

Deviation Report

Record ID: DEV_20250807_205402 **Generated:** August 07, 2025 08:55 PM

Report Information			
Title:	Deviation during packaging of Oxytocin Injection	Priority:	Major
Status:	In Progress	Deviation Type:	Not specified
Date of Occurrence:	Not specified	Department(s):	Manufacturing
Batch/Lot Number:	10000274	Quantity Impacted:	N/A
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, a deviation was identified in lot number 10000274. The deviation pertains to the packaging department and involves an unspecified issue that occurred during the packaging phase. The quantity impacted is not available, and the exact date of occurrence is not specified.

Event Timeline

- The deviation was identified during the packaging process of lot 10000274. Specific dates and times of the occurrence and detection are not provided.

Root Cause Analysis

- A structured investigation should be conducted to determine the root cause of the deviation, following the guidelines of Q10-Pharmaceutical-Quality-System. The investigation should explore potential variability in the packaging process and assess any equipment or procedural failures that may have contributed to the deviation. The level of effort and documentation should be proportional to the risk level, as outlined in ICH Q9.

Impact Assessment

- The impact of the deviation on product quality and patient safety must be assessed. This includes evaluating whether the deviation could affect the integrity, efficacy, or safety of the Oxytocin Injection. Since the quantity impacted is not specified, a thorough review of the entire batch should be conducted to determine if the deviation affects the entire lot or specific units.

CAPA Plan

- Corrective Actions:
 - Immediately halt the packaging process for lot 10000274 until the root cause is identified and addressed.
 - Inspect all packaged units from the affected lot to ensure compliance with quality standards.
- Preventive Actions:
 - Review and update packaging procedures to prevent recurrence of similar deviations.
 - Implement additional training for packaging personnel on updated procedures and deviation management.
 - Enhance monitoring and control measures during the packaging process to detect potential deviations early.
 - The effectiveness of the CAPA plan should be evaluated through follow-up audits and process performance reviews to ensure continual improvement and compliance with regulatory standards.