

Add icon Add cover

5. BMR - Primary Packaging - Line Clearance & Setup

Batch Manufacturing Record

Section 14.0: Primary Packaging - Line Clearance & Setup

Document ID: BMR/ASP325/001

Page: 25 of 40

Purpose: To verify and document that the manufacturing area, equipment, and all materials are clean, correct, and properly set up before commencing the primary packaging of Batch ASP-25-001. No part of the packaging 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:	22-Feb-2025
2	Time of Line Clearance:	08:00
3	Packaging Area / Room ID:	Packaging Suite P-101
4	Blister Packing Machine ID:	BPM-01
5	Reference to Previous Product:	Ibuprofen Tablets 400mg
6	Reference to Previous Batch No.:	IBU-25-015

Part A: Area & Equipment Verification

	Checklist Item	Specification / Requirement	Status / Comments	Performed By (Operator)	Verified By (QA)
1	Area Clearance	Area must be free of all previous materials, documents, and waste.	Verified	Priya Singh	Meena Iyer
2	Equipment Status	Blister Packing Machine (BPM-01) must be visibly clean.	Checked	Priya Singh	Meena Iyer
3	Equipment Logbook Check	Logbook (LOG-USE-BPM-01) must show a "Clean" status.	Verified	Priya Singh	Meena Iyer

4	Hoppers & Feed Tracks	The tablet hopper and feed tracks must be clean and dry.	Checked	Priya Singh	Meena Iyer
5	Environmental Conditions	Temperature, RH, and Pressure must be within limits.	Within Specification	Priya Singh	Meena Iyer

Part B: Critical Material Verification

	☰ Checklist Item	☰ Specification / Requirement	☰ Status / Comments	☰ Performed By (Operator)	☰ Verified By (QA)
1	Bulk Product	Staged containers of tablets must be for Batch ASP-25-001.	Verified	Priya Singh	Meena Iyer
2	Printed Lid Foil	Roll must have correct Batch No. (ASP-25-001) and Expiry (Feb-2028).	Verified, Details Match	Priya Singh	Meena Iyer
3	Base Film	Correct base film (PVC/PVDC-250/60) must be staged.	Verified	Priya Singh	Meena Iyer
4	Reject Bins	All reject bins must be empty and clean before starting.	Checked	Priya Singh	Meena Iyer

Part C: Machine Setup Verification

	☰ Parameter	☰ Required Setting	☰ Status / Comments	☰ Performed By (Operator)	☰ Verified By (QA)
1	Forming Tool Set ID	FT-ASP-10	ID Matches BMR	Priya Singh	Meena Iyer
2	Sealing Temperature	180 °C ± 5 °C	Within Specification (181 °C)	Priya Singh	Meena Iyer
3	Sealing Pressure	4 Bar ± 0.5 Bar	Within Specification (4.1 Bar)	Priya Singh	Meena Iyer
4	Print Sensor	Aligned and functional	Verified Functional	Priya Singh	Meena Iyer

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 Batch ASP-25-001.

Conclusion: Based on the verification of all checklist items above, the Primary 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>	22-Feb-2025	08:00
2	Verified By (Quality Assurance)	Meena Iyer	<i>Meena Iyer</i>	22-Feb-2025	08:15