

Deviation Report

Record ID: DEV_20250805_162601 Page: 1 of 1

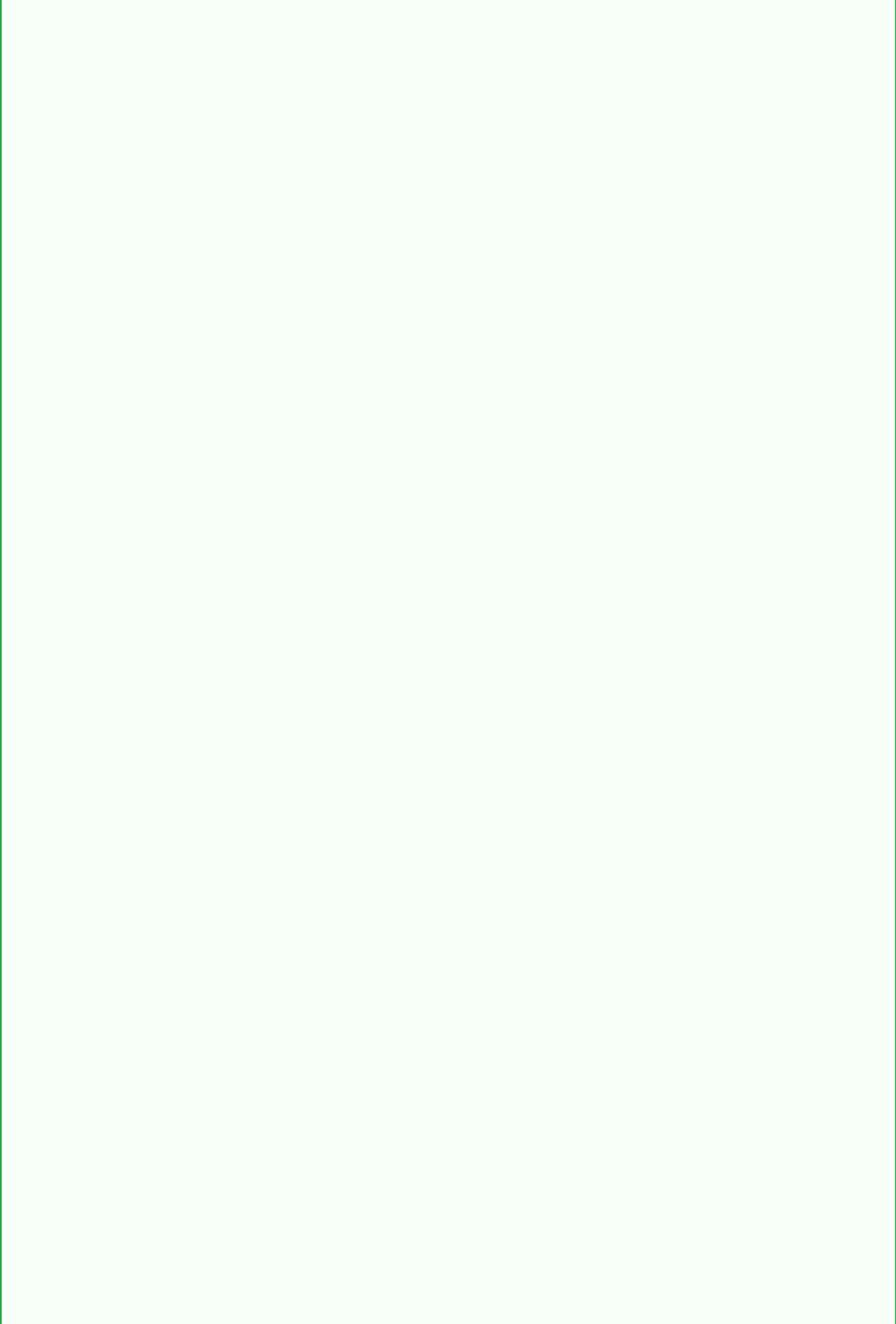
Deviation Information			
Title:		Priority:	Minor
Status:	Open	Deviation Type:	Not specified
Date of Occurrence:	Not specified	Department(s):	QA, QC
Batch/Lot Number:	10000295	Quantity Impacted:	Lot
Planned Deviation:	No		

Deviation Description

Original Description:

On 02JUN2025, during AQL its was observed that Major Process defects criteria Additional details: Reinspection occurred on 03JUN2025, Lot did not pass the 2nd visual inspection

AI-Enhanced Technical Analysis



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Enhanced Analysis of Deviation

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1. Technical Assessment with Regulatory Context

The deviation observed on 02JUN2025 during the Acceptable Quality Level (AQL) inspection indicates a failure to meet the Major Process Defects criteria, which is a critical quality parameter. The subsequent reinspection on 03JUN2025 confirmed that the lot did not pass the second visual inspection, suggesting persistent quality issues. According to JYPharm-3-138, a thorough investigation is required for any deviation, including documenting the investigation process, conclusions, and follow-up actions. The failure to meet established standards is a clear departure from the approved manufacturing process, as outlined in Q7-Good-Manufacturing-Practice-Guidance-for-Active-Pharmaceutical-Ingredients.

