Deviation Report

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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:**	289
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 13 March 2025, during the commencement of the filling process for batch 10000245, operators observed a slight discoloration on the forceps. This deviation falls under the category of Equipment-related issues within the Manufacturing department. The incident was documented in accordance with Good Manufacturing Practice (GMP) standards, specifically referencing 21 CFR Part 211.67(b) concerning the maintenance and cleaning of equipment.

Event Timeline

- Date of Occurrence: 13 March 2025
- Batch/Lot Number: 10000245
- Quantity Impacted: 289 units
- Department: Manufacturing

Root Cause Analysis

A structured investigation was conducted in alignment with Q10-Pharmaceutical-Quality-System guidelines, focusing on determining the root cause of the equipment discoloration. The analysis revealed that the discoloration was due to inadequate cleaning procedures, which failed to remove residual material from previous operations. This was attributed to a deviation from the established cleaning protocol, as outlined in 21 CFR Part 211.67(b).

⚠ Impact Assessment

The risk assessment categorized this deviation as a moderate impact on product quality, given that the discoloration did not directly contact the product. However, potential cross-contamination cannot be entirely ruled out. The deviation was evaluated against Process-Validation--General-Principles-and-Practices to ensure that no adverse effects on product quality or patient safety were present.

CAPA Plan

1. Immediate Correction:
2. The affected batch 10000245 was quarantined pending further investigation.
3. The forceps were re-cleaned and inspected to ensure compliance with GMP standards.
4. Preventive Actions:
5. Review and revise the existing cleaning procedures to enhance the removal of residual materials.
6. Conduct training sessions for operators on the updated cleaning protocols to prevent recurrence.
7. Implement a routine audit schedule to ensure adherence to cleaning procedures.
8. Monitoring and Verification:
9. Establish a monitoring program to verify the effectiveness of the revised cleaning procedures.
10. Document and review the outcomes of the training sessions and audits to ensure continuous compliance.

    The CAPA plan aims to address the root cause and mitigate future risks, ensuring compliance with regulatory requirements and maintaining product quality and safety.