Deviation Report

Record ID: DEV_20250808_142640 **Generated:** August 08, 2025 02:29 PM

Report Information

TITLE:	Skipped step 6.4.12 for Norepinephrine formulation operation in lot 10000311	**PRIORITY:**	MAJOR
STATUS:	In Progress	**DEVIATION TYPE:**	Process
DATE OF OCCURRENCE:	June 09, 2025	**DEPARTMENT(S):**	Manufacturing
BATCH/LOT NUMBER:	10000311	**QUANTITY IMPACTED:**	N/A
PLANNED DEVIATION:	No	**INITIATOR:**	Matt

User Input - Original Deviation Description

Skipped the step 6.4.12 for Norepinephrine formulation operation in lot 10000311 on 09 Jun 2025. During batch record review it was noted that step 6.4.12 was listed as N/A (not applicable). The step states to initiate mixing of the vessel using an agitator setting of NLT 30% and to ensure proper agitation is observed without aeration of the product. Note: This step occurs prior to addition of any components.

AI-Generated Analysis

Deviation Summary

A deviation occurred in the manufacturing process of Norepinephrine for lot 10000311 on June 9, 2025, when step 6.4.12 was incorrectly marked as not applicable. This step involves initiating mixing with an agitator setting of not less than 30% to ensure proper agitation without aeration. The deviation was identified during a batch record review. The quantity impacted is not applicable, and the current status involves ongoing investigation.

Event Timeline

- June 9, 2025: Step 6.4.12 was skipped during the Norepinephrine formulation operation for lot 10000311.
- Post-June 9, 2025: Deviation identified during batch record review when step 6.4.12 was marked as N/A.

Root Cause Analysis

Root cause investigation focuses on the following areas based on the deviation details:

- Process: Step 6.4.12 needs evaluation of the agitator setting and mixing parameters to ensure compliance with the required process conditions.
- Personnel: Review the decision to mark step 6.4.12 as N/A for compliance with the relevant SOP.
- Equipment: The agitator requires review to ensure it is capable of achieving the specified setting of not less than 30% without causing aeration.

⚠ Impact Assessment

- Product Quality: The deviation in mixing speed may affect the content uniformity and stability of the Norepinephrine formulation.
- Batch Disposition: The batch requires additional testing to assess content uniformity and ensure product quality.
- Risk Level: Classified as Major due to potential impact on product quality and process integrity.
- Other Batches: No immediate risk to other batches identified, as this deviation is specific to lot 10000311.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine batch 10000311 pending further investigation and testing.
- Initiate sampling of the batch for content uniformity and stability testing.

Corrective Actions:

- Reprocess batch 10000311 using the correct mixing parameters as specified in step 6.4.12.
- Retrain operators on the importance of adhering to all process steps and the correct procedure for marking steps as N/A.

Preventive Actions:

- Revise SOP to include a mandatory verification step for critical process parameters, such as mixing speed.
- Implement an automated alarm system to alert operators if the agitator setting deviates from the specified range.
- Conduct regular audits of batch records to ensure compliance with all process steps.