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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.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2	2. Equipment Status	Cartoning Machine (CAR-01) must be visibly clean.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3	3. Equipment Logbook Check	The logbook (LOG-USE-CAR-01) must be reviewed. The last entry must show a status of "Clean".	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4	4. Hoppers & Feeders	The blister pack hopper and leaflet feeder must be clean, empty, and correctly adjusted.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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 ASP-25-001.	✓	✓
2	6. Printed Cartons	Verify the correct component is staged: Material Code: PM-CAR-01 Lot Number: PP-CAR-2025-01-456 Text: Confirmed for Aspirin 325mg.	✓	✓
3	7. Patient Information Leaflets (PILs)	Verify the correct component is staged: Material Code: PM-PIL-01 Lot Number: PP-PIL-2025-01-789 Version: 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 / Pharmacode Scanner	Aligned and functional	Verified	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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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 (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