Standard Operating Procedure

Title: Batch Review and Release for Supply – Non-Sterile Products

Department	Quality Management		Document no	QMS-185	
Title: Batch Review and Release for Supply - Non-Sterile Products					
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1. PURPOSE

This standard Operating Procedure (SOP) describes the process of release for supply of non-sterile finished goods and bulk product manufactured at a GMP site.

2. SCOPE

This procedure describes processes which need to be followed when conducting release for supply. The release covers:

2.1 Finished product release for supply

2.2 Releasing part of a batch for supply (Partial release for supply)

3. RESPONSIBILITY

3.1 Quality Assurance

It is the responsibility of the QA Manager (Dispositions) to ensure that this SOP is followed by the personnel in charge of conducting release for supply.

It is the responsibility of the QA Associate (authorized QA person) conducting release for supply to follow the directions outlined in this procedure and to ensure the released product meets both regulatory and marketing authorization requirements.

3.2 Production Department

It is the responsibility of the Production Site Manager to ensure that the manufacturing and packaging operators have completed all sections of the M/FBRs (Batch Record) or that appropriate comments and actions are taken and documented. Site Production Manager is also responsible for making sure that all QC physical analysis were conducted prior to filling and packing the bulk product.

3.3 Approved Laboratory:

It is the responsibility of Approved Laboratory to carry out Quality Control Analysis.

3.4 Warehouse

It is the responsibility of the warehouse personnel to organize shipping of the product once it has been released by QA.

4. MATERIALS REQUIRED/REFERENCES

4.1 Appendix A: Form 935 - Finished Product Audit Record – Blending, Tableting, Packaging and QC

4.2 Appendix B: Form 940 - Visual Inspection of Final Finished Product

change in specification is approved by a Change Control and once the change control is approved the spreadsheet is updated by a QA Associate

6.2.5 The QA Manager must be informed of any non compliant results for investigation and action.

6.2.6 QA Associate must review the M/FBR in accordance with the checklist in "**Form 935**: Finished Product Audit Record – Blending, Tableting, Packaging and QC" and each review must be signed and dated immediately after it is checked. If a discrepancy is found it must be resolved or satisfactorily explained by the production department prior to release for supply of the product by QA.

6.2.7 All bulk released for packing are packed according to the FBR (Finished Batch Record).

6.3 Checking through Form 935 (Product Release Form)

6.3.1 M/FBR issued by an authorized person. The 'Authorized' field in the M/FBR must be signed/dated by an authorized person.

6.3.2 BOM/Shop Traveler: Ensure BOM/Shop Traveler page is present.

6.3.3 Correct quantities of materials are dispensed and checked by second operator.

6.3.4 Cleaning cards: Must be present and completed – No fields left blank.

6.3.5 In-process tests: Must be within specification or a deviation must be raised.

6.3.6 Correct packaging materials issued/used. Batch number and expiry date: Ensure that Batch number and shelf life recorded is correct on all documents and labels. The shelf life of the product is recorded on the packing document (FBR) for that product.

6.3.7 Line clearance: Ensure line clearance is performed.

6.3.8 Reconciliation page: Ensure reconciliation page is present and all reconciliation values are within limits. Any out of reconciliation limits must be explained.

6.3.9 Deviations: Check for any open deviation reports raised for either packed or manufactured batch. Any deviation must be closed before releasing a batch for supply.

6.3.10 C of A: Refer to the List of Export and Third-Party Products and check if C of A / C of C need to be issued.

6.3.11 Review the details recorded in **Form 935** to be checked and verified against the batch records. Attach this to **Form 940**.

6.3.12 Once the **Form 935** checklist is completed, sign the field entitled 'Final Authorization by QA' at the bottom of the Form.

6.3.13 Complete the electronic disposition in the ERP system.

6.3.14 Screen print of release transactions should be printed, initialed and dated. This need to be counter signed by second QA Associate.

6.3.15 Print required number of "Release for Supply" disposition labels, one for each pallet and one sample to be applied to the batch records. Trained warehouse staff to apply the label, one for each pallet.

6.3.16 Upon completion of all release transaction, email notification is to be sent appropriate personnel, e.g. QA Managers, Logistics and, Inventory managers, Export coordinator, Product Manager.

Line Clearance and set up	
Rework sheet attached if there is a rework	
All signatures present and all information correctly completed on FBR	
Cleaning cards present and cards filled in correctly	
Reconciliations within limits, discrepancies explained.	
Filling/Blistering Quality Control Checks	
Sample pages of printed packaging materials (signed) are present and correct.	
Labelling QC inspection is done	
Final packing and palletising completed correctly.	
Packaging component reconciliation done	
Any Deviations (DR No:_____) Completed: Yes/No	
COA / Additional documents issued (if required)	

FULL RELEASE PROCESS	QA Initials/date
Confirm quantity for release equals lot quantity in ERP System	
Product is physically checked for BN and expiry	
ERP release	
E-mail notification sent to related persons	

PARTIAL RELEASE PROCESS	QA Initials/Date
Quantity releasing:	
Product is physically checked for BN and expiry	
ERP release	
E-mail notification sent to related persons	

Comments:_____

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APPENDIX B: Form 940 - Visual Inspection of Final Finished Product

Product Name:	
Item Code:	
MO Number:	
No: of Pallets	

AUDIT REQUIEMENTS

	DETAILS	INITIAL/DATE	COMMENTS
Batch Number			
Expiry Date			
Packaging Code/s			
General Condition of the product			

Comments