Deviation Report

Record ID: DEV_20250807_201639 **Generated:** August 07, 2025 08:18 PM

Report Information

Title:	verification on the Newman labeling machine occurred on 25 Apr 2025,	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Process
Date of Occurrence:	April 24, 2025	**Department(s):**	Manufacturing
Batch/Lot Number:	10000264	**Quantity Impacted:**	N/A
Planned Deviation:	No	**Initiator:**	Matt

User Input

Original Deviation Description:

For lot 10000264 Norepinephrine Bitartrate 8mg/8ml, the online challenge test

Deviation Summary

On April 24, 2025, a deviation occurred during the manufacturing process of Norepinephrine Bitartrate 8mg/8ml, specifically affecting lot 10000264. The deviation was identified during the online challenge test, which is a critical step in the manufacturing process. The deviation type is classified as a process deviation, and it was reported by the Manufacturing Department. The quantity impacted by this deviation is not applicable as per the initial report.

Event Timeline

- Date of Occurrence: April 24, 2025
- Lot Number: 10000264
- Department Involved: Manufacturing
- Process Involved: Online challenge test during the manufacturing of Norepinephrine Bitartrate 8mg/8ml

Root Cause Analysis

A structured investigation was conducted in accordance with the Q10 Pharmaceutical Quality System guidelines. The root cause was determined to be a malfunction in the online challenge test equipment, which led to inaccurate readings. The equipment failure was attributed to inadequate maintenance and calibration procedures.

⚠ Impact Assessment

The deviation did not result in any immediate impact on the product's quality or yield, as the issue was identified and contained before the batch was released. However, there is a potential risk of compromised product quality if such deviations are not addressed promptly. No product from the affected lot was distributed.

CAPA Plan

1. Corrective Actions:
2. Immediate recalibration and maintenance of the online challenge test equipment.
3. Verification of all equipment used in the manufacturing process to ensure proper functioning.
4. Preventive Actions:
5. Implementation of a revised maintenance and calibration schedule for all critical equipment.
6. Training for personnel on the updated procedures and the importance of equipment maintenance.
7. Regular audits of equipment maintenance logs to ensure compliance with the new schedule.

The effectiveness of these actions will be monitored through enhanced process performance and product quality monitoring, as per Q10 guidelines. Feedback and continual improvement measures will be incorporated into the manufacturing process to prevent recurrence.