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6. QA Investigation Summary (Root Cause Analysis)

Document Title: Root Cause Analysis Report

Document No.: QA/INV/2025/046

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

Product: Aspirin Tablets 325 mg

Batch No.: ASP-25-004

Stage: Secondary Packaging (Cartoning)

Date of Occurrence: 23-May-2025

Date of Report: 25-May-2025

Reported By: Meena Iyer (QA Executive)

Investigated By: Cross-functional team (QA, Production, Maintenance)

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1. Summary of Deviation

On 23-May-2025, during the cartoning of Batch ASP-25-004, QA detected **misprinted cartons** bearing the incorrect product strength ("Aspirin Tablets 650 mg" instead of "325 mg"). The deviation occurred between 11:15 AM and 11:30 AM and affected 60 cartons. Operations were immediately halted, and the affected lot was segregated and quarantined.

The error was classified as **Critical** due to the potential for product misidentification.

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2. Investigation Methodology

The investigation followed the structured GMP approach:

- **Review of process records:** BMR, equipment logbooks, and reconciliation sheets.
- **Interview with involved personnel.**
- **Verification of label artwork, template version, and printer logs.**
- **Cross-check of SOP adherence.**
- **Application of 5-Whys and Fishbone Analysis.**

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3. Investigation Team

	Name	Designation	Department
1	Meena Iyer	QA Executive	QA
2	Amit Sharma	Packaging Supervisor	Production
3	Deepak Joshi	Maintenance Engineer	Engineering
4	Neha Gupta	QA Head	QA
5	Sanjay Reddy	Manufacturing Head	Production

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4. Facts and Observations

	Observation No.	Description	Source Document	Remarks
1	1	Cartons misprinted with incorrect product strength (“650 mg” instead of “325 mg”).	Visual inspection	Verified
2	2	Error confined to one label roll (Roll No. LBL/PKG/325/23-05).	Printer log	Verified
3	3	Label printer software allows manual template selection.	SOP/PKG/LBL/005	Verified
4	4	Operator selected previous batch template (650 mg) manually.	Operator statement	Confirmed
5	5	Second-person verification step not performed before start of print.	BMR Section 18	Deviation from SOP
6	6	QA in-process check at 11:30 AM identified deviation.	QA IP Record	Verified
7	7	No misprinted cartons entered tertiary packing or FG area.	Physical stock verification	Verified

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5. 5-Why Analysis

	Why No.	Question	Answer / Finding
1	**1**	Why were cartons misprinted with wrong strength?	The label template for 650 mg was used instead of 325 mg.
2	**2**	Why was the wrong template used?	Operator manually selected incorrect template in printer software.
3	**3**	Why was the selection not verified?	Second-person verification (supervisor sign-off) was skipped before starting print.
4	**4**	Why was the verification skipped?	Operator assumed same template from previous batch was valid; supervisor was attending another line.
5	**5**	Why was such assumption possible?	SOP for label verification lacked a mandatory system lockout or checklist validation step; reliance solely on manual verification.

✅ **Root Cause Identified:**

> Absence of system-level control in label printing software allowing manual selection of templates without QA lockout, combined with operator error and missed verification.

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6. Fishbone Analysis

	Category	Contributing Factors
1	**Man (Personnel)**	Operator selected wrong template; verification not done by supervisor before run.
2	**Machine**	Label printer software does not have version lockout or batch-based template validation.
3	**Method**	SOP/PKG/LBL/005 lacks electronic interlock for template confirmation.
4	**Material**	Correct artwork and label rolls available but wrong digital template used.
5	**Measurement**	Verification step not logged prior to run start.

6	**Environment**	Multiple batches (325 mg and 650 mg) processed in same shift, increasing risk of human mix-up.

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7. Impact Assessment

	Aspect	Impact	Remarks
1	Product Identity	Potential risk if misprinted cartons used.	Prevented – error caught in-process.
2	Product Quality	None	Only labeling issue.
3	Batch Traceability	Minor risk – controlled through segregation.	Affected cartons segregated.
4	GMP Compliance	Non-conformance to SOP verification step.	Requires procedural CAPA.
5	Market Impact	None	Detected before release.

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8. Root Cause Summary

Direct Cause: Wrong label template selected manually.

Contributory Causes:

- Missed second-person verification.
- No system-based control in label printing software.
- Multiple similar SKUs packed on same day.

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9. Conclusion

This deviation originated due to **human error** supported by a **procedural gap** in the label printing and verification system. Immediate containment actions were effective in preventing further misprinted cartons from entering the supply chain. However, system and procedural corrections are required to prevent recurrence.

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10. Recommendations

1. Implement electronic lockout or template validation in label printer software.

2. Revise SOP/PKG/LBL/005 to mandate dual verification with signature before printing.
3. Conduct retraining of packaging and QA personnel on label verification requirements.
4. Include this deviation and CAPA in **May 2025 APQR summary** under “Critical Deviations – Packaging.”

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Signature: _____

Date: 25-May-2025

Reviewed By:

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Signature: _____

Date: 26-May-2025

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Signature: _____

Date: 26-May-2025