

Deviation Report

Record ID: DEV_20250808_144448 Generated: August 08, 2025 02:45 PM

Report Information			
TITLE:	Norepinephrine lot discrepancy with sales orders	PRIORITY:	MAJOR
STATUS:	In Progress	DEVIATION TYPE:	Material
DATE OF OCCURRENCE:	February 11, 2025	DEPARTMENT(S):	Warehouse
BATCH/LOT NUMBER:	1000186, 1000187	QUANTITY IMPACTED:	160 units
PLANNED DEVIATION:	No	INITIATOR:	Clara-Lea

User Input - Original Deviation Description

On 11 Feb 2025 Norepinephrine lot didn't match sales orders. Was discovered as SAP was stating to pull from certain Lots, but there was not enough physical quantity of that Lot. For Lot 1000186 SAP showed a quantity of 187 but the physical count was 27. For Lot 1000187 SAP showed a quantity of 4 but the physical count was 164.

AI-Generated Analysis

Deviation Summary

On February 11, 2025, a discrepancy was identified in the warehouse department involving Norepinephrine lots 1000186 and 1000187. The SAP system indicated a quantity of 187 units for lot 1000186 and 4 units for lot 1000187, but the physical counts were 27 and 164 units, respectively. This resulted in a total quantity impact of 160 units. The deviation was discovered when the sales orders did not match the available physical inventory.

Event Timeline

- February 11, 2025: Discrepancy discovered between SAP system inventory and physical count for Norepinephrine lots 1000186 and 1000187.

Root Cause Analysis

Root cause investigation focuses on the following areas based on the deviation details:

- Material: Norepinephrine lots 1000186 and 1000187 require verification of inventory management and tracking accuracy in the SAP system.
- Process: Inventory management process needs evaluation of data entry and reconciliation procedures to ensure alignment between system records and physical stock.
- Personnel: Review actions of staff responsible for inventory updates and reconciliation for compliance with relevant SOPs, focusing on data entry accuracy and verification practices.

⚠ Impact Assessment

- **Product Quality:** No direct impact on product quality is identified from the inventory discrepancy.
- **Batch Disposition:** The affected lots require reconciliation and verification of inventory records to ensure accurate stock levels.
- **Risk Level:** Classified as Major due to the significant discrepancy in inventory records, which could affect order fulfillment and inventory management.
- **Other Batches:** Potential risk to other batches if similar discrepancies in inventory management are present across other products.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine lots 1000186 and 1000187 until inventory reconciliation is completed.
- Conduct a physical recount of all Norepinephrine lots to verify current stock levels.

Corrective Actions:

- Reconcile SAP system data with physical inventory for lots 1000186 and 1000187.
- Retrain warehouse personnel on accurate data entry and inventory reconciliation procedures.

Preventive Actions:

- Implement a double verification process for inventory data entry in the SAP system.
- Revise SOPs to include regular audits of inventory records and physical stock.
- Introduce automated alerts for significant discrepancies between SAP records and physical counts.

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