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10. QA Review and Approval Note

Deviation Reference: DEV/PKG/2025/046

Batch No.: ASP-25-004 **Product:** Aspirin Tablets 325 mg

Stage: Secondary Packaging (Cartoning)

Date of Occurrence: 23-May-2025

Reviewed By: Neha Gupta (QA Executive)

Reviewed On: 24-May-2025

Approved By: Sanjay Reddy (QA Manager) **Date:** 25-May-2025

1. QA Observations and Evaluation

1. The deviation was correctly identified as *Critical* since mislabeling has a direct potential to compromise **product identification, traceability, and regulatory compliance**.
2. The event was confined to the **packaging stage** only. All affected units were contained within the production floor under QA supervision; **no affected material was released** to the warehouse or market.
3. The investigation was thorough, covering review of:
    - Batch Manufacturing Record (Sections 18.0 & 19.0)
    - Equipment Logbook (CAR-01) entries dated 23-May-2025
    - Packaging reconciliation data showing 60 defective cartons
    - Label template audit trail from the printing workstation
4. The **root cause** (operator selection of incorrect template version) was found valid and substantiated by evidence.
5. The **CAPA plan** addresses both immediate containment and long-term prevention through a mix of **procedural, technical, and behavioral controls**.

6. QA has verified that line clearance and reprinting were carried out post-deviation in compliance with SOP/PKG/LBL/002 and SOP/QC/PKG/006.

2. QA Disposition Decision

- **Affected Material:** 60 misprinted cartons were destroyed under QA supervision (Record No. QA/DEST/2025/045).
- **Batch Status:** Acceptable for further processing. No rework or relabeling required.
- **Final Decision:** Batch ASP-25-004 released for secondary packaging continuation after corrective measures were implemented.
- **QA Authorization:**
  - *Neha Gupta* – QA Executive, verified corrective action on 24-May-2025
  - *Sanjay Reddy* – QA Manager, approved deviation closure for release on 25-May-2025

3. QA Comments

> Investigation methodology, corrective actions, and documentation are satisfactory. The deviation handling process demonstrated effective cross-functional coordination between QA, Production, and Engineering. No product quality impact identified. The deviation is considered controlled and closed, pending CAPA verification in subsequent batches.