

Deviation Report

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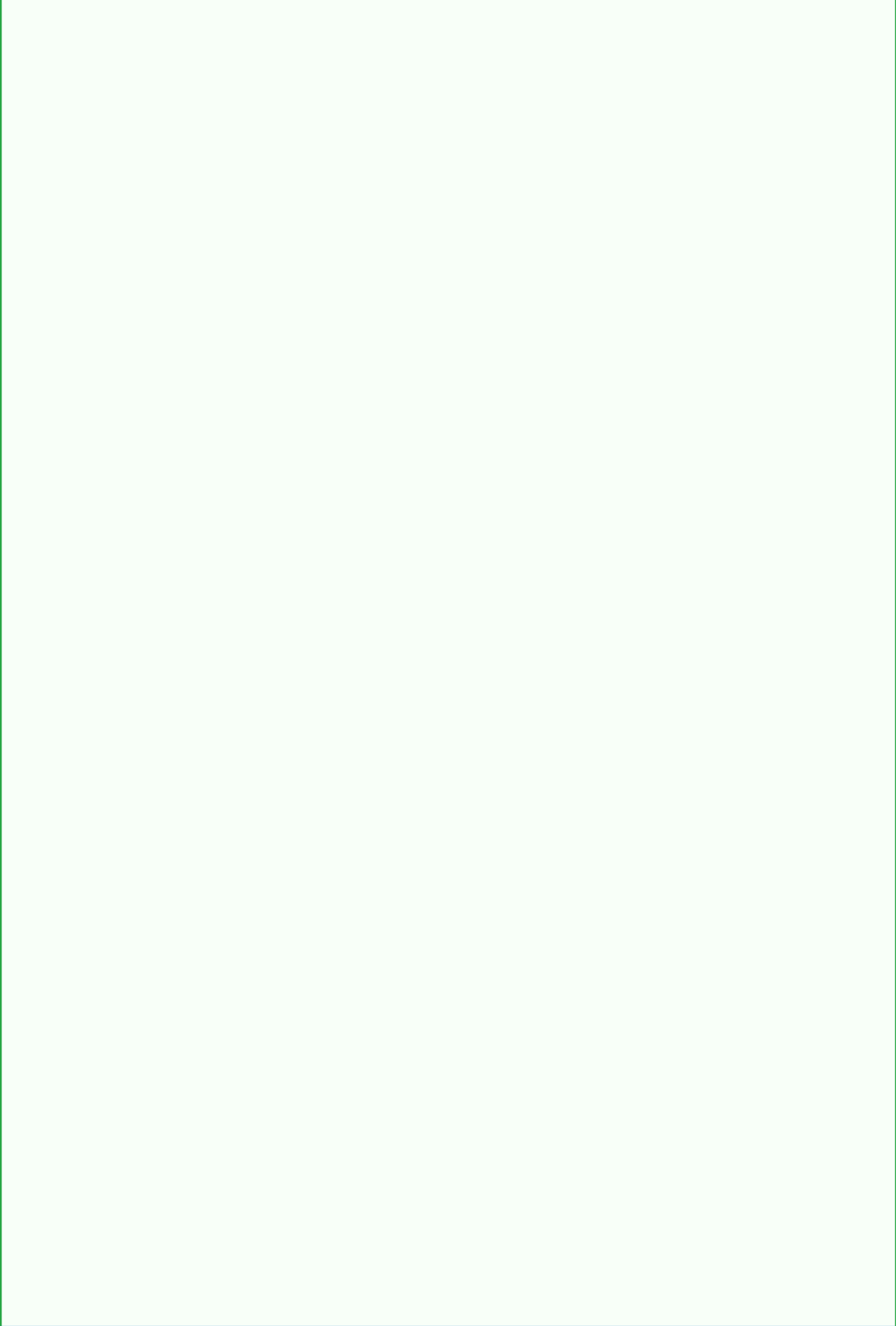
Deviation Information			
Title:	(10 USP units/mL) and Norepinephrine lot 10000296, New in-house labels were	Priority:	Major
Status:	In Progress	Deviation Type:	Not specified
Date of Occurrence:	Not specified	Department(s):	Not specified
Batch/Lot Number:	The labels did not run on the Newman labeling machine using the settings used on	Quantity Impacted:	the previous labels which and was causing multiple issues such as breaking of the
Planned Deviation:	No		

Deviation Description

Original Description:

During the packaging of lot 10000274 Oxytocin Injection, USP 30 USP units/ 3mL

AI-Enhanced Technical Analysis



1. Deviation Summary

During the packaging process of Oxytocin Injection, USP 30 USP units/ 3mL, lot number 10000274, a deviation occurred involving the Newman labeling machine. The machine failed to properly run the labels due to incorrect settings, leading to multiple issues, including ribbon breakage and undetected labels by the rejection sensor.

2. Event Timeline

2. Date of Occurrence: Not explicitly stated.

3. Batch/Lot Affected: Oxytocin labels, part number 10000024, lot number 100038763.

4. Equipment Involved: Newman labeling machine.

5. Issue Identification: The deviation was identified when the labeling machine failed to process the labels correctly, causing ribbon breakage and failure of the rejection sensor to detect labels.

3. Root Cause Analysis

The root cause of the deviation was the use of incorrect settings on the Newman labeling machine. The settings used were intended for a different label type (Norepinephrine labels, part number 10005423, lot number 100038868) and were not suitable for the Oxytocin labels.

4. Impact Assessment

The deviation impacted the labeling process of lot 10000274, potentially affecting the integrity and traceability of the product. There is a risk of mislabeling, which could lead to incorrect product identification and potential regulatory non-compliance.

5. Corrective and Preventive Action (CAPA) Plan

6. Corrective Actions:

6. Immediately halt the labeling process for the affected lot.

7. Reconfigure the Newman labeling machine with the correct settings for Oxytocin labels.

8. Inspect all labeled units from the affected lot to ensure proper labeling and integrity.

• Preventive Actions:

- Implement a verification step in the labeling process to ensure correct machine settings before operation.

- Conduct training sessions for operators on the importance of verifying

- Update the standard operating procedures (SOPs) to include detailed instructions for setting verification and cross-checking with label specifications.

These actions aim to prevent recurrence and ensure compliance with GMP standards.

Immediate Actions

Original Response:

No immediate actions were taken at the time of reporting.

Risk Assessment Information

Initial Risk Assessment (User Input):

No initial risk assessment provided.

Investigation Information

**Investigation
Assignee:**

Matt

Initiator:

Matt

Investigation Results:

See AI-generated analysis for detailed findings.

Final Conclusion:

Analysis completed using AI-enhanced regulatory guidance.