. Consult any SOPs listed above to ensure target limit results have been attained.

5.4. Each page of each document received must be evaluated for accuracy and completion.

5.5. Any issues with documentation that is less than the criteria listed below should be actioned as detailed in Section 4 above.

5.5.1. **A DR (See SOP QMS-035) must be raised if any of the following are noted during evaluation of Batch Documents:**

5.5.1.1. Critical entries have been left blank, e.g. missing signature on Line Clearance.

5.5.1.2. Excessive, (i.e. greater than 5) non-critical entries are missing. (A production operator may correct non-critical entries, e.g. missing one tick, without raising a DR.)

5.5.1.3. An entry is recorded incorrectly and not corrected, e.g. incorrect date.

5.5.1.4. Documents indicate there has been an absence of due care, e.g. illegible entries; multiple (greater than 5) entries marked as corrected by operators.

9.1. Authorised QA Person responsible for batch release for sale will ensure the following before a batch is released for sale:

9.1.1. Batch documents (completed MI Sheet, Forms and Records) are correctly checked for completeness and consistency.

9.1.2. All in-process and finished product testing were done according to Finished Product Specifications and Test Report.

9.1.3. Stability samples are taken according to stability program. Retention samples are correctly checked and managed.

9.1.4. Batch documentation checklist (**Form-555**) is correctly checked, filled up and signed by both authorised production staff and QA Staff.

9.1.5. QA Inspection Sheet (**Form-565**) is correctly filled up, signed and no data has inconsistency or no test result is out of specification.

9.1.6. All Deviation Reports (**Form-450**) raised were successfully completed, corrective actions are implemented and preventative actions are listed.

9.2. If all the actions are meeting the in-house and regulatory requirements, the Authorised QA Person will sign the Batch Document Checklist to release the batch.

9.3. Authorised QA Person will produce appropriate number of RELEASED stickers, sign and send those to warehouse to labelled the pallets in Quarantine.

9.4. For any unsuccessful inspection or non conformance authorised QA Person will hold the batch before the non-conformance is investigated (See SOP **QMS-125**) and the assignable cause will be determined.

9.5. For any critical or serious defect or non-conformance authorised QA Person will reject the batch by stamping a RED reject stamp on the checklist and sign the form. Appropriate number of reject stickers will be produced and signed and send to warehouse to stick those onto the rejected pallets.

10. Rework

10.1. If a BPN is reworked, see SOP **QMS-065** and ensure the following is received: Form-380 should be filled out by production and sent with relevant Batch Documentation again for evaluation and consequent release of the batch.

11. Summary of Changes

Version #	Revision History
QMS-090	New

End of Procedure

Batch Reconciliation Sheet for Tablet Packing

(Ref. SOP MAN-060; MAN-080)

	Material Code	Lab. Batch Number	Received Qty	Rejected Qty	Returned Qty	Sent to IP
Slip Sheet						
Shippers						
Shipper labels						

Tablets Reconciliation		Cartons Reconciliation	
A. No. of Tablets Received		A. No. of Cartons Received	
No. of Tablets Packed		No. of Cartons Packed	
No. of Tablets Sampled		No. of Cartons Sampled	
No. of Tablets Rejected		No. of Cartons Rejected	
No. of Tablets Returned		No. of Cartons Returned	
B. Total Tablets Used		B. Total Cartons Used	
(B/A) x 100 = Tablets Yield		(B/A) x 100 = Cartons Yield	

Goods Booking Slip

(Ref. SOP MAN-080; MAN-035; WAR-040)

Finished Product Movement Direction

Storage Type	Storage Bin	Sign	Date
Q (Quarantine)			
Finished goods Store			
Comment if item is rejected:			

Goods Booking Number: YYXXZZZZ	**Date:**
Product Code:	**Product Name:**
Batch Production Number (BPN):	**No. of pallets:**
Process Line:	**No. of retention Samples:**

Item #	Material Code	Material Description	Mfg's Batch #	Initial Qty.	Qty. after sampled	Date & Qty. after Re- sampled (if applicable)	
							Date:

Receiving store person:	**Sign:**	**Date:**
Sampler:	**Sign:**	**Date:**
Sampler (if re-sampled):	**Sign:**	**Date:**

Deviation Report Form

(Ref. SOP QMS-035; MAN-080)

3. QA Management Response Tasks

QA Manager to evaluate the deviation and assess the potential impact to the product quality, validation and regulatory requirement. Asses efficacy of the actions taken. Approve the DR)

Name:	**Sign:**	**Date:**
Follow up Tasks		
Task 1:		
Assigned To	**Planned finished date**	
Confirm Task 1 completed:	**Sign:**	**Date:**
Task 2:		
Assigned To	**Planned finished date**	
Confirm Task 2 completed:	**Sign:**	**Date:**
QA manager Approval Task		
Confirm follow up tasks completed:	**Sign:**	**Date:**

List all follow up tasks in the QA Metrics Sheet. Place the completed report into completed DR file. If a DR is process related affecting any BPN, attach one completed copy with the batch documents.

Batch Documentation Checklist For Tablet Packing

(Ref. SOP QMS-075; QMS-085; QMS-090)

Production is to complete Sections 1 & 2
Quality Assurance Department is to complete Section 3
SECTION 1

PRODUCT NAME:	**BPN:**	**CODE:**

Tick appropriate boxes	✓
Put a N/A against boxes which are NOT APPLICABLE	N/A

SECTION 2
The following manufacturing documents and samples must accompany the checklist:

	Production ✓	Prod **Initial**	QA ✓
Manufacturing Instruction Sheets for all the process phases			
Deviation Report Form (If any **DR** raised)			
Printed Material Sample Sheet/s			
Bulk Tablet Sampling Form/s **(if applicable)**			
Line Clearance, Opening and Cleaning Form/s			
Finished Good Retention **Samples**			
Material Transfer Order Form/s			
Vacuum Leak Test - Hourly Form			
Vacuum Leak Test - New Foil and PVC Roll Form			
In-Process Check - Shipper Form			
In-Process Check-Blister and Carton form			
Batch Reconciliation Sheet for Tablet Packing			
IBC Cleaning Tag/s			
IBC Identification Label/s			
Checkweigher Weight Record **(if applicable)**			
Pallet Booking Information			

If any deviation raised write the DR Number/s: **(Attach the copy of deviation report/s)**		
If any work-order raised during the batch write the order number/s:		
Name of authorised production person (print name):		
Signature of Authorised production person:		**Date:**
Comments:		

Form-560
Issue date:

Test and Retention Sample Log Book

(Ref. SOP MAN-120)

BPN (Batch no)	Product Description (In-process finished Goods or Final packed product)	Product Code	No. Samples (Retention and Test)	No. Stability samples	Date Samples Placed in Cupboard	Operator Sign	Sign Carton Coded with BPN/Exp	Date Test Sample Taken	Lab. Staff Sign	Date Removed by QAO	QAO Sign

