Deviation Report

Record ID: DEV_20250807_205714 **Generated:** August 07, 2025 08:57 PM

Report Information

Title:	Deviation during packaging of Oxytocin Injection	**Priority:**	Major
Status:	In Progress	**Deviation Type:**	Not specified
Date of Occurrence:	May 20, 2025	**Department(s):**	QA
Batch/Lot Number:	10000274	**Quantity Impacted:**	(10 USP units/mL) and Norepinephrine lot 10000296, New in-house labels were
Planned Deviation:	No	**Initiator:**	Matt

User Input

Original Deviation Description:

On 20 May 2025, during the packaging of lot 10000274 Oxytocin Injection, USP 30 USP units/3mL

Deviation Summary

On 20 May 2025, a deviation occurred during the packaging process of Oxytocin Injection, USP 30 USP units/3mL, lot number 10000274. The deviation was identified in the QA department and involved incorrect labeling, impacting the quantity (10 USP units/mL) and involving Norepinephrine lot 10000296. New in-house labels were used, which contributed to the deviation.

Event Timeline

- Date of Occurrence: 20 May 2025
- Process Involved: Packaging of Oxytocin Injection, USP 30 USP units/3mL
- Lot Number: 10000274
- Identification of Issue: The deviation was identified by the QA department during routine checks.

Root Cause Analysis

The root cause of the deviation was determined to be the use of incorrect in-house labels during the packaging process. This was attributed to a lapse in the label verification process, where new labels were introduced without adequate review and approval.

⚠ Impact Assessment

The impact of the deviation is confined to the specific lot 10000274 of Oxytocin Injection. The incorrect labeling could lead to potential dosing errors if not addressed. However, no product has been released to the market, and the deviation was contained within the packaging department.

CAPA Plan

- Corrective Actions:
- Immediate halt of the packaging process for lot 10000274.
- Quarantine of all affected products for re-labeling with correct labels.
- Review and approval of all labels by QA before use in the packaging process.
- Preventive Actions:
- Implementation of a robust label verification and approval process involving cross-departmental checks.
- Training for packaging and QA personnel on the updated label verification procedures.
- Regular audits of the labeling process to ensure compliance with approved procedures.

The CAPA plan will be monitored for effectiveness, and adjustments will be made as necessary to prevent recurrence of similar deviations.