Deviation Report

Record ID: DEV_20250807_190125 **Generated:** August 07, 2025 07:02 PM

Report 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	**Initiator:**	Clara-Lea

User Input

Original Deviation Description:

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

Deviation Summary

During the packaging process of Oxytocin Injection, USP 30 USP units/3mL, lot number 10000274, there was a failure in the labeling process on the Newman labeling machine. The issue involved the labels not running correctly, leading to multiple issues such as ribbon breakage and undetected labels through the Newman labeler rejection sensor.

Event Timeline

- Date of Occurrence: Not explicitly provided.
- Batch/Lot Affected: Oxytocin labels with part number 10000024 and lot number 100038763.
- Equipment Involved: Newman labeling machine.
- Identification of Issue: The issue was identified during the packaging process when labels failed to run correctly on the Newman labeling machine.

Root Cause Analysis

The root cause of the deviation was the use of incorrect settings on the Newman labeling machine, which were not suitable for the Oxytocin labels. The settings used were those intended for Norepinephrine labels (part number 10005423 and lot number 100038868), leading to operational failures such as ribbon breakage and undetected labels.

⚠ Impact Assessment

The deviation impacted the labeling process of Oxytocin Injection, USP 30 USP units/3mL, potentially affecting the correct identification and traceability of the product. This could lead to compliance issues with labeling regulations and pose a risk to product quality and patient safety if not addressed.

CAPA Plan

- Immediate Correction: Adjust the settings on the Newman labeling machine to those appropriate for the Oxytocin labels. Re-run the affected batch to ensure proper labeling.
- Root Cause Mitigation: Conduct a review of the labeling machine settings protocol to ensure that correct settings are used for each product type. Implement a double-check system before starting the labeling process.
- Preventive Action: Train operators on the importance of verifying machine settings before use. Update the Standard Operating Procedures (SOPs) to include a checklist for machine settings verification.
- Monitoring and Review: Implement a monitoring system to track labeling machine performance and conduct regular audits to ensure compliance with the updated SOPs. Conduct a follow-up review to assess the effectiveness of the CAPA plan.