Deviation Report

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Report Information

Title:	Deviation during packaging of lot 10000274 Oxytocin Injection	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Not specified
Date of Occurrence:	May 20, 2025	**Department(s):**	Manufacturing
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 was identified during the packaging process of Oxytocin Injection, USP 30 USP units/3mL, specifically associated with lot 10000274. The deviation pertains to the incorrect application of new in-house labels, impacting the integrity and compliance of the packaging operation. This occurrence was detected within the Manufacturing department and categorized under Packaging deviations.

Event Timeline

- Date of Occurrence: 20 May 2025
- Batch/Lot Affected: 10000274 (Oxytocin Injection, USP 30 USP units/3mL)
- Quantity Impacted: (10 USP units/mL) and Norepinephrine lot 10000296
- Department: Manufacturing

Root Cause Analysis

An investigation was conducted in alignment with Q10-Pharmaceutical-Quality-System guidelines, employing a structured approach to determine the root cause. The analysis revealed that the deviation stemmed from a failure to adhere to JYPharm-3-138 regulatory requirements, specifically the omission of operator initials during significant packaging steps and inadequate verification of identity and conformity with packaging instructions. This lapse in procedural compliance was attributed to insufficient training of personnel responsible for the packaging operation.

⚠ Impact Assessment

The deviation was assessed for its potential impact on product quality and regulatory compliance. The risk was categorized as moderate, given the potential for mislabeling to affect product traceability and patient safety. However, no adverse events have been reported to date. The deviation does not compromise the chemical integrity of the product, but it necessitates immediate rectification to maintain GMP standards.

CAPA Plan

In accordance with CAPA methodology outlined in Q10-Pharmaceutical-Quality-System, the following actions have been implemented:

1. Immediate Correction:
2. Re-labeling of affected batches (10000274 and 10000296) to ensure compliance with packaging instructions and regulatory requirements.
3. Training Enhancement:
4. Conduct comprehensive training sessions for all packaging personnel, emphasizing the importance of procedural adherence and documentation accuracy.
5. Process Improvement:
6. Revise the packaging SOP to include a mandatory checklist for operator initials and in-process control checks, ensuring alignment with JYPharm-3-138 standards.
7. Monitoring and Review:
8. Implement a quarterly audit of packaging operations to monitor adherence to revised procedures and identify any emerging trends or deviations.

These actions are designed to prevent recurrence, enhance process understanding, and ensure sustained compliance with GMP standards.