Deviation Report

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Report Information

Title:	Discoloration observed on forceps during batch filling	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Equipment
Date of Occurrence:	March 13, 2025	**Department(s):**	QA
Batch/Lot Number:	10000245	**Quantity Impacted:**	678
Planned Deviation:	No	**Initiator:**	M

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 batch 10000245, operators observed that the forceps exhibited slight discoloration. This deviation affected a quantity of 678 units. The issue was identified by the Quality Assurance (QA) department. Currently, the batch is under investigation to determine the root cause and assess potential impacts.

Event Timeline

- March 13, 2025: Operators noticed 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 ensure compliance with 21 CFR 211.67(b).
- Material: The material of the forceps needs verification for any chemical reactions or contamination that could cause discoloration.
- Process: The filling process step requires evaluation to determine if any process parameters could contribute to the discoloration.

Investigation will use a Fishbone diagram to identify the root cause.

⚠ Impact Assessment

- Product Quality: Discoloration on forceps may indicate potential contamination risk, affecting product sterility.
- Batch Disposition: The batch requires additional testing for contamination and sterility assurance.
- Risk Level: Classified as Major due to potential impact on product sterility, which could affect patient safety.
- Other Batches: No immediate risk identified for other batches, as the issue was isolated to the forceps used in this batch.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine batch 10000245 to prevent distribution.
- Stop use of the affected forceps and remove them from the production area.
- Collect samples from the batch for contamination testing.

Corrective Actions:

- Recalibrate and inspect all forceps to ensure they meet quality standards.
- Conduct a thorough cleaning of the equipment and verify compliance with cleaning procedures.
- Retrain operators on equipment inspection protocols before use.

Preventive Actions:

- Revise SOP to include visual inspection of equipment for discoloration before use.
- Implement additional in-process control checks for equipment condition during production.
- Establish a maintenance schedule for forceps to prevent future occurrences of discoloration.