Deviation Report

Record ID: DEV_20250814_192311 **Generated:** August 14, 2025 07:24 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:**	full batch
PLANNED DEVIATION:	Yes	**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. 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 observed that the forceps exhibited slight discoloration. This deviation was planned to test the material. The entire batch is impacted. 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 during the start of the filling process for batch 10000245.

Root Cause Analysis

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

- Equipment: The forceps require review of maintenance and cleaning procedures to ensure compliance with 21 CFR 211.67(b) and to determine if discoloration is due to inadequate cleaning or maintenance.
- Material: The material of the forceps requires verification to ensure it is not contributing to the discoloration and that it meets the required specifications.
- Process: The filling process needs evaluation to determine if any process parameters could have contributed to the discoloration observed on the forceps.

⚠ Impact Assessment

- Product Quality: The discoloration of forceps may indicate potential contamination, affecting the sterility of the batch.
- Batch Disposition: The batch requires additional testing to assess sterility and ensure no contamination has occurred.
- Risk Level: Classified as Major due to the potential impact on product sterility and patient safety.
- Other Batches: No immediate risk to other batches identified, as the issue appears isolated to the equipment used for this batch.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine batch 10000245 to prevent further processing or distribution.
- Stop the use of the discolored forceps and remove them from the production area.
- Sample the batch for sterility testing to assess potential contamination.

Corrective Actions:

- Recalibrate and inspect the forceps to ensure they meet the required specifications and are free from discoloration.
- Conduct a thorough review and update of the cleaning and maintenance procedures for the forceps.

Preventive Actions:

- Implement a routine inspection schedule for equipment to detect discoloration or other anomalies early.
- Revise SOPs to include specific checks for equipment discoloration and ensure compliance with cleaning protocols.
- Train operators on the importance of equipment inspection and immediate reporting of any anomalies.