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7. CAPA Implementation Record

Document Title: Corrective and Preventive Action (CAPA) Report

Document No.: QA/CAPA/2025/046

Linked Deviation No.: QA/DEV/2025/046

Linked RCA No.: QA/INV/2025/046

Product: Aspirin Tablets 325 mg

Batch No.: ASP-25-004

Stage: Secondary Packaging (Cartoning)

Date of Deviation: 23-May-2025

CAPA Initiation Date: 26-May-2025

Prepared By: Meena Iyer (QA Executive)

Reviewed By: Neha Gupta (QA Head)

Approved By: Sanjay Reddy (Manufacturing Head)

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1. Reference Summary

Deviation QA/DEV/2025/046 reported misprinting of 60 cartons with incorrect strength (“650 mg” instead of “325 mg“). Root Cause Analysis (QA/INV/2025/046) concluded that the **absence of system-level lockout** and **missed second-person verification** allowed wrong template selection.

CAPA aims to:

- Eliminate recurrence through **system, procedural, and training improvements**.
- Reinforce QA–Production verification checkpoints.

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2. Corrective Actions (Immediate)

	Action Description	Responsible Person	Target Date	Status	Verification
1	Segregated and rejected 60 misprinted cartons under QA supervision.	Amit Sharma (Supervisor)	23-May-25	Completed	QA verified rejection record.
2	Quarantined affected label roll and sealed printer until investigation.	Meena Iyer (QA)	23-May-25	Completed	QA inspection record attached.

3	Conducted 100% visual check of remaining printed cartons and labels.	QA Team	23-May-25	Completed	No further errors found.
4	Verified correct label template in software before resuming operation.	Deepak Joshi (Maintenance)	24-May-25	Completed	Printer log attached.
5	Batch released after QA confirmation.	Neha Gupta (QA Head)	25-May-25	Completed	Release note dated 25-May-25.

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3. Preventive Actions (Long-Term)

	Action Description	Department	Responsible Person	Target Completion	Status
1	Revise **SOP/PKG/LBL/005 – Label Printing and Verification** to include: a) Mandatory two-person verification (operator + supervisor). b) Checklist verification before printing.	QA	Meena Iyer	15-Jun-25	In progress
2	Implement **label template lockout** in printer software — restrict template selection to batch ID.	Engineering	Deepak Joshi	30-Jun-25	Pending
3	Introduce a **Label Verification Record Sheet** (annex to BMR Section 18).	QA	Meena Iyer	10-Jun-25	In progress
4	Conduct retraining of all packaging and QA personnel on revised SOP and verification steps.	HR / QA	Neha Gupta	20-Jun-25	Planned
5	Include deviation learnings in **Monthly QA Review** and **APQR – May 2025** under critical deviations.	QA	Neha Gupta	30-Jun-25	Pending

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4. Risk Evaluation (Post-CAPA)

	Risk Type	Pre-CAPA Rating	Post-CAPA Rating	Risk Reduction Justification
1	Label misprint recurrence	High	Low	Two-person verification and software lockout minimize human error.
2	Wrong template selection	High	Low	Automated restriction implemented.
3	SOP non-adherence	Medium	Low	Retraining and checklists introduced.
4	Traceability gap	Medium	Negligible	All rejected cartons accounted for in reconciliation.

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5. Verification of Effectiveness (Planned)

	Verification Criteria	Method	Frequency	Responsible
1	Random label verification compliance audit	QA internal audit	Monthly (3 months)	QA Executive
2	Printer software lockout validation	Engineering validation log	One-time	Engineering
3	Training effectiveness assessment	Knowledge quiz & observation	Within 1 month of training	QA & HR
4	APQR deviation trend analysis	QA Annual Review	Annually	QA Head

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6. Training Record Cross-Reference

	Training Record ID	Date	Description	Department	Trainer
1	TR/QA/2025/089	20-Jun-25	SOP/PKG/LBL/005 Revision Training – Dual Verification	Production / QA	Neha Gupta

2	TR/ENG/2025/024	22-Jun-25	Label Printer Software Lockout Implementation	Engineering	Deepak Joshi

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7. Attachments

- Deviation Report (QA/DEV/2025/046)
- RCA Report (QA/INV/2025/046)
- Revised SOP draft (SOP/PKG/LBL/005, Rev. 02)
- Label destruction record (to be attached as Document 4)
- Training attendance sheet (TR/QA/2025/089)

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8. QA Review & Closure

Effectiveness Verification:

CAPA verified as effective — no similar deviation reported in June-July 2025.

Printer lockout validation completed and found satisfactory (Validation Report VAL/ENG/2025/021).

Closure Date: 31-Jul-2025

Reviewed By: Neha Gupta (QA Head)

Signature: _____

Approved By: Sanjay Reddy (Manufacturing Head)

Signature: _____

✅ **Outcome Summary:**

All corrective actions successfully closed; preventive actions implemented systemically. Deviation considered closed and CAPA effective. This record will be cited in **APQR May 2025 (Critical Deviation Section)**.