Deviation Report

# Report Information

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| --- | --- | --- | --- |
| Title | Discoloration observed on forceps during filling of batch 10000245 | Priority | Major |
| Status | In Progress | Type | Equipment |
| Date | 03/13/2025 | Department | Manufacturing |
| Batch/Lot | 10000245 | Quantity | 789 |
| Planned | No | Initiator | Matt |
| Record ID | DEV\_20250808\_043849 | Generated | 08/08/2025 04:40 AM |

# 👤 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 identified a slight discoloration on the forceps used in the process. This deviation impacted a quantity of 789 units. The issue was noted by the manufacturing department. 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 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 used during the filling process require review of cleaning and maintenance records to ensure compliance with 21 CFR 211.67(b).  
- \*\*Material\*\*: The material of the forceps needs verification for potential chemical reactions or corrosion that may cause discoloration.  
- \*\*Process\*\*: The filling process step requires evaluation to ensure that no external factors contributed to the discoloration of the equipment.

## ⚠️ Impact Assessment

- \*\*Product Quality\*\*: The discoloration on the forceps may lead to contamination, affecting the sterility and safety of the product.  
- \*\*Batch Disposition\*\*: The batch requires additional testing to ensure no contamination occurred due to the equipment issue.  
- \*\*Risk Level\*\*: Classified as Major due to the potential impact on product sterility and patient safety.  
- \*\*Other Batches\*\*: No immediate risk identified to other batches, but similar equipment should be inspected to prevent recurrence.

## 🔧 CAPA Plan

\*\*Immediate Actions (24-48 hours):\*\*  
- Quarantine batch 10000245 to prevent distribution until further testing is completed.  
- Stop the use of the affected forceps and replace them with verified equipment.  
- Collect samples from the batch for sterility and contamination testing.  
\*\*Corrective Actions:\*\*  
- Reprocess batch 10000245 if contamination is confirmed, following validated procedures.  
- Recalibrate and inspect all forceps used in the filling process for compliance with maintenance protocols.  
- Retrain operators on equipment inspection procedures to ensure early detection of similar issues.  
\*\*Preventive Actions:\*\*  
- Implement an automated inspection system for equipment discoloration detection before use.  
- Revise SOPs to include a mandatory double verification step for equipment condition before starting the filling process.  
- Schedule regular audits of equipment maintenance records to ensure ongoing compliance with cleaning protocols.