

Deviation Report

Record ID: DEV_20250805_160307 Page: 1 of 1

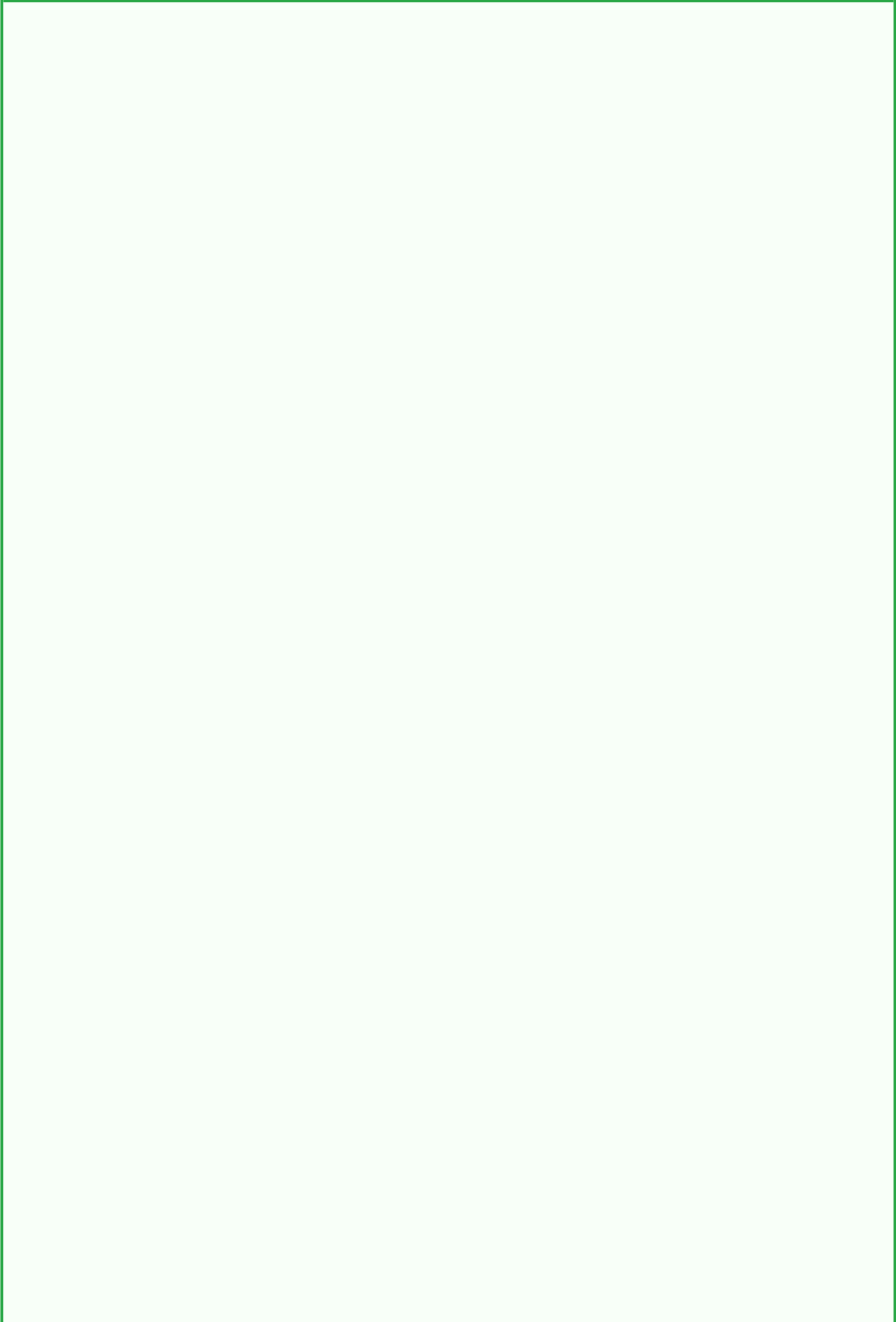
Deviation Information			
Title:		Priority:	Minor
Status:	Open	Deviation Type:	Not specified
Date of Occurrence:	Not specified	Department(s):	Not specified
Batch/Lot Number:	test	Quantity Impacted:	test
Planned Deviation:	No		

Deviation Description

Original Description:

On 02JUN2025, during AQL its was observed that Major Process defects criteria Additional details: was exceeded, with major process defects during 100% visual inspection also not

AI-Enhanced Technical Analysis



#

Enhanced Analysis of Deviation

##

1. Technical Assessment with Regulatory Context

The deviation observed on 02JUN2025 indicates that the major process defects criteria were exceeded during the Acceptable Quality Level (AQL) inspection. This is a critical issue as it suggests that the manufacturing process is not in control and that the quality of the product may be compromised. According to **Q7 Guidance****, any out-of-specification (OOS) results must be thoroughly investigated, documented, and analyzed to determine if a significant problem exists. The ****21 CFR Part 211**** further emphasizes the necessity of investigating discrepancies in specifications, regardless of whether the batch has been distributed, and mandates a comprehensive review of related batches and products.**

##

2. Potential Quality Impact

The exceeding of major process defects during a 100% visual inspection raises significant concerns regarding product quality. Potential impacts include:

- Compromised efficacy or safety of the pharmaceutical product.**
- Increased risk of product recalls or market withdrawals.**
- Damage to the company's reputation and trust with regulatory bodies and consumers.**
- Possible financial implications due to rework, waste, or regulatory fines.**

##

3. Regulatory Compliance Implications

Failure to adequately investigate and address the deviation could lead to non-compliance with regulatory standards, resulting in:

- Warning letters or sanctions from regulatory agencies (e.g., FDA).
- Increased scrutiny during future inspections.
- Potential legal ramifications if product quality issues lead to patient harm.

##

4. Key Investigation Points

To address the deviation effectively, the following investigation points should be considered:

- ****Root Cause Analysis****: Identify the underlying cause(s) of the major process defects. This may include reviewing manufacturing processes, equipment calibration, operator training, and raw material quality.
- ****Data Analysis****: Assess historical data for trends in defect rates, including comparisons with previous batches and other products.
- ****Impact Assessment****: Evaluate the impact of the defects on the affected batch and any other batches produced around the same timeframe.
- ****Corrective Actions****: Develop and implement corrective actions to prevent recurrence, including process adjustments, enhanced training, or equipment upgrades.
- ****Documentation****: Ensure all findings, actions taken, and conclusions are thoroughly documented in accordance with regulatory requirements.

By addressing these points, the organization can work towards resolving the deviation and ensuring compliance with applicable regulations.

Immediate Actions

Original Response:

No immediate actions were taken at the time of reporting.

Risk Assessment Information

Initial Risk Assessment (User Input):

No initial risk assessment provided.

Investigation Information

**Investigation
Assignee:**

Not assigned

Initiator:

test

Investigation Results:

Investigation pending.

Final Conclusion:

Investigation in progress.