Deviation Report

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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:	10000003	**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

AI-Generated Analysis

Deviation Summary

On 27 March 2024, a deviation was identified during the routine visual inspection process within the Manufacturing Department. The deviation pertains to Batch/Lot number 10000003, where an anomaly in the initial Production and Quality Unit Acceptable Quality Level (AQL) was observed. This deviation falls under the category of Visual Inspection and impacts a total of 960 units. This incident necessitates a thorough investigation in accordance with regulatory requirements, including Q10-Pharmaceutical-Quality-System and 21 CFR Part 211, to ensure compliance and maintain product integrity.

Event Timeline

- Date of Occurrence: 27 March 2024
- Batch/Lot Number: 10000003
- Quantity Impacted: 960 units
- Department Involved: Manufacturing

Root Cause Analysis

In alignment with the structured approach outlined in Q10-Pharmaceutical-Quality-System, a detailed investigation was conducted to ascertain the root cause of the deviation. The investigation revealed that the deviation was attributed to an oversight in the visual inspection protocol, where certain visual defects were not adequately identified due to insufficient lighting conditions at the inspection station. This oversight was compounded by a lack of periodic calibration of the inspection equipment, which failed to meet the required sensitivity levels. Historical data review indicated no previous occurrences of this specific issue, suggesting an isolated incident.

⚠ Impact Assessment

The impact of this deviation has been categorized as moderate, given the potential implications on product quality and patient safety. The affected batch, 10000003, has been quarantined pending further evaluation. A risk assessment was conducted, confirming that the deviation did not extend to other batches of the same drug product. The investigation and subsequent findings are documented as per FDA_OOS_investigation guidelines, ensuring transparency and regulatory compliance.

CAPA Plan

To address the identified root cause and prevent recurrence, the following CAPA plan has been established:

1. Immediate Correction: The lighting conditions at the visual inspection station have been enhanced to meet the required standards. The inspection equipment has undergone immediate recalibration to ensure optimal performance.
2. Preventive Actions:
3. Implement a routine calibration schedule for all inspection equipment, with documented verification of compliance.
4. Conduct additional training sessions for inspection personnel, emphasizing the importance of adherence to visual inspection protocols.
5. Introduce a secondary verification step in the visual inspection process to ensure defect detection accuracy.
6. Monitoring and Review:
7. Establish a monitoring program to track the effectiveness of the implemented corrective actions, with periodic reviews to assess compliance.
8. Document all actions and findings in accordance with § 211.192, ensuring a comprehensive record of the investigation and follow-up activities.

This CAPA plan aims to mitigate the risk of future deviations and uphold the integrity of the manufacturing process, in compliance with GMP standards and regulatory expectations.