

Standard Operating Procedure

Title: Evaluation of Batch Documentation and Release for Sale

Department	Quality Management		Document no	QMS-090	
Prepared by:		Date:		Supersedes:	
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Approved by:		Date:		Review Date:	

Document Owner

Quality Assurance Manager

Affected Parties

All Quality Assurance and Laboratory colleagues.

Purpose

To define procedures for evaluating Batch Documents for release for sale.

Scope

This SOP is to be followed by the Quality Assurance Staffs responsible for checking Batch Documents and retention samples.

Definition

DR	Deviation Report
Batch Documents	A collection of all relevant documents, including MI sheets, generated throughout the manufacturing process of a particular batch. Also includes samples of printed cartons, leaflet, shipper labels, Line Clearances/Opening forms collected altogether.
Finished product	A formulated product that has undergone all stages of production including packaging in its final container.
Material Code	A number assigned to a finished product type or component. May also be referred to as "Code" or "Material number".
Batch Production Number	Unique identifying number assigned to a <u>finished product</u> .
Lab. batch number	Unique identifying number assigned to a <u>component</u> or <u>raw material</u> on receipt. Also referred to as "Laboratory number".
Retention Sample	A <u>representative</u> sample of finished product, which is to be retained for its shelf life and storage conditions plus 1 year.
MI Sheet	Manufacturing instruction sheet containing information and instruction pertaining to the manufacture of a BPN. Forms part of Batch Documents.
Bill of Materials (BOM)	List of registered components assigned to a finished product.
Certificate of Analysis (C of A)	Certificate supplied to a customer that lists test results completed for a batch. This also includes certificates received from suppliers listing tests completed on the raw material received.
Lot size	Total quantity of finished good packs (or units) produced.

Related Documents

Form-085	Released Stickers
Form-120	Printed Material Sample Sheet
Form-125	Example- Batch Reconciliation Sheet for Tablet Packing
Form-150	Example-Logbook for Tablet Batch Documents

Standard Operating Procedure

Title: Evaluation of Batch Documentation and Release for Sale

8.QA Inspection Sheet	6
9.Release of Batches	6
10.Rework	7
11.Summary of Changes	7

Procedure

1. Summary of Evaluation of Samples and Batch Documents by QA

- 1.1. Evaluation of each sample against Batch Documents for physical conformity.
- 1.2. Evaluation of Batch Documents against their appropriate Checklists for completeness, correctness and conformance to reconciliation limits.
- 1.3. Evaluation and completion of "QA Inspection Sheet" for conformity to specifications.
- 1.4. Prioritisation of urgent products.
- 1.5. Recording of Deviation Report (DR) and other delays and filing of completed DR with Batch Documents.
- 1.6. Final Release of Finished Product by Authorised QA Person (see SOP **QMS-070**).

2. Training of QA Staff

- 2.1. Quality Assurance Staff who will be authorised to evaluate the batch documents must be adequately trained. Three (3) Batch Documents should be counter evaluated by the trainer to ensure eligibility of the QA Staff for correctness prior to batch document checking.

3. Receiving/Collecting of Samples

- 3.1. The manufactured products of a BPN are placed in the retention Sample Room by production operators. Samples are logged into the Test and Retention Samples Logbook (**Form-560**) by production staff. (See SOP **MAN-120**).
- 3.2. There are two (2) types of samples:
 - **Bulk samples:** In-Process manufactured Goods, prior to packing.
 - **Packed samples:** These are samples in the Finished Goods pack.
- 3.2.1. **Bulk Samples**

Bulk samples are delivered in a plastic bag and are accompanied by a Finished Product Specification and Test Report for the corresponding BPN. A Laboratory representative will collect these. Sample log book will be signed by laboratory staff.
- 3.2.2. **Packed samples**

Packed Samples of a BPN are delivered in the final packs. Test and stability samples are to be collected by a laboratory Staff. Retention samples are to be collected by QA staff. The sample logbook (**Form-560**) is to be signed and dated on removal of the samples.
- 3.2.3. Retention and test samples both come together. For test samples, laboratory staff will remove the required test samples from the retention samples packs, leaving the rest for the QA staff to evaluate. Laboratory staff has to sign on the finished sample 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.

