

**Finished Product Audit Record – Blending, Tableting, Packaging and QC**

(Ref. SOP QMS-185 Batch Review and Release for Supply - Non-Sterile)

| <b>Manufacturing Document Checklist</b>   | <b>QA Initials/Date</b> |
|---|-------------------------|
| BULK ITEM CODE: _____ ITEM DESCRIPTION: _____<br>BATCH NO: _____ DOM: _____         |                         |
| BOM/Shop Traveller present.   |                         |
| Correct quantity of materials dispensed and used.                                   |                         |
| Rework sheet attached if there is a rework  |                         |
| All signatures present and all information correctly completed on MBR               |                         |
| Cleaning cards present and cards filled in correctly                                |                         |
| Reconciliations within limits, discrepancies explained.                             |                         |
| QC Results within specifications, discrepancies explained. Results recorded in MBR. |                         |
| Any Deviations (DR No: _____) Completed: Yes/No                                     |                         |
| Bulk Packed / Bulk Release for Packing  |                         |

| <b>Tableting Document Checklist</b>  | <b>QA Initials/Date</b> |
|--|-------------------------|
| ITEM CODE: _____<br>BATCH NO: _____  |                         |
| BOM/Shop Traveller present.  |                         |
| Cleaning cards present and cards filled in correctly                         |                         |
| QC Results within specifications, discrepancies explained. Results recorded. |                         |
| Tableting Quality Control Inspection   |                         |
| Compression Reconciliation Yield   |                         |

| <b>Packaging Document Checklist</b>                                   | <b>QA Initials/Date</b> |
|---|-------------------------|
| PACKED ITEM CODE:<br>BATCH NOs:<br>DOM: _____ Expiry Date: _____      |                         |
| BOM/Shop Traveller present.   |                         |
| Correct quantity of materials dispensed and used.                     |                         |
| 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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**Final authorisation by QA**

**Authorised By:** \_\_\_\_\_ **Sign:** \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_