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2. Potential Quality Impact

The failure to pass the AQL inspection raises concerns about the overall quality and safety of the product. Major process defects can lead to compromised product integrity, which may affect efficacy and patient safety. If the defects are systemic, they could also indicate broader issues in the manufacturing process, potentially impacting other batches or products. The inability to confirm product quality through visual inspection necessitates a comprehensive evaluation of the manufacturing process and controls.

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3. Regulatory Compliance Implications

Failure to address this deviation in compliance with JYPharm-3-138 and Q7 guidelines may result in regulatory scrutiny, including potential citations during inspections. Non-compliance could lead to product recalls, market withdrawal, or sanctions from regulatory bodies, impacting the company's reputation and financial standing.

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4. Key Investigation Points

- ****Root Cause Analysis****: Identify the underlying causes of the major process defects. This may involve reviewing manufacturing procedures, equipment calibration, and operator training.
- ****Impact Assessment****: Evaluate whether other batches of the same product or different products may be affected by similar defects.
- ****Corrective and Preventive Actions (CAPA)****: Develop and implement CAPA to address identified issues and prevent recurrence.
- ****Documentation Review****: Ensure all relevant documentation, including batch records and inspection reports, is reviewed and updated to reflect findings and actions taken.
- ****Stakeholder Communication****: Inform relevant stakeholders, including quality assurance, production, and regulatory affairs teams, about the findings and actions taken.

This structured approach will help ensure compliance with regulatory requirements and maintain product quality and safety.

Immediate Actions

Original Response:

was exceeded, with major process defects during 100% visual inspection also not

AI Assessment of Immediate Actions

Immediate Actions to Address the Crimp Excursion Deviation:

1. **Quarantine Affected Batch**: Immediately isolate Batch 10000295 from the production area and warehouse. Clearly label it as "Quarantined - Crimp Excursion" to prevent any further processing, distribution, or use of the affected lot.
2. **Notify Quality Assurance and Regulatory Affairs**: Inform the Quality Assurance (QA) team and Regulatory Affairs of the deviation. Ensure that they are aware of the situation and can assist in assessing the impact on product quality and compliance.
3. **Conduct a Root Cause Analysis (RCA)**: Assemble a cross-functional team (including production, quality control, and engineering) to initiate a preliminary investigation into the crimp excursion. Document initial findings and potential causes within the next 24 hours.
4. **Collect and Preserve Evidence**: Gather all relevant documentation, including batch records, equipment logs, and any quality control data related to Batch 10000295. Take photographs

Risk Assessment Information

Initial Risk Assessment (User Input):
meeting criteria.

AI Risk Assessment

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Risk Assessment for Pharmaceutical Deviation

****Deviation Details:****

- Date: 02JUN2025
- Type: Crimp Excursion Lot
- Quantity Impacted: Lot

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1. Product Quality Risk: ****High****

- ****Justification:**** Major process defects, such as crimping issues, can compromise the integrity of the product packaging, potentially leading to contamination or degradation of the pharmaceutical product. This can affect the product's efficacy and shelf life.

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2. Patient Safety Risk: ****High****

- ****Justification:**** If the crimping defect leads to compromised sterility or dosage accuracy, it poses a significant risk to patient safety. Patients may receive ineffective or contaminated products, which could result in adverse health outcomes.

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3. Regulatory Risk: ****Medium****

- ****Justification:**** Deviations from established manufacturing processes can trigger regulatory scrutiny and potential non-compliance issues. While the severity of the defect is high, the regulatory impact may vary depending on the response and corrective actions taken by the company.

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4. Overall Risk Level: ****High****

- ****Justification:**** Given the high product quality and patient safety risks, the overall risk level is assessed as high.
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Investigation Information

Investigation Assignee: Not assigned

Initiator: CL

Investigation Results:

Investigation pending.

Final Conclusion:

Investigation in progress.