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# 1. Secondary Packaging - Line Clearance & Setup

## Batch Manufacturing Record

### Section 18.0: Secondary Packaging - Line Clearance & Setup

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**Purpose:** To verify and document that the manufacturing area, equipment, and all materials are clean, correct, and properly set up before commencing the secondary packaging (cartoning) of Batch **ASP-25-001**. No part of the cartoning operation may begin until this section is fully completed and signed by both Production and Quality Assurance.

|   | ≡ Field Name                     | ≡ Data                    |
|---|----------------------------------|---------------------------|
| 1 | Date of Line Clearance:          | 23-Feb-2025               |
| 2 | Time of Line Clearance:          | 08:00                     |
| 3 | Packaging Area / Room ID:        | Packaging Suite P-101     |
| 4 | Cartoning Machine ID:            | CAR-01                    |
| 5 | Reference to Previous Product:   | Paracetamol Tablets 500mg |
| 6 | Reference to Previous Batch No.: | PCM-25-081                |

### Part A: Area & Equipment Verification

|   | ≡ Checklist Item           | ≡ Specification / Requirement   | ≡ Operator Check (Priya Singh) | ≡ Verifier Check (Meena Iyer) |
|---|----------------------------|---|--------------------------------|-------------------------------|
| 1 | 1. Area Clearance          | Area must be completely free of all blisters, cartons, leaflets, and documents from the previous batch. | ✓                              | ✓                             |
| 2 | 2. Equipment Status        | Cartoning Machine (CAR-01) must be visibly clean.   | ✓                              | ✓                             |
| 3 | 3. Equipment Logbook Check | The logbook (LOG-USE-CAR-01) must be reviewed. The last entry must show a status of "Clean".            | ✓                              | ✓                             |
| 4 | 4. Hoppers & Feeders       | The blister pack hopper and leaflet feeder must be clean, empty, and correctly adjusted.                | ✓                              | ✓                             |

Part B: Critical Material Verification

Instruction: This is a critical step. Verify that the correct in-process and packaging materials have been staged for this batch.

|   | ≡ Checklist Item                       | ≡ Specification / Requirement  | ≡ Operator Check (Priya Singh) | ≡ Verifier Check (Meena Iyer) |
|---|--|--|--------------------------------|-------------------------------|
| 1 | 5. Blister Packs                       | Verify the staged containers hold blister packs for Batch <b>ASP-25-001</b> .  | ✓                              | ✓                             |
| 2 | 6. Printed Cartons                     | Verify the correct component is staged: <br> <b>Material Code:</b> PM-CAR-01 <br> <b>Lot Number:</b> PP-CAR-2025-01-456 <br> <b>Text:</b> Confirmed for Aspirin 325mg. | ✓                              | ✓                             |
| 3 | 7. Patient Information Leaflets (PILs) | Verify the correct component is staged: <br> <b>Material Code:</b> PM-PIL-01 <br> <b>Lot Number:</b> PP-PIL-2025-01-789 <br> <b>Version:</b> ART-PIL-ASP325-EN-v3.0    | ✓                              | ✓                             |
| 4 | 8. Reject Bins                         | All reject bins for mis-formed or empty cartons must be empty and clean before starting.   | ✓                              | ✓                             |

Part C: Machine Setup Verification

|   | ≡ Parameter               | ≡ Required Setting         | ≡ Actual Setting Verified | ≡ Operator Check (Priya Singh) | ≡ Verifier Check (Meena Iyer) |
|---|---------------------------|----------------------------|---------------------------|--------------------------------|-------------------------------|
| 1 | Carton Feeder Guide Rails | Set for CAR-ASP325-30-EN   | Verified                  | ✓                              | ✓                             |
| 2 | Leaflet Feeder            | Set for PIL-ASP325-EN-v3.0 | Verified                  | ✓                              | ✓                             |
| 3 | Glue System Temperature   | 160 °C ± 5 °C              | 161 °C                    | ✓                              | ✓                             |
|   |                           |                            |                           |                                |                               |

|   |                                 |                           |          |  |  |
|---|---------------------------------|---------------------------|----------|--|--|
| 4 | Barcode /<br>Pharmacode Scanner | Aligned and<br>functional | Verified |  |  |
|---|---------------------------------|---------------------------|----------|--|--|

Part D: Final Release for Production

Comments / Discrepancies:

No discrepancies noted. The line is cleared and set up with the correct materials and parameters for the secondary packaging of Batch ASP-25-001.

**Conclusion:** Based on the verification of all checklist items above, the Secondary Packaging Line is hereby released for the manufacturing of Batch No. ASP-25-001.

|   | ≡ Role                          | ≡ Print Name | ≡ Signature        | ≡ Date      | ≡ Time |
|---|---------------------------------|--------------|--------------------|-------------|--------|
| 1 | Line Cleared By<br>(Production) | Amit Sharma  | <i>Amit Sharma</i> | 23-Feb-2025 | 08:00  |
| 2 | Verified By (Quality Assurance) | Meena Iyer   | <i>Meena Iyer</i>  | 23-Feb-2025 | 08:15  |