Deviation Report

Record ID: DEV_20250807_194449 **Generated:** August 07, 2025 07:46 PM

Report Information

Title:	was exceeded, with major process defects during 100% visual inspection also not	**Priority:**	Major
Status:	In Progress	**Deviation Type:**	Not specified
Date of Occurrence:	Not specified	**Department(s):**	QA, QC
Batch/Lot Number:	criteria for Major Defects.Lot # 10000295	**Quantity Impacted:**	Lot
Planned Deviation:	No	**Initiator:**	Matt

User Input

Original Deviation Description:

On 02JUN2025, during AQL its was observed that Major Process defects criteria

Deviation Summary

On June 2, 2025, during the Acceptable Quality Level (AQL) inspection, it was observed that Lot 10000295 did not meet the criteria for Major Process defects. The issue was identified by the Quality Assurance (QA) and Quality Control (QC) departments. A reinspection on June 3, 2025, confirmed that the lot failed the second visual inspection as well.

Event Timeline

- June 2, 2025: Initial AQL inspection conducted; Major Process defects identified in Lot 10000295.
- June 3, 2025: Reinspection performed; Lot 10000295 failed the second visual inspection.

Root Cause Analysis

The root cause analysis is ongoing. Initial findings suggest potential deviations in the manufacturing process that led to the defects. A structured investigation is being conducted in accordance with Q10 Pharmaceutical Quality System guidelines to determine the exact root cause.

⚠ Impact Assessment

The impacted quantity is the entire Lot 10000295. The deviation has been documented as per Q7 Good Manufacturing Practice Guidance. The potential impact on product quality is being assessed, with a focus on whether the defects could affect the safety or efficacy of the product.

CAPA Plan

- Immediate Corrective Action: The affected lot has been quarantined to prevent distribution.
- Preventive Action: A review of the manufacturing process and equipment is underway to identify any systemic issues. Training sessions will be conducted for personnel to reinforce adherence to quality standards.
- Long-term CAPA: Implementation of enhanced process monitoring and control measures to prevent recurrence. A review of historical data to identify any similar past occurrences and address them accordingly.