Deviation Report

Record ID: DEV_20250812_212515 **Generated:** August 12, 2025 09:26 PM

Report Information

TITLE:	Discoloration observed on forceps during filling of batch 10000245	**PRIORITY:**	MAJOR
STATUS:	In Progress	**DEVIATION TYPE:**	Equipment
DATE OF OCCURRENCE:	March 13, 2025	**DEPARTMENT(S):**	Manufacturing
BATCH/LOT NUMBER:	10000245	**QUANTITY IMPACTED:**	2L
PLANNED DEVIATION:	Yes	**INITIATOR:**	CL

User Input - Original Deviation Description

On 13 March 2025 during the start of filling of batch 10000245 the operators noticed the forceps exhibited slight discoloration. This deviation was planned to test the material.

AI-Generated Analysis

Deviation Summary

On March 13, 2025, during the start of the filling process for batch 10000245, operators identified a slight discoloration on the forceps used. This deviation was planned to test the material. The impacted quantity is 2 liters. The current status involves ongoing investigation to determine the root cause and assess the impact on product quality.

Event Timeline

- March 13, 2025: Operators noticed slight discoloration on the forceps at the start of filling batch 10000245.

Root Cause Analysis

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

- Equipment: The forceps require review of cleaning and maintenance procedures to ensure compliance with established protocols.
- Material: The material used for the forceps requires verification for potential contamination or degradation that could lead to discoloration.

⚠ Impact Assessment

- Product Quality: The discoloration of the forceps may affect the sterility or purity of the product in batch 10000245.
- Batch Disposition: The batch requires additional testing to ensure no compromise in product quality due to potential contamination.
- Risk Level: Classified as Major due to potential impact on product quality and patient safety.
- Other Batches: No immediate risk identified for other batches, but similar equipment should be inspected to prevent recurrence.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine batch 10000245 to prevent distribution until further testing is completed.
- Stop use of the affected forceps and replace them with verified equipment.
- Sample the batch for comprehensive testing to assess potential contamination.

Corrective Actions (address this event):

- Recalibrate and inspect all forceps used in the process to ensure compliance with specifications.
- Conduct a thorough cleaning and maintenance check of all equipment involved in the filling process.

Preventive Actions (prevent recurrence):

- Revise SOP to include a mandatory inspection of equipment for discoloration before use.
- Implement additional in-process control checks for equipment condition during critical steps.
- Train operators on the importance of equipment inspection and immediate reporting of anomalies.