Deviation Report

# Report Information

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| --- | --- | --- | --- |
| Title | Discoloration observed on forceps during batch filling | Priority | Major |
| Status | In Progress | Type | Equipment |
| Date | 03/13/2025 | Department | QA |
| Batch/Lot | 10000245 | Quantity | 678 |
| Planned | No | Initiator | M |
| Record ID | DEV\_20250808\_035106 | Generated | 08/08/2025 03:51 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 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.