Deviation Report

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Report Information

Title:	Discoloration of 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:**	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 noticed that the forceps exhibited slight discoloration. This deviation impacted 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 any potential 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 records to ensure compliance with established procedures.
- Process: The filling process step needs evaluation to determine if any deviations in handling or environmental conditions contributed to the discoloration.
- Personnel: Review operator actions for compliance with relevant SOPs regarding equipment inspection and handling.

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

⚠ Impact Assessment

- Product Quality: Discoloration of forceps may indicate potential contamination risk, affecting product sterility.
- Batch Disposition: The batch requires additional sterility testing to ensure product safety.
- Risk Level: Classified as Major due to potential impact on product sterility and patient safety.
- Other Batches: No immediate risk identified for other batches; however, further investigation is needed to confirm.

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 sterility 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 SOPs.
- Retrain operators on equipment inspection procedures to ensure compliance.

Preventive Actions:

- Implement an automated alert system for equipment discoloration detection.
- Revise SOPs to include mandatory double verification of equipment condition before use.
- Introduce additional in-process control checks at the filling step to monitor equipment condition.