

11. CAPA Implementation and Effectiveness Verification Log

Purpose:

To confirm the successful execution of Corrective and Preventive Actions (CAPA) as identified in the deviation investigation and to ensure effectiveness through procedural change, system improvement, and personnel retraining.

CAPA Reference: Linked to Deviation Report DEV/PKG/2025/046

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Reviewed By: Sanjay Reddy (QA Manager)

Period Covered: 24-May-2025 to 31-Jul-2025

1. Corrective Actions Implementation

	Action ID	Corrective Action Description	Execution Date	Responsible Dept.	Verification / Remarks
1	CA-01	Immediate segregation and destruction of 60 misprinted cartons under QA supervision (QA/DEST/2025/045).	24-May-2025	Production / QA	Verified by QA. Photographic evidence and destruction log attached.
2	CA-02	Reprinting of replacement cartons with verified print template and resumption of packaging.	24-May-2025	Production	Verified by QA prior to restart. Reprinted cartons checked for print accuracy and alignment.
3	CA-03	Documentation of deviation closure and re-entry of machine into service post-QA clearance.	25-May-2025	QA	All entries signed and dated in BMR and equipment log.

2. Preventive Actions Implementation

	≡ Action ID	Preventive ≡ Action Description	≡ Planned Date	≡ Completion Date	≡ Responsible Dept.	≡ Verification
1	PA-01	Introduce a dual-verification step for print template approval before packaging start-up.	31-May-2025	12-Jun-2025	QA / Production	Implemented via SOP/PKG/LBL/00 2 Rev. 02. Verified by QA documentation audit.
2	PA-02	Implement software-based label template lock in printer workstation to prevent wrong version selection.	10-Jun-2025	09-Jun-2025	Engineering	Successfully validated; system prevents use of outdated templates.
3	PA-03	Conduct operator retraining on "Label Verification and Template Control."	15-Jun-2025	14-Jun-2025	HR / QA	Training record TR/PKG/2025/07 signed by all attendees.
4	PA-04	Introduce barcode verification step prior to production initiation.	30-Jun-2025	30-Jun-2025	QA / IT	Implemented; confirmed in July batch pre-run checks.

3. Effectiveness Verification

- CAPA effectiveness was evaluated during packaging of **Batch ASP-25-005** (June) and **Batch ASP-25-006** (July).
- No recurrence of label-related deviations or line stoppages reported.
- System audit conducted by QA on 31-Jul-2025 confirmed adherence to revised SOPs and functioning of the label lock control.
- Result:** CAPA deemed effective and sustainable.

Verified By: Sanjay Reddy (QA Manager)

Date: 31-Jul-2025