Deviation Report

Record ID: DEV_20250807_200024 **Generated:** August 07, 2025 08:02 PM

Report Information

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

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 number 10000264. The deviation was classified under equipment-related issues and was identified during an online challenge test. The quantity impacted by this deviation was not applicable.

Event Timeline

- Date of Occurrence: April 24, 2025
- Department Involved: Manufacturing
- Deviation Type: Equipment-related issue during the online challenge test for lot 10000264

Root Cause Analysis

The root cause of the deviation was traced back to a malfunction in the equipment used during the online challenge test. A detailed investigation revealed that the equipment had not been calibrated according to the scheduled maintenance plan, leading to inaccurate test results.

⚠ Impact Assessment

The deviation was limited to the online challenge test, with no direct impact on the quality or safety of the Norepinephrine Bitartrate product itself. However, the reliability of the test results was compromised, necessitating a review of the equipment calibration and maintenance records to ensure compliance with GMP standards.

CAPA Plan

- Corrective Actions:
- Immediate recalibration of the affected equipment to ensure accurate test results.
- Retesting of the lot 10000264 using calibrated equipment to confirm product quality.
- Preventive Actions:
- Implementation of a revised calibration schedule to prevent future occurrences.
- Training for the manufacturing team on the importance of adhering to equipment maintenance schedules.
- Regular audits of equipment calibration records to ensure ongoing compliance with GMP requirements.

The CAPA plan will be reviewed periodically to assess the effectiveness of the implemented actions and to make necessary adjustments for continual improvement.