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8. BMR - IPQC Monitoring for Primary Packaging

Batch Manufacturing Record

Section 16.0: IPQC Monitoring Log for Primary Packaging

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Purpose: To provide a running, time-stamped record of all in-process quality checks performed during the primary packaging of Batch ASP-25-001, ensuring the process remained in a state of control.

	≡ Field	≡ Details
1	Date of Operation:	22--Feb-2025
2	Packaging Area / Room ID:	Packaging Suite P-101
3	Blister Packing Machine ID:	BPM-01
4	Governing SOP:	SOP/QC/PKG/001

16.1 Personnel Initial Key

	≡ Full Name	≡ Initials	≡ Signature
1	Priya Singh	PS	<i>Priya Singh</i>

16.2 IPQC Monitoring Log

Sampling Frequency: Every 60 minutes.

	Time of Check	Blister Leaves ≡ Sampled for Testing	Leak Test ≡ (Methylene Blue)	Print Quality ≡ & Legibility	Empty Pocket Rejection ≡ System Check	Comments / Actions Taken	Performed By (Operator)	Verified By ≡ (Supervisor)
1	09:00	2	Pass	Pass	Pass	All parameters normal.	Priya Singh	Amit Sharma
2	10:00	2	Pass	Pass	Pass	All parameters normal.	Priya Singh	Amit Sharma

3	11:00	2	Pass	Pass	Pass	All parameters normal.	Priya Singh	Amit Sharma
4	12:00	2	Pass	Pass	Pass	All parameters normal.	Priya Singh	Amit Sharma
5	13:30	2	Pass	Pass	Pass	All parameters normal.	Priya Singh	Amit Sharma
6	14:30	2	Pass	Pass	Pass	All parameters normal.	Priya Singh	Amit Sharma
7	15:15	2	Pass	Pass	Pass	Observation: Noticed a minor increase in the rate of rejected blisters. Action: Paused the line, checked and cleared the tablet feed track of minor dust buildup. Restarted line. Rejection rate returned to normal.	Priya Singh	Amit Sharma
8	16:30	2	Pass	Pass	Pass	All parameters normal.	Priya Singh	Amit Sharma
9	Total Sampled:	16						

16.3 Final Sign-off

Conclusion:

All required in-process quality checks were performed at the specified frequencies. All tests passed. A minor observation at 15:15 was appropriately addressed and resolved, with no impact on product quality. The process remained in a state of control.

Operator:

- **Department:** Production
- **Designation:** Packaging Operator
- **Name:** Priya Singh
- **Signature:** *Priya Singh*
- **Date:** 22-Feb-2025

Supervisor Review & Approval:

- **Department:** Production
- **Designation:** Packaging Supervisor
- **Name:** Amit Sharma
- **Signature:** *Amit Sharma*
- **Date:** 22-Feb-2025