

Deviation Report

Record ID: DEV\_20250812\_194151      Generated: August 12, 2025 07:42 PM

Report Information			
TITLE:	Norepinephrine lot discrepancy with sales	PRIORITY:	MAJOR
STATUS:	In Progress	DEVIATION TYPE:	Material
DATE OF OCCURRENCE:	February 11, 2025	DEPARTMENT(S):	QA
BATCH/LOT NUMBER:	orders. Was discovered as SAP was stating to pull from certain Lots, but	QUANTITY IMPACTED:	there was not enough physical quantity of that Lot. For Lot 1000186 SAP
PLANNED DEVIATION:	No	INITIATOR:	Matt

User Input - Original Deviation Description

On 11 Feb 2025 Norepinephrine lot didn't match sales

## AI-Generated Analysis

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### Deviation Summary

On February 11, 2025, a discrepancy was identified in the Norepinephrine lot 1000186, where the physical quantity did not match the sales orders as indicated by SAP. This issue was discovered by the Quality Assurance (QA) department when SAP attempted to pull from certain lots, revealing insufficient physical stock. The deviation involves a material issue impacting the batch/lot in question.

### Event Timeline

- February 11, 2025: The QA department discovered a discrepancy between the SAP system's sales orders and the physical quantity available for Norepinephrine lot 1000186.

### Root Cause Analysis

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

- Material: Norepinephrine lot 1000186 requires verification of inventory records and physical stock levels to identify discrepancies between SAP data and actual quantities.
- Process: The inventory management process needs evaluation to ensure accurate synchronization between SAP system data and physical stock levels.
- Personnel: Review the actions of personnel responsible for inventory management and SAP data entry for compliance with relevant SOPs to determine if human error contributed to the discrepancy.

## ⚠ Impact Assessment

- **Product Quality:** There is no direct impact on product quality as the deviation pertains to inventory management rather than product specifications.
- **Batch Disposition:** The affected batch, lot 1000186, requires a thorough reconciliation of inventory records and may need additional verification to ensure correct stock levels.
- **Risk Level:** Classified as Major due to the potential impact on supply chain and order fulfillment, although no direct product quality issues are identified.
- **Other Batches:** There is a potential risk to other batches if similar inventory discrepancies exist, necessitating a broader review of inventory records.

## CAPA Plan

### Immediate Actions (24-48 hours):

- Quarantine Norepinephrine lot 1000186 to prevent further discrepancies in order fulfillment.
- Conduct an immediate inventory count of all Norepinephrine lots to identify any additional discrepancies.
- Halt any further SAP transactions involving the affected lot until reconciliation is complete.

### Corrective Actions (address this event):

- Reconcile SAP data with physical inventory for lot 1000186 to ensure accurate records.
- Retrain personnel on proper inventory management procedures and SAP data entry to prevent future errors.

### Preventive Actions (prevent recurrence):

- Implement a double verification process for SAP inventory entries to ensure accuracy.
- Revise SOPs to include routine audits of SAP data against physical inventory.
- Introduce automated alerts in SAP for inventory discrepancies to prompt immediate investigation.