DR	Deviation Report
BPN	Batch Production Number
RBPN	Reworked Batch Production Number
WIP	Work in Progress Area
PS1	Production Staging Area 1
PS2	Production Staging Area 2
IP	Interim Production Staging Area

Related Documents

TEM-115	Protocol Rework- Manufactured Finished Goods
TEM-125	Protocol Rework- In Process Manufactured Goods
Form-515	Goods Return for Rework Form
Form-555	Example-Batch Documentation Checklist for Tablet Packing
Form-055	Material Transfer Order Form
Form-510	Product to be reworked
WAR-015	Warehouse Processing Issues, Return and Rejects
QMS-085	Example-Checklist for Batch Documentation
QMS-035	Deviation Report System
MAN-055	Procedures for Line Clearance, Line Opening and Line Cleaning
MAN-060	Reconciliation of Component and Product
QMS-110	Management and Control of Contract Work

EHS Statement

No safety, health or environmental hazards impact on the implementation of this SOP.

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Procedure

1. Rework Procedure

1.1. If a process deviation or quality concern is noted, a Deviation Report (**DR**) is to be raised detailing the problem with the batch production clearly identifying the part of the batch that has been affected. See SOP **QMS-035**.

1.2. Deviation Report could be generated for either In-process Manufactured Goods or Manufactured finished goods kept in the warehouse waiting for distribution.

1.13. Goods will be transferred to process area (WIP/PS1/PS2/IP) as requested in the form. One copy of 'Goods Return For Rework form' will be kept in the warehouse. The original will be sent with the goods. Finished goods are to be transferred in the way separated from the other Raw materials and Components.

1.14. When the goods are transferred production operator should check the pallet for correct product code and batch number. Label the pallets with 'Product to be Reworked Form' (**Form-510**).

1.15. If additional components are required a request will be sent from production by issuing 'Material Transfer Order Form' **(Form-055)**. See SOP **WAR-015** for issuing of components.

1.16. The Rework proceeds. The Rework Protocol must be followed and signed off.

1.17. On completion of the Rework the Rework Protocol and samples are forwarded to the QA. The form 'Batch Documentation Checklist **Form-555** must be included with the Rework documents. Page 1 of this form must be completed by Production. See **SOP QMS-085.**

1.18. All activities, relating to the Rework MUST be documented. All documentation, relating to the Rework MUST be included with the batch documents. Information can be included in the DR or in the specific Rework Protocol

1.19. After rework and before the pallets are sent to the Warehouse, remove the signs and clean them using IPA.

2. Procedure for Reworking Product at Contract Manufacturer

The procedure for Reworking product at a contract manufacturer is covered in **SOP QMS-110.**

3. Rework Protocols

All Reworks must be carried out with an approved Protocol. A Rework cannot be started until approved by QA.

The following templates are to be used:

- **TEM-115 / TEM-125**.

The Protocol must replicate the usual production process as closely as possible. Checks and tests performed in the usual production process MUST be included in the Protocol. For example, if check-weighing of packed cartons is part of the usual production process, then it must be included in the Rework Protocol.

The Rework Protocol can be prepared by an Operations team member or a QA Staff. Usually the Protocol generated as a response to DR.

The Protocol is to be checked and approved as follows prior to execution:

Prepared by:	QA Team member or Operations Team member
Checked by:	Production Manager (or delegate)
Approved by:	Quality Assurance Manager (or delegate)

3.1. Protocol for Manufactured Finished Goods Rework, TEM- 115.

TEM-115 is to be used when a Finished Good is being repacked from one BPN to another RBPN

The following information is to be provided in the request for Rework Protocol for Manufactured Finished Good:

- Why the Rework is being done.
- The related DR number
- Initial BPN and Expiry
- Quantity (excluding original sample qty)

6. Summary of Changes

Version #	Revision History
QMS-065	New

End of Procedure

Goods Return For Rework Form

(Ref. SOP QMS-065)

Goods Return for Rework					
PRODUCTION TO FILL UP			**WAREHOUSE TO FILL UP**		
Initial Goods Booking Slip No:			**Picked by:**	**Sign:**	**Date:**
Created By:	**Sign:**	**Date:**	**Checked by:**	**Sign:**	**Date:**
Process Line:			**No. of Full Shipper:**	**No. of Part Shipper:**	
Product Code			Product Code		
Product Description			Product Description		
Batch Production No			Batch Production No		
Expiry Date			Expiry Date		
Qty. to be Returned (Total Units)			Qty. Picked (Total Units)		
No of Shipper			No of Shipper		
No. of Pallets			No. of Pallets		
Destination area (WIP/PS1/PS2/IP)			Source Storage Type		
			Source Storage Bin		
Shipper Label No	From:	To:	Shipper Label No	From:	To:

Production checked by: **Pallet qty:**

Batch Documentation Checklist For Tablet Packing

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

Signature of Authorised production person:		**Date:**
Comments:		

SECTION: 3

PRODUCT NAME:		**CODE:**	
EXPIRY DATE:		**BATCH (BPN) NO:**	
DEVIATION REPORT:		**PROCESS LINE:**	
MANUFACTURING INSTRUCTION:			
All Phases Complete Checked (**MI Sheet Status must be completed and Signed off**)		Time / Date Blistering Finished	
		Time / Date Packing Started	
Expiry Date Checked		Time / Date Packing Finished	
Incomplete Entries Checked		Carton % Yield Checked	
PI Sheet Comments Checked		Leaflets % Yield Checked	
Manufacturing Date (***C of A***)	/ /	Label % Yield Checked	
Time / Date Blistering Started		Tablet % Yield Checked	
Retention Samples & Printed Materials Checked– Product Code, Description, BPN, Expiry Date, Pack Size, Temperature			
Shipper Label Checked – Product Code, Description, BPN, Expiry Date, Pack Size, Temperature,			
QUANTITY Batch Size:	Retention Samples: Stability Samples:	Packs to "Quarantine":	
Checklist Checked By	**Print Name:**		
Signature:		**Date:**	
Batch Document and QA Inspection Sheet Reviewed By	**Initial:**	**Date:**	
Name of Authorised QA Person (Print Name):			
Signature of Authorised QA Person:		**Release Date:**	

