Deviation Report

Record ID: DEV_20250807_194813 **Generated:** August 07, 2025 07:49 PM

Report 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:	N/A	**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, lot number 10000264. The deviation was identified during the online challenge test subsequent to the completion of vial labeling. The specific nature of the deviation was not detailed in the provided information, but it pertains to the manufacturing department.

Event Timeline

- April 24, 2025: Deviation identified during the online challenge test following vial labeling completion for lot 10000264.

Root Cause Analysis

The root cause analysis is not explicitly provided in the description. However, it is essential to conduct a thorough investigation as per FDA guidelines (§ 211.192) to determine the underlying cause of the deviation. This includes reviewing whether the issue has occurred previously and assessing the potential causes related to equipment, process, or human error.

⚠ Impact Assessment

The impact assessment should evaluate the extent to which the deviation affects the quality, safety, and efficacy of the product. This includes determining if other batches or products are affected, as per JYPharm-3-138 guidelines. The quantity impacted is not specified, so a detailed review of production records and testing results is necessary to assess the deviation's impact.

CAPA Plan

- Immediate Correction: Isolate the affected lot 10000264 and halt further distribution until a thorough investigation is completed.
- Investigation: Conduct a detailed investigation to identify the root cause, involving a review of equipment, processes, and personnel involved in the labeling and testing stages.
- Documentation: Maintain a comprehensive written record of the investigation, including conclusions and follow-up actions, as required by JYPharm-3-138 and § 211.192.
- Preventive Actions: Implement process improvements or retraining of personnel to prevent recurrence of the deviation. This may include revising SOPs or enhancing monitoring of the labeling process.
- Follow-Up: Monitor subsequent batches for similar issues and review the effectiveness of the implemented preventive measures.