# INVESTIGATION REPORT [HIGH SEVERITY]

Ref ID: DEV-2024-0312 | Rev 01 | CONFIDENTIAL
Status: Audit Ready | Generated: 2024-10-13

| | | | |
|---|---|---|---|
| **Batch ID** | BTC0048 | **Product** | Paracetamol Tablets 500mg |
| **Plant** | Unit-III Hyderabad | **Severity** | HIGH |

## AI Generated Summary

The investigation report for batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad highlights a deviation in the granulation process. The Inlet Air Temperature exceeded the upper limit of 70°C, reaching 74.8°C on 2024-10-12 at 08:00, and the Product Bed Temperature reached 78.2°C at 08:15. Equipment ID EQP_GRAN_01 was involved. LIMS results indicate a failure in the assay with a result of 2.3%, below the specification of 1.5%-3%. The batch is currently on HOLD as per the Deviation Report.

## 01. Incident Overview

| BATCH NUMBER | INCIDENT DATE | DEVIATION TYPE | DEPARTMENT |
|---|---|---|---|
| BTC0048 | 2024-10-12 | Temperature Deviation | Granulation |

## 02. Detected Deviations

| SIGNAL/EXCEPTION | DURATION | PEAK VALUE | LIMIT |
|---|---|---|---|
| Inlet Air Temperature | 1 hour 15 minutes | 74.8°C | 70°C |
| Product Bed Temperature | 1 hour 15 minutes | 78.2°C | 70°C |

## 3. Executive Summary

Batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad experienced a deviation on 2024-10-12. The Inlet Air Temperature reached 74.8°C, exceeding the upper limit of 70°C, and the Product Bed Temperature reached 78.2°C. Equipment ID EQP_GRAN_01 was involved. LIMS results showed an assay failure with a result of 2.3%, below the specification range of 1.5%-3%. The batch is currently on HOLD.

## 4. Deviation Description

The first deviation was recorded on 2024-10-12 at 08:00 with the Inlet Air Temperature reaching 74.8°C. The operator ID was not recorded. The temperature progressively rose, with the Product Bed Temperature reaching 78.2°C at 08:15. Immediate actions included stopping the process and initiating an investigation as per the Deviation Report.

## 05. Root Cause Analysis

| PROBABLE CAUSE | METHODOLOGY |
| --- | --- |
| Equipment ID EQP_GRAN_01 had a calibration overdue by 15 days. The thermocouple drift was recorded at +4°C, as per Maintenance Log | The investigation involved reviewing equipment maintenance records |
| **CONCLUSION** | |
| The root cause was identified as overdue calibration of EQP_GRAN_01, with a thermocouple drift of +4°C. Maintenance Log WO-2024-0 | |

## 6. Scope of Review

The review focused on the granulation process parameters, equipment performance, and LIMS results for batch BTC0048.

## 7. Exceptions

The primary exceptions were the Inlet Air Temperature and Product Bed Temperature exceeding their respective upper limits.

## 8. CAPA

CAPA actions included recalibration of EQP_GRAN_01 (WO-2024-0456), replacement of the thermocouple, and requalification of the equipment. A requalification report was generated post-maintenance.

## 9. Impact Assessment

LIMS results indicate the product was impacted. The assay result of 2.3% is below the specification of 1.5%-3%, referencing OOS-2024-0098. The batch is on HOLD.

## 10. Conclusion

The batch BTC0048 is currently on HOLD. An OOS investigation (OOS-2024-0098) is ongoing due to assay failure. Equipment EQP_GRAN_01 has been recalibrated and returned to service.

## 11. Regulatory Compliance

| Standard | Status |
| --- | --- |
| 21 CFR Part 211 | Non-Compliant |

## Compliance Checklist

| Standard | Description | Status |
|---|---|---|
| 21 CFR Part 211 | Current Good Manufacturing Practice for Finished Pharmaceuticals | ✗ Fail |

**Evidence Coverage Score: 95% — High Confidence**

AI Insight: The deviation was primarily due to equipment calibration issues, which have been addressed through CAPA actions. Continuous monitoring and timely calibration are recommended to prevent recurrence.