Deviation Report

Record ID: DEV_20250808_043849 **Generated:** August 08, 2025 04:40 AM

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:**	789
Planned Deviation:	No	**Initiator:**	Matt

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.

AI-Generated Analysis

Deviation Summary

On March 13, 2025, during the start of filling for batch 10000245, operators identified a slight discoloration on the forceps used in the process. This deviation impacted a quantity of 789 units. The issue was noted by the manufacturing department. 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 used during the filling process require review of cleaning and maintenance records to ensure compliance with 21 CFR 211.67(b).
- Material: The material of the forceps needs verification for potential chemical reactions or corrosion that may cause discoloration.
- Process: The filling process step requires evaluation to ensure that no external factors contributed to the discoloration of the equipment.

⚠ Impact Assessment

- Product Quality: The discoloration on the forceps may lead to contamination, affecting the sterility and safety of the product.
- Batch Disposition: The batch requires additional testing to ensure no contamination occurred due to the equipment issue.
- Risk Level: Classified as Major due to the potential impact on product sterility and patient safety.
- Other Batches: No immediate risk identified to 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 the use of the affected forceps and replace them with verified equipment.
- Collect samples from the batch for sterility and contamination testing.

Corrective Actions:

- Reprocess batch 10000245 if contamination is confirmed, following validated procedures.
- Recalibrate and inspect all forceps used in the filling process for compliance with maintenance protocols.
- Retrain operators on equipment inspection procedures to ensure early detection of similar issues.

Preventive Actions:

- Implement an automated inspection system for equipment discoloration detection before use.
- Revise SOPs to include a mandatory double verification step for equipment condition before starting the filling process.
- Schedule regular audits of equipment maintenance records to ensure ongoing compliance with cleaning protocols.