# Deviation Report

**Record ID:** DEV_20250807_193405 **Generated:** August 07, 2025 07:34 PM

## Report Information

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| **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:** | Matt |

## 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, a deviation occurred involving the Newman labeling machine. The machine failed to properly apply labels due to incorrect settings, leading to issues such as ribbon breakage and undetected labels by the rejection sensor. This deviation was identified during routine operations in the Manufacturing department.

## Event Timeline

- Date of Occurrence: The specific date is not provided, but the issue was noted during the packaging of lot 10000274.
- Equipment Involved: Newman labeling machine.
- Batch/Lot Numbers: Oxytocin labels were part number 10000024 and lot number 100038763. Norepinephrine labels, used as a reference, were part number 10005423 and lot number 100038868.

## 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 were based on the previous labels used for Norepinephrine, leading to mechanical issues such as ribbon breakage and failure of the rejection sensor to detect missing labels.

## ⚠ Impact Assessment

The deviation impacted the labeling process for lot 10000274 of Oxytocin Injection. The incorrect labeling settings could potentially lead to mislabeling or unlabeled products reaching the market, posing a risk to product quality and regulatory compliance. However, the exact quantity of impacted units is not specified in the provided information.

## CAPA Plan

- Corrective Actions:
- Immediately halt the use of the Newman labeling machine for lot 10000274.
- Re-evaluate and adjust the machine settings specifically for Oxytocin labels to ensure compatibility.
- Conduct a thorough inspection of the affected lot to identify and rectify any labeling issues.
- Preventive Actions:
- Implement a standardized procedure for verifying and adjusting labeling machine settings for each specific product and label type.
- Train operators on the importance of setting verification and the potential impact of deviations.
- Enhance the labeling machine's maintenance and calibration schedule to prevent similar issues in the future.
- Conduct a review of the labeling process to identify any other potential areas for improvement and ensure compliance with GMP standards.

This structured approach aims to address the immediate deviation and prevent recurrence, aligning with the principles of ICH Q10 Pharmaceutical Quality System.