Deviation Report

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Report Information

TITLE:	Packaging issue with new in-house labels for Oxytocin and Norepinephrine lots	**PRIORITY:**	MAJOR
STATUS:	In Progress	**DEVIATION TYPE:**	Not specified
DATE OF OCCURRENCE:	May 20, 2025	**DEPARTMENT(S):**	Manufacturing
BATCH/LOT NUMBER:	10000274, 10000296	**QUANTITY IMPACTED:**	whole batch
PLANNED DEVIATION:	No	**INITIATOR:**	Clara-Lea

User Input - Original Deviation Description

On 20 May 2025 during the packaging of lot 10000274 Oxytocin Injection, USP 30 USP units/3mL (10 USP units/mL) and Norepinephrine lot 10000296, New in-house labels were used. Oxytocin labels were part number 10000024 and lot number 100038763. Norepinephrine labels were part number 10005423 and lot number 100038868. The labels did not run on the Newman labeling machine using the settings used on the previous labels which and was causing multiple issues such as breaking of the ribbon and undetected labels through Newman labeler rejection sensor.

AI-Generated Analysis

Deviation Summary

On May 20, 2025, during the packaging of Oxytocin Injection, USP lot 10000274 and Norepinephrine lot 10000296, new in-house labels were used, leading to issues on the Newman labeling machine. The labels, with part numbers 10000024 and 10005423, did not function properly, causing ribbon breakage and undetected labels. The entire batches were impacted. The deviation was identified during the packaging process in the Manufacturing department.

Event Timeline

- May 20, 2025: New in-house labels were used for Oxytocin Injection, USP lot 10000274 and Norepinephrine lot 10000296.
- May 20, 2025: Issues were identified with the Newman labeling machine, including ribbon breakage and undetected labels.

Root Cause Analysis

Root cause investigation focuses on the following areas based on the deviation details:

- Equipment: The Newman labeling machine requires review of label compatibility and sensor functionality, as the new labels did not run properly.
- Material: The new in-house labels, part numbers 10000024 and 10005423, require verification for compatibility with the Newman labeling machine.
- Process: The packaging process needs evaluation of label application settings and machine calibration to ensure proper label detection and application.

⚠ Impact Assessment

- Product Quality: The improper labeling process may lead to incorrect or missing labels, affecting product identification and traceability.
- Batch Disposition: The affected batches, 10000274 and 10000296, require additional inspection and testing to ensure label accuracy and product integrity.
- Risk Level: Classified as Major due to the potential for mislabeling, which could lead to product recalls or regulatory non-compliance.
- Other Batches: No immediate risk identified to other batches, as the issue is specific to the new labels used in these two lots.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine batches 10000274 and 10000296 to prevent distribution.
- Stop the use of the Newman labeling machine until label compatibility is confirmed.
- Conduct a sample inspection of labels for accuracy and adhesion.

Corrective Actions (address this event):

- Recalibrate the Newman labeling machine to ensure proper label application.
- Verify and adjust label settings to match machine specifications.
- Retrain operators on the correct setup and operation of the labeling machine with new labels.

Preventive Actions (prevent recurrence):

- Implement a compatibility check procedure for new labels before use in production.
- Revise SOPs to include a verification step for label and machine compatibility.
- Introduce additional in-process controls to detect label application issues early.