

Deviation Report

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Report Information			
Title:	Discoloration of 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:	Yes	Initiator:	cl

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. This deviation was planned to test the material

AI-Generated Analysis

Deviation Summary

On March 13, 2025, during the initiation of the filling process for batch 10000245, operators observed a slight discoloration on the forceps. This deviation was part of a planned test for the material. The impacted quantity is 678 units. The deviation is currently under investigation by the QA department to determine the root cause and assess any potential impact on product quality.

Event Timeline

- March 13, 2025: Operators noticed slight 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 used during the filling process require review of cleaning and maintenance procedures to ensure compliance with established protocols.
- **Material:** The material of the forceps needs verification for potential chemical reactions or degradation that could cause discoloration.

Investigation will use Fishbone diagram to identify the root cause.

⚠ Impact Assessment

- **Product Quality:** The discoloration on the forceps may introduce contamination risk, potentially 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 and patient safety.
- **Other Batches:** No immediate risk identified for other batches, as this deviation is specific to the equipment used in batch 10000245.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine batch 10000245 to prevent distribution until further testing is complete.
- Stop use of the discolored forceps and remove them from the production area.
- Collect samples from the batch for sterility and contamination testing.

Corrective Actions (address this event):

- Recalibrate and inspect all forceps to ensure they meet quality standards before use.
- Conduct a thorough cleaning of the equipment involved in the filling process.
- Retrain operators on the importance of equipment inspection before use.

Preventive Actions (prevent recurrence):

- Revise SOP to include mandatory inspection of equipment for discoloration before each use.
- Implement additional in-process control checks for equipment condition during production.
- Establish a regular maintenance schedule for all equipment to prevent similar issues.