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 | QA |
| Batch/Lot | 10000245 | Quantity | 678 |
| Planned | No | Initiator | M |
| Record ID | DEV\_20250808\_034131 | Generated | 08/08/2025 03:42 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 initiation of the filling process for batch 10000245, operators identified a deviation involving slight discoloration of the forceps used. This deviation impacted a total of 678 units. The occurrence was noted by operators in the Quality Assurance (QA) department. The deviation is categorized under equipment-related issues. Currently, the affected batch is under investigation to determine the root cause and appropriate corrective actions.

## ⏰ Event Timeline

- March 13, 2025: Operators in the QA department commenced the filling process for batch 10000245.  
- During the start of the filling process, operators noticed slight discoloration on the forceps.  
- The deviation was documented, and the batch was flagged for further investigation.

## 🔍 Root Cause Analysis

A systematic root cause analysis is required to understand why this deviation occurred. The Ishikawa (Fishbone) Diagram methodology will be employed, focusing on the following categories:  
- \*\*Man (People):\*\* Investigate training records to ensure operators were adequately trained and procedures were followed. Review communication protocols to confirm clear instructions were provided.  
- \*\*Method (Process):\*\* Examine Standard Operating Procedures (SOPs) and batch records to ensure compliance with established processes. Review process parameters for any deviations.  
- \*\*Machine (Equipment):\*\* Assess calibration records, maintenance logs, and performance logs of the forceps to identify any anomalies or lapses.  
- \*\*Material:\*\* Evaluate raw material specifications, storage conditions, and supplier data to rule out material-related causes.  
- \*\*Measurement:\*\* Verify in-process controls, testing methods, and specifications to ensure accurate measurements were taken.  
- \*\*Environment:\*\* Assess environmental conditions such as temperature, humidity, and clean room status to identify any potential contributing factors.  
The investigation team should use this framework to systematically identify all contributing factors.

## ⚠️ Impact Assessment

This deviation requires assessment across multiple risk dimensions:  
- \*\*Quality Impact:\*\* The potential impact on product quality includes concerns about specifications, stability, and efficacy of the affected batch.  
- \*\*Patient Safety Risk:\*\* The risk level is assessed as Major due to the equipment-related nature of the deviation, which could potentially affect product quality.  
- \*\*Regulatory Impact:\*\* The deviation may require reporting to regulatory authorities, and it could impact compliance status.  
- \*\*Product Disposition:\*\* Decisions need to be made regarding the disposition of the affected batch, including potential rework or rejection.  
- \*\*Supply Impact:\*\* There is a potential impact on product availability, depending on the outcome of the investigation and disposition decisions.  
- \*\*Similar Products/Batches:\*\* Other batches using the same equipment or process should be evaluated for similar issues.  
- \*\*Risk Classification:\*\* The preliminary risk level is classified as Major due to the potential impact on product quality and patient safety.  
A detailed risk assessment matrix should be completed by the Quality team.

## 🔧 CAPA Plan

- \*\*Immediate Actions:\*\*  
- Implement containment measures to prevent further use of the discolored forceps.  
- Segregate affected materials to prevent distribution.  
- Notify relevant stakeholders, including regulatory bodies if necessary, within 24 hours.  
- \*\*Corrective Actions:\*\*  
- Conduct a thorough investigation to determine the root cause of the discoloration within 5 business days.  
- Perform additional testing on the affected batch to assess quality impact.  
- Update documentation, including SOPs and batch records, as needed based on investigation findings.  
- \*\*Preventive Actions:\*\*  
- Implement system improvements to prevent recurrence, such as enhanced equipment maintenance protocols.  
- Identify training needs and conduct refresher training for operators within 30 days.  
- Review and update process changes to enhance robustness.  
- Enhance monitoring of equipment and environmental conditions to detect potential issues early.  
All actions should be documented and tracked to ensure timely completion and effectiveness.