

Deviation Report

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| Report Information | | | |
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| 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): | QA |
| Batch/Lot Number: | 10000245 | Quantity Impacted: | 678 |
| Planned Deviation: | No | Initiator: | M |

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.