# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Quality Assurance | **SOP No.:** |
| **Title:** Final Inspection and Batch Release of Finished Products | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

1. **Purpose:** The purpose of this SOP is to define the procedure for the final inspection and release of finished products.

2. **Scope:** This SOP is applicable to the final inspection by QA department for the finished goods prior to the release to Bonded Store Room (BSR) for part and full and Quarantine release of a batch to the BSR at …….

3. **References, Attachments & Annexures:**
   - 3.1 **References:**
     - 3.1.1 In House
   - 3.2 **Attachments:** NA
   - 3.3 **Annexures:**
     - 3.3.1 Annexure -1: Final Inspection Report
     - 3.3.2 Annexure -2: Material Transfer Note
     - 3.3.3 Annexure -3: Flow Chart of Quarantine Release

4. **Responsibilities:**
   - 4.1 **Production/Packing:**
     - 4.1.1 To carry out the manufacturing as per BMR and packing of batch as per BPR/pack profile for domestic product and BPR/pack profile/export guidelines for export batch.
     - 4.1.2 To generate through ERP and send signed Material Transfer Note (unconfirmed) to QA.
     - 4.1.3 To record transfer related details in Batch Record.
     - 4.1.4 To arrange for the transfer of the batch to BSR along with transfer note.
   - 4.2 **Quality Assurance (QA) Department:**
     - 4.2.1 To ensure that packing carried as per Batch Packing Record or Export guidelines as applicable.
     - 4.2.2 To check and sign Material Transfer Note (unconfirmed) sent by production/packing supervisor.
     - 4.2.3 To make Final Inspection Report.
     - 4.2.4 To review the Batch Records, Test Requisition Cum Report, observation made during manufacturing and packing.
     - 4.2.5 To collect control sample and stability sample of different pack styles (if any).
     - 4.2.6 To inform the concerned supervisor and QA head in case of any discrepancy.
   - 4.3 **Warehouse:**
     - 4.3.1 To check receipt and dispatch of goods in intact and proper condition.
     - 4.3.2 To store the packed goods in a segregated manner.
     - 4.3.3 To confirm receipt in ERP system and send signed Material Transfer Note (unconfirmed copy) to QA Head or designee.
   - 4.4 **Quality Control (QC):**
     - 4.4.1 To send Test cum Requisition report to concerned packing personnel.
     - 4.4.2 To release the batch of finished product in LIMS on the basis of results of analysis.

4.4.3 To send COA to concerned QA person.

4.5 **Quality Assurance (QA) Head or designee:**

4.5.1 To release the batch in ERP for dispatch.

4.5.2 To send the Material Transfer Note (confirmed and unconfirmed generated through ERP) to BSR for signing and filing in BMR/BPR.

4.5.3 To release the batch for quarantine.

4.5.4 To ensure implementation of the SOP.

4.6 **Regulatory Affairs, Quality Head and Plant Head or designee:**

4.6.1 To review and approve the SOP.

5. **Distribution:**

5.1 Production
5.2 Quality Control
5.3 Quality Assurance
5.4 Packing
5.5 Warehouse

6. **Abbreviations & Definitions of Terms:**

6.1 **Abbreviations:**

6.1.1 **LIMS:** Laboratory Information Management System.
6.1.2 **COA:** Certificate of Analysis.
6.1.3 **MRO:** Material Requisition Order.
6.1.4 **BSR:** Bonded Storage Room.
6.1.5 **BMR/BPR:** Batch Manufacturing Record/ Batch Packing Record
6.1.6 **SOP:** Standard Operating Procedure
6.1.7 **QC :** Quality Control
6.1.8 **QA :** Quality Assurance
6.1.9 **A. R. No.:** Analytical Report Number
6.1.10 **RDPK :** Ready for Packing
6.1.11 **BSRQ :** Bonded Store Room Quarantine

6.2 **Definitions of Terms:** NA

7. **Procedure:**

7.1 The BMR is reviewed by the QA personnel responsible for manufacturing activities.
7.2 The packing operations shall be monitored by Packing and QA personnel. Thus based on all document review (BMR/BPR) the QA personnel shall assign the batch for the dispatch.
7.3 Ensure that the batch document is reviewed by QA during manufacturing and packing of the batch as per SOP.
7.4 **Preparation of Final Inspection Report:**

7.4.1 After receiving the signed unconfirmed ERP generated Material Transfer Note (Attachment-2) from Production Supervisor, concerned QA check the quantity and prepare the Final Inspection Report (Attachment – 1).
7.4.2 To review the Test cum Requisition Report for B. No.
7.4.3 The Reference BMR/BPR no. will be the record no. of BMR/BPR.
7.4.4 Write the Transfer Note No. and date on which the Transfer note was prepared.
7.4.5 Write Product Name, Batch No., Batch Size, Mfg. Date, Exp. Date, Unit Pack, Pack Style, Quantity Released, Price and other details from the BPR.
7.4.6 All the activity listed in the checklist to be filled with OK/Not OK/"-"/NA.
7.4.7 In case of Quarantine Release, it shall be mentioned in remark.

