Deviation Report

Record ID: DEV_20250808_192436 **Generated:** August 08, 2025 07:25 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 filling batch 10000245, operators noticed slight discoloration on the forceps. This deviation was planned to test the material. The full batch is impacted. The deviation occurred in the Manufacturing department and is classified as an Equipment deviation. The current status involves ongoing investigation to determine the root cause.

Event Timeline

- March 13, 2025: Operators identified slight discoloration on the forceps during 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 identify any lapses that could cause discoloration.
- Material: The material of the forceps requires verification for potential chemical reactions or contamination that may lead to discoloration.

⚠ Impact Assessment

- Product Quality: The discoloration of forceps may indicate potential contamination, affecting product purity.
- Batch Disposition: The batch requires additional testing for contamination and product integrity.
- Risk Level: Classified as Major due to potential contamination risk, which could compromise product safety and efficacy.
- Other Batches: No immediate risk identified for other batches unless similar equipment is used without verification.

CAPA Plan

Immediate Actions (24-48 hours):

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

Corrective Actions:

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

Preventive Actions:

- Revise SOPs to include regular inspection and documentation of equipment condition before use.
- Implement additional training for operators on identifying and reporting equipment anomalies.
- Introduce a routine verification process for equipment material integrity to prevent future occurrences.