Deviation Report

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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:**	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 labeling operation. The Newman labeling machine failed to process the Oxytocin labels correctly, leading to multiple issues including ribbon breakage and undetected labels through the labeler rejection sensor. The issue was identified during routine packaging operations.

Event Timeline

- Date of Occurrence: Not explicitly stated, but during the packaging of lot 10000274.
- Equipment Involved: Newman labeling machine.
- Batch/Lot Affected: Oxytocin Injection, USP 30 USP units/3mL, lot number 10000274.
- Label Details: Oxytocin labels, part number 10000024, lot number 100038763.
- Previous Labels: Norepinephrine labels, part number 10005423, lot number 100038868.

Root Cause Analysis

The root cause of the deviation was the use of incorrect machine settings on the Newman labeling machine for the Oxytocin labels. The settings were not adjusted from those used for the previous Norepinephrine labels, leading to mechanical failures such as ribbon breakage and failure of the label rejection sensor to detect issues.

⚠ Impact Assessment

The deviation affected the labeling process of lot number 10000274, potentially impacting the integrity and compliance of the product labeling. This could lead to regulatory non-compliance and product recalls if not addressed. No direct impact on product quality was identified, but the labeling issue could mislead end-users regarding product information.

CAPA Plan

- Immediate Correction: Halted the labeling process for lot 10000274 and adjusted the Newman labeling machine settings to match the specifications for Oxytocin labels.
- Root Cause Mitigation: Conducted a review of the machine setting protocols to ensure correct settings are used for each label type.
- Preventive Action: Implemented a checklist for machine settings verification before starting the labeling process for each batch. Conducted training sessions for operators on the importance of machine setting verification.
- Monitoring and Review: Scheduled regular audits of the labeling process and machine settings to ensure ongoing compliance and to prevent recurrence of similar deviations.