Deviation Report

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Report Information

Title:	Deviation in online challenge test for Norepinephrine Bitartrate	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Procedure
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

A deviation occurred during the manufacturing of Norepinephrine Bitartrate 8mg/8ml for lot number 10000264. The issue was identified during the online challenge test, which is a part of the standard manufacturing procedure. The deviation was classified under the "Procedure" type and was reported by the Manufacturing department on April 24, 2025.

Event Timeline

- Date of Occurrence: April 24, 2025
- Process Involved: Online challenge test during manufacturing
- Batch/Lot Number: 10000264

Root Cause Analysis

The root cause of the deviation was determined to be a procedural error during the execution of the online challenge test. A review of the standard operating procedures (SOPs) revealed that the test parameters were not correctly followed, leading to the deviation.

⚠ Impact Assessment

The impact of this deviation on the product quality and process performance was assessed. Since the deviation was identified during the online challenge test, no product was released with this issue. Therefore, there was no impact on the final product quality or patient safety. The quantity impacted is not applicable as the deviation was caught during the testing phase.

CAPA Plan

- Corrective Actions:
- Immediate retraining of the personnel involved in the online challenge test on the correct SOPs and test parameters.
- Review and revision of the SOPs to ensure clarity and prevent future procedural errors.
- Preventive Actions:
- Implementation of a more robust monitoring system to ensure adherence to SOPs during the online challenge test.
- Regular audits and refresher training sessions for the manufacturing team to reinforce the importance of following procedures accurately.
- Incorporation of CAPA methodology to continually improve the process and prevent recurrence of similar deviations.

The effectiveness of the CAPA plan will be evaluated through follow-up audits and monitoring of future batches to ensure compliance and process improvement.