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12. Management Review Summary

Deviation Reference: DEV/PKG/2025/046

Review Period: May – July 2025

Date of Review Meeting: 05-Aug-2025

Presented By: Sanjay Reddy (QA Manager)

Attendees:

- Mr. Arun Sharma – Plant Head
- Mr. Amit Sharma – Production Head
- Ms. Neha Gupta – QA Executive
- Mr. Sanjay Reddy – QA Manager
- Mr. Rajeev Tiwari – Engineering Head

1. Summary of Incident

- A label misprint deviation occurred on 23-May-2025 during secondary packaging of Batch ASP-25-004.
- Root cause identified as **incorrect label template selection** by operator due to oversight during setup.
- Incident was promptly contained; no product released with incorrect labeling.
- CAPA actions completed as per approved plan within stipulated timelines.

2. Review of Corrective and Preventive Actions

- QA verified that all corrective and preventive measures were implemented

and validated.

- Post-CAPA verification across two consecutive batches confirmed **zero recurrence**.
- The engineering control (template lock) has eliminated operator dependency for version control.
- Revised SOP (Rev. 02) integrated into QMS and shared across packaging teams.

3. Management Analysis

- The deviation was handled effectively with prompt communication and cross-functional involvement.
- Demonstrated robustness of deviation handling system and responsiveness of QA oversight.
- Training and procedural updates have strengthened overall compliance posture.
- The CAPA demonstrates sustainable preventive control, validated over subsequent operations.

4. Management Decisions and Recommendations

1. Continue the **template lock mechanism** across all labeling and printing machines by end of Q3-2025.
2. Initiate **quarterly label version audits** to verify SOP compliance.
3. Reinforce “first carton print verification” as a mandatory QA checkpoint in packaging checklist.
4. Include this deviation and its CAPA outcome as a **learning case study** in the **Annual Product Quality Review (APQR 2025)** under “Critical Deviations – Packaging Stage.”

5. Final Disposition

- **CAPA Closure Date:** 31-Jul-2025
- **Deviation Status:** Closed

- **Closure Authorized By:**

- *Sanjay Reddy* (QA Manager)
- *Arun Sharma* (Plant Head)

This deviation case is archived under QA-Records-2025-DEV-046 and will be referenced in APQR documentation as an example of effective CAPA implementation resulting in process improvement.