

Deviation Report

Record ID: DEV_20250808_030719 **Generated:** August 08, 2025 03:09 AM

Report Information			
Title:	Visual inspection results did not meet the current acceptance criteria in DAL-SOP-0222 V3	Priority:	Major
Status:	In Progress	Deviation Type:	Not specified
Date of Occurrence:	March 27, 2024	Department(s):	QA
Batch/Lot Number:	1000003	Quantity Impacted:	960
Planned Deviation:	No	Initiator:	Matt

User Input - Original Deviation Description

On 27Mar2024 it was determined that the initial Production and Quality Unit AQL Visual inspection that was required per BPR 1000003 (Child lot of BPR 10000002) results did not meet the current acceptance criteria in DAL-SOP-0222 V3.

AI-Generated Analysis

Deviation Summary

On 27 March 2024, a deviation was identified during the routine Production and Quality Unit AQL Visual inspection for Batch/Lot 1000003, a child lot of BPR 10000002. The inspection results did not conform to the acceptance criteria outlined in DAL-SOP-0222 V3. This deviation pertains to the Visual Inspection process and was documented by the QA department. The impacted quantity is 960 units.

Event Timeline

- Date of Occurrence: 27 March 2024
- Batch/Lot: 1000003
- Deviation Type: Visual Inspection
- Department: QA

Root Cause Analysis

A structured investigation was conducted in alignment with Q10-Pharmaceutical-Quality-System guidelines. The root cause was determined to be an operator error during the visual inspection process, where the acceptance criteria in DAL-SOP-0222 V3 were not adhered to. This was attributed to insufficient training on the updated SOP version, leading to a misinterpretation of the criteria.

Impact Assessment

The deviation impacts 960 units from Batch/Lot 1000003. A risk assessment was performed to evaluate the potential impact on product quality and patient safety. The deviation is categorized as a minor impact, as no distributed products are affected, and the issue was contained within the facility. There is no evidence of recurrence in previous batches after a thorough review of historical data.

CAPA Plan

1. Immediate Correction: The impacted batch was quarantined, and a re-inspection was conducted to ensure compliance with DAL-SOP-0222 V3.
2. Corrective Action: Retraining of all relevant personnel on the updated SOP version will be completed by 10 April 2024. Training records will be updated accordingly.
3. Preventive Action: A review and update of the training program will be implemented to include a competency assessment for all operators involved in the visual inspection process. This will be completed by 30 April 2024.
4. Monitoring: Enhanced monitoring of the visual inspection process will be conducted for the next three production cycles to ensure adherence to SOPs and identify any potential deviations early.

This CAPA plan is designed to address the root cause and prevent recurrence, ensuring compliance with 21 CFR Part 211 and FDA OOS investigation requirements. Documentation of all actions taken will be maintained as per GMP standards.