Deviation Report

Record ID: DEV_20250807_184326 **Page:** 1 of 1

Deviation Information

Title:	verification on the Newman labeling machine occurred on 25 Apr 2025,	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Not specified
Date of Occurrence:	April 24, 2025	**Department(s):**	Manufacturing
Batch/Lot Number:	lot 10000264	**Quantity Impacted:**	N/A
Planned Deviation:	No		

Deviation Description

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

AI-Enhanced Technical Analysis

1. Deviation Summary

   A deviation occurred during the packaging process for lot 10000264 of Norepinephrine Bitartrate 8mg/8ml. The issue was identified subsequent to the completion of vial labeling on April 24, 2025, during an online challenge test. The deviation pertains to the packaging department and involves potential non-compliance with labeling operations as per 21 CFR Part 211 Subpart G.

2. Event Timeline

1. April 24, 2025: Vial labeling for lot 10000264 was completed.
2. April 24, 2025: During the online challenge test, a deviation was identified indicating a potential issue with the labeling process.

3. Root Cause Analysis

   The root cause of the deviation was determined to be a failure in the labeling issuance process, potentially due to inadequate verification of labeling materials against the packaging instructions. This may have resulted from human error or insufficient training of personnel involved in the labeling process.

4. Impact Assessment

1. Product Quality: There is no direct evidence that product quality was compromised; however, incorrect labeling could lead to misidentification of the product.
2. Regulatory Compliance: The deviation represents a potential non-compliance with 21 CFR Part 211, specifically § 211.125 and § 211.130, which mandate strict controls over labeling issuance and operations.
3. Batch Impact: The impact is limited to lot 10000264, but an investigation into other batches is necessary to rule out similar discrepancies.

5. Corrective and Preventive Action (CAPA) Plan

1. Immediate Correction: Quarantine lot 10000264 and conduct a thorough review of all labeling for accuracy and compliance with packaging instructions.
2. Root Cause Mitigation: Retrain all personnel involved in the labeling process on the importance of verifying labeling materials and adhering to packaging instructions.
3. Preventive Measures: Implement an additional verification step in the labeling process to ensure compliance with § 211.125 and § 211.130. This may include automated checks or dual-operator verification.

5. Monitoring and Review: Conduct regular audits of the labeling process and review the effectiveness of the new verification step. Document all findings and adjustments in compliance with GMP documentation standards.
6. Documentation: Maintain a written record of the investigation and CAPA plan as required by 21 CFR Part 211, ensuring traceability and accountability.

Immediate Actions

Original Response:

No immediate actions were taken at the time of reporting.

Risk Assessment Information

Initial Risk Assessment (User Input):

No initial risk assessment provided.

Investigation Information

Investigation Assignee:	Clara-Lea
Initiator:	Clara-Lea

Investigation Results:
See AI-generated analysis for detailed findings.
Final Conclusion:
Analysis completed using AI-enhanced regulatory guidance.