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# 5. Deviation Report – DEV/PKG/2025/046

## Document 1: Deviation Report Form (Initial Report)

**Document Title:** Deviation Report Form

**Document No.:** QA/DEV/2025/046

**Type:** Critical Deviation – Label Misprint during Secondary Packaging

**Product:** Aspirin Tablets 325 mg

**Batch No.:** ASP-25-004

**Stage:** Secondary Packaging (Cartoning)

**Date of Occurrence:** 23-May-2025

**Detected By:** Amit Sharma (Packaging Supervisor)

**Reported To:** Meena Iyer (QA Executive)

**Time of Detection:** 11:30 AM

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### 1. Description of Deviation

During routine in-process inspection at 11:30 AM on 23-May-2025, the QA Inspector observed that cartons printed for Batch ASP-25-004 displayed incorrect product text and label alignment. The printed carton text read "**Aspirin Tablets 650 mg**" instead of "**Aspirin Tablets 325 mg.**"

The error was detected on approximately 60 cartons out of the running lot of 8,205. The printing deviation was confined to a single label roll. The operation was immediately stopped, and affected materials were quarantined under QA supervision.

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### 2. Immediate Action Taken

- Cartoning operation stopped immediately.
- All cartons on conveyor and packing table isolated and counted.
- 60 misprinted cartons segregated and labeled as "Rejected – Label Misprint."
- QA informed at 11:35 AM; area placed under hold status.
- Deviation Report QA/DEV/2025/046 initiated.

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### 3. Batch Status

Batch ASP-25-004 placed on **hold** pending QA investigation and risk assessment. No cartons released for tertiary packing or dispatch at the time of detection.

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### 4. Impact Assessment

- Misprinted cartons confined to single roll used between 11:15–11:30 AM.
- No cartons from affected roll entered finished goods area.
- Product identity, traceability, and potency not compromised.
- No impact on product quality; however, labeling error classified as **Critical** due to traceability risk.

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## 5. Probable Root Cause (Preliminary)

Operator selected incorrect label template from label printer software drop-down list. The batch and strength were manually entered without independent verification.

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## 6. Immediate Containment

- 60 cartons rejected and quarantined under QA supervision.
- Label printing operation temporarily suspended.
- Label roll and printer examined for data error.
- QA sealed printer access until investigation completed.

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## 7. Proposed Investigation Team

| | Role | Name | Department |
|---|---|---|---|
| 1 | QA Executive | Meena Iyer | Quality Assurance |
| 2 | Packaging Supervisor | Amit Sharma | Production |
| 3 | Engineering Support | Deepak Joshi | Maintenance |
| 4 | Manufacturing Head | Sanjay Reddy | Production |

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## 8. Reference Documents

- BMR/ASP325/004 – Section 18 & 19
- Equipment Logbook – LOG-USE-CAR-01
- SOP/OP/CAR/001 – Operation of Cartoning Machine
- SOP/PKG/LBL/005 – Label Printing and Verification
- QA/INV/2025/046 – RCA Report (to be attached post-investigation)

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## 9. QA Classification

☑ Critical

☐ Major

☐ Minor

**Justification:** Incorrect printed text on secondary packaging component leading to potential product identification error. Detected prior to release; no market impact.

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**Initiated By (QA):**

Name: Meena Iyer

Signature: _____

Date: 23-May-2025

**Reviewed By (QA Head):**

Name: Neha Gupta

Signature: _____

Date: 24-May-2025

**Status:** Under Investigation