7.5 **Approval of Finished Goods Transfer Note for release:**

7.5.1 QA Head or designee should confirm the material for dispatch in respective site or location in ERP as applicable after verification of the following:
7.5.1.1 Product Name on BMR and BPR.
7.5.1.2 Manufacturing date, Expiry date and Batch No. against transfer note, Final Inspection Report, BMR and BPR.
7.5.1.3 Unit and Quantity for release shall be correctly mentioned and verified against BPR and transfer note.
7.5.1.4 Release of bulk finished product by QC through LIMS and QC shall send COA to concerned QA person.
7.5.1.5 Check BMR/BPR for completeness of:
7.5.1.5.1 Yield and accountability within limit at all critical stages.
7.5.1.5.2 Closing of all changes in BMR/BPR after its final authorization.
7.5.1.5.3 Closing of all change controls after completion of impact analysis.
7.5.1.5.4 Closing of all events.
7.5.1.5.5 Closing of corrective action in case of events.
7.5.1.5.6 For reprocess/rework batches, ensure that the stability sample has been withdrawn.
7.5.1.5.7 Ensure that the material return note for excess printed packaging material is attached.
7.5.1.5.8 After the completion of audit of BMR, if found Ok put (√) in the box provided on the BMR file.
7.5.1.5.9 Completion of all correction, change controls or events reviewed by shop floor QA.
7.5.1.5.10 Availability of COA
7.5.1.6 In case of any discrepancies inform to concern Production Supervisor, QA Head & Quality Head.

7.5.2 The batch can be decided for dispatch after satisfactory review of above points and completion of BPR upto that particular stage. The batch packing reconciliation can be done before final qty. transfer of the batch.

7.5.3 Upon satisfactory checks, QA Head and authorized QA designee shall release the batch in ERP system.

7.5.4 Concerned QA shall print and sign the confirmed copy (generated through ERP) of Material Transfer Note.

7.5.5 Signed Confirmed and Unconfirmed copy of Material Transfer Note shall be sent to BSR for signing by concerned BSR person and submit the unconfirmed copy in BSR as record.

7.5.6 Concerned QA shall attach the signed confirmed copy in the BMR/BPR along with the Final Inspection Report.

7.6 **Quarantine Release:**

7.6.1 QA shall review BMR/BPR as per step 7.5.

7.6.2 QA Head/Designee shall release the batch for Quarantine through ERP as per Annexure-3. In this case, QC shall not send COA to concerned QA.

7.6.3 After receipt of approved copy of COA from QC, QA shall finally transfer the stock of the batch from Quarantine location to Release location.

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## Annexure-1
## Final Inspection Report

| | | | | | |
|---|---|---|---|---|---|
| **Type of Transfer (Part/Full):** | | | | | |
| **BMR/BPR No.:** | | | | | |
| **BSR Transfer Note No.:** | | | **Date:** | | |
| **Product:** | **Unit Pack:** | | | | |
| **Batch No.:** | **Pack Style:** | | | | |
| **Batch Size:** | **Quantity Released:** | | | | |
| **Mfg. Date:** | **P.S./Export /MRP** | | | | |
| **Exp. Date:** | | | | | |

**Checklist**

| S.No. | Activity | | | | Report (OK/Not OK/NA/Mention Qty. (where applicable)) |
|---|---|---|---|---|---|
| 1. | Mfg. Lic. No. | | | | |
| 2. | Batch No. | | | | |
| 3. | Mfg. Date | | | | |
| 4. | Exp. Date | | | | |
| 5. | Price | | | | |
| 6. | Package Insert | | | | |
| 7. | Packaging material accountability | | | | |
| 8. | Samples | QC | Stability | Control | |
| 9. | Document completeness | | | | |
| 10. | Unit Pack/Shipper | | | | |
| 11. | Product Identity | | | | |
| 12. | No. of Shipper to be transferred to BSR | | | | |
| 13. | Availability of COA (Yes/No) | | | | |
| 14. | Event/Investigation Status | | | | |
| 15. | Change Control Status | | | | |
| 16. | Shop Floor Observation Status | | | | |
| 17. | Others | | | | |

**Conclusion: Approved/Not approved for BSR transfer**

| Inspected by | | Approved by | |
|---|---|---|---|
| **Sign & Date** | **QA** | **Sign & Date** | **QA** |

**Annexure-2**
**Company Name**
**Material Transfer Note**
**Final Product**

Transfer Note No: Date:

Work Order No: Date:
Item Code: Description:

Start Date: Mfg. Date: Exp. Date:

| Lot No. | Lot SL | Quantity | Unit | QC Reqd. (Y/N) | QC Order No. | Location |
|---|---|---|---|---|---|---|
| | | | | | | |

Q.C. Qty Passed: Q.C. Qty Rejected:

Q.C. Qty Sample: Q.C. Qty Transferred:

Remarks:

Pack Code: No. of Articles:

Q. C. ref:
Entered By: Confirmed By:

Date: Date:

Transfer By: Received By:
Date: Date:

**Annexure-3**
**Flow Chart of Quarantine Release**

**Packing Dept. shall provide the Packed Product List for Quarantine Release**

**QA shall release the QC Order in RDPK Location**

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**Packing Officer shall create Work Order Receipt**

↓

**Work Order Receipt shall be confirmed by BSR**

↓

**QC Order shall be generated automatically**

↓

**QA shall prepare Packing list in ERP**

↓

**QA shall generate and confirm the QC transfer into BSRQ location**

↓

**BSR shall prepare Distribution Order in Type C3 and Price NEXC2**

↓

**BSR shall prepare Distribution Issue**

↓

**After receiving Approved copy of COA from QC, QA shall finally transfer stock of the batch from Quarantine location (BSRQ) to Release location (FRSH).**

## 8. History:

| Version No. | | Effective Date | |
|---|---|---|---|
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