Deviation Report

Record ID: DEV_20250807_212030 **Generated:** August 07, 2025 09:22 PM

Report Information

Title:	Initial Production and Quality Unit AQL determination	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Not specified
Date of Occurrence:	March 27, 2024	**Department(s):**	Manufacturing
Batch/Lot Number:	BPR 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

Deviation Summary

On 27 March 2024, a deviation was identified during the visual inspection process within the Manufacturing Department. The deviation pertains to the initial Production and Quality Unit Acceptable Quality Level (AQL) assessment for Batch/Lot BPR 1000003. This deviation falls under the category of Visual Inspection and impacts a total quantity of 960 units. The occurrence of this deviation necessitates a thorough investigation in accordance with Q10-Pharmaceutical-Quality-System and 21 CFR Part 211 requirements.

Event Timeline

- Date of Occurrence: 27 March 2024
- Batch/Lot Number: BPR 1000003
- Quantity Impacted: 960 units
- Department Involved: Manufacturing

Root Cause Analysis

A structured investigation was conducted to determine the root cause of the deviation. The investigation adhered to the guidelines outlined in FDA_OOS_investigation and 21 CFR Part 211, ensuring a comprehensive review of the visual inspection process. The root cause was identified as a calibration error in the inspection equipment, which led to inaccurate AQL assessments. Historical data was reviewed to ascertain if similar issues had occurred previously, confirming this was an isolated incident.

⚠ Impact Assessment

The deviation's impact was assessed in accordance with GMP compliance standards. The risk to product quality and patient safety was evaluated and categorized as low, given that the deviation was detected prior to product distribution. The assessment confirmed that no other batches were affected, and the integrity of the remaining stock was verified.

CAPA Plan

A CAPA plan has been developed to address the root cause and prevent recurrence. The action items include:

1. Immediate Correction: Recalibration of the inspection equipment was completed on 28 March 2024 to ensure accurate AQL assessments.
2. Preventive Measures: Implementation of a routine calibration schedule for all inspection equipment, with the first review scheduled for 30 April 2024.
3. Training: Conduct a training session for all relevant personnel on the updated calibration procedures by 15 April 2024.
4. Monitoring: Establish a monitoring protocol to track the effectiveness of the corrective actions, with the first evaluation set for 31 May 2024.

The CAPA plan will be documented and reviewed in accordance with § 211.192, ensuring compliance with regulatory requirements and maintaining product quality standards.