Deviation Report

# Report Information

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| --- | --- | --- | --- |
| Title | was exceeded, with major process defects during 100% visual inspection also not | Priority | Major |
| Status | In Progress | Type | Not specified |
| Date | Not specified | Department | QA, QC |
| Batch/Lot | criteria for Major Defects.Lot # 10000295 | Quantity | Lot |
| Planned | No | Initiator | Matt |
| Record ID | DEV\_20250807\_194449 | Generated | 08/07/2025 07:46 PM |

# 👤 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.