Standard Operating Procedure

Title: Evaluation of Batch Documentation and Release for Sale

6. Evaluating Manufacturing Instruction (MI) Sheet

- 6.1. Check all phases are completed and signed off by authorised production person. Check for correctness and completeness of the MI sheet and relevant entries are made in accordance with GMP documentation rules. (See SOP **QMS-020**)
- 6.2. MI Sheets "Comments section" **must be read and understood** . If any DR is raised by the production personnel worked on the line, those DR numbers are to be recorded in the "Deviation report" section of the checklist.
- 6.3. Check the following MI sheet entries are matching with the respective "Finished Product Specification" (**TEM-145**)
 - Batch number (BPN) (e.g. B XXXXXX)
 - Batch number format and coding on all packing components.
 - Expiry Date correctly calculated
 - Expiry Date format and coding on all packing components.
 - Correct product name and product number
 - Line clearance, line opening and cleaning entries are made properly and signed off.
 - Batch start up challenges are carried out and signed off.
 - All in-process checks are carried out according to procedure and signed off.
- 6.4. Check the packaging Artworks are matching with the respective "Packaging Material Specification" (**TEM-150**)
 - Correct product name and strength/concentration on the packaging samples.
 - Correct storage condition and temperature is printed.
 - Correct graphics are printed on the packaging.
 - Correct quantity and/or volume are printed.
 - Other relevant artworks are matching with the regulatory specification.
- 6.5. Check the following MI sheet entries are matching with the respective "Bill of Materials" (**TEM-155**)
 - Correct raw material code and description
 - Correct packaging component code and description
 - All components listed in the Bill of Materials are correctly issued, no component is missing. Check the attached Material Transfer Orders (see SOP **QMS-085**) for the issued components.
- 6.6. Check the Reconciliation Sheet (**Form-125**) is correctly filled up with quantity received, quantity used and quantity returned for each raw material and packaging component. Check the reconciliation calculation for the raw material, finished product and packaging components are correct and within the limit (See SOP **MAN-060**).
- 6.7. Check the pallet booking entries are correct and consistent on the MI sheet entries, Pallet booking Information form (**Form-540**) and on the Reconciliation sheet. Check the followings:
 - Number of booked out in the lot
 - Total finished product quantity booked out.
 - Good booking slip number
 - Check all pallet booking entries are signed off by authorised production personnel.
 - Quantity of Retention and Stability samples.

Standard Operating Procedure

Title: Evaluation of Batch Documentation and Release for Sale

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- 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 label 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 check list 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)

Product Description:	BPN:	Code:	Line:	Date:
Retention Samples:	Total Pack Quantity:			

Material Code	Lab. Batch Number	Received Qty	Rejected Qty	Returned Qty	Sent to IP
Tablets					
PVC Film					
Printed Foil					
Cartons					
Leaflets					

Batch Reconciliation Sheet for Tablet Packing

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

Leaflets Reconciliation	Labels Reconciliation
A. No. of Leaflets Received	A. No. of Labels Received
No. of Leaflets Packed	No. of Labels Packed
No. of Leaflets Sampled	No. of Labels Sampled
No. of Leaflets Rejected	No. of Labels Rejected
No. of Leaflets Returned	No. of Labels Returned
B. Total Leaflets Used	B. Total Labels Used
$(B/A) \times 100 = \text{Leaflets Yield}$	$(B/A) \times 100 = \text{Labels Yield}$

To calculate reject tablets	Floor	Machine	In Process	Total
A. No of reject blisters				
B. Weight of 1 empty blister				
C. Total Weight of empty blisters				
D. Total Weight of Tablets and blisters containing tablets				
E. Total Weight of reject tablets				
F. Weight of 1 single tablet				
$A \times B = C$ $D - C = E$				
$E \div F = \text{No of Reject Tablets}$				

Setup time
= Start of Line Clearance to 1st full shipper

Processing time
= 1st full shipper to start of Line Cleaning (including backlog)

Tear Down time
= Start of Line Cleaning to end of Line Cleaning

Deviation Report Form
(Ref. SOP QMS-035; MAN-080)

DR Number:	DRX-YYYY	Priority	
Author (Reported by)		Date Reported	Area/Team Responsible
DR Type: (fill in applicable information)			
DR5 Customer Complaint Deviation			
Customer No.:		Delivery Doc. No.:	
Sales Order No.:		Customer Material No.:	
Sold to Party No.:			
DR8 Material Complaint Deviation			
Vendor No. or Vendor Name:		Purchasing Doc. Number:	
Material Doc. No.:		Vendors Material No.:	
DR1 Process / Procedural Deviation			
Product code:		Equipment No.	
MI Sheet No.:		Batch (BPN):	
DR4 Audit Deviation			
Audit Ref. No.		Audit Type	
DR2 EHS Deviation			
<u>Deviation Title</u>			
<u>Description</u> (Must be filled in for all deviation types)			

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:
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Follow up Tasks

Task 1:

Assigned To		Planned finished date	
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Confirm Task 1 completed:	Sign:	Date:
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Task 2:

Assigned To		Planned finished date	
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Confirm Task 2 completed:	Sign:	Date:
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QA manager Approval Task

Confirm follow up tasks completed:	Sign:	Date:
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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:
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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			

