

# 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 on 2024-10-12 identified deviations in the granulation process. The Inlet Air Temperature exceeded the upper limit of 70°C, reaching 74.8°C, and the Product Bed Temperature exceeded the upper limit of 70°C, reaching 78.2°C. Equipment ID EQP\_GRAN\_01 was involved. LIMS results showed all tests passed, and the batch disposition is on HOLD pending further review.

## 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	74.8°C	70°C
Product Bed Temperature	45 minutes	78.2°C	70°C

## 3. Executive Summary

Batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad experienced deviations on 2024-10-12. The Inlet Air Temperature reached 74.8°C, exceeding the limit of 70°C, and the Product Bed Temperature reached 78.2°C, exceeding the limit of 70°C. These deviations occurred on equipment ID EQP\_GRAN\_01. LIMS results indicated all tests passed, and the batch disposition 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 increased, with the Product Bed Temperature reaching 78.2°C at 08:15. Immediate actions included reducing the temperature and adjusting the process parameters as per the Deviation Report.

## 05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 had a calibration overdue by 10 days. This analysis was conducted using equipment logs, Maintenance Log WO-2024-0456, and a 5M analysis to identify root causes.	Root Cause Analysis (RCA) using 5M (Man, Machine, Method, Material, Mother Nature) to identify root causes.
CONCLUSION	
The root cause was identified as overdue calibration and thermocouple drift on equipment ID EQP_GRAN_01. Maintenance Log WO-2024-0456.	

## 6. Scope of Review

The review focused on the granulation process parameters and equipment performance during the batch BTC0048 production.

## 7. Exceptions

The primary exceptions were temperature deviations in the granulation process, specifically with the Inlet Air and Product Bed Temperatures.

## 8. CAPA

CAPA actions included recalibration of EQP\_GRAN\_01, replacement of the thermocouple, and requalification of the equipment as per Maintenance Log WO-2024-0456.

## 9. Impact Assessment

LIMS results showed all tests passed. However, due to the temperature deviations, the batch disposition is on HOLD pending further review.

## 10. Conclusion

The current batch status is on HOLD. No OOS investigation is required as LIMS results passed. Equipment EQP\_GRAN\_01 has been recalibrated and returned to service.

## 11. Regulatory Compliance

Standard	Status
21 CFR Part 211	Compliant

## Compliance Checklist

Standard	Description	Status
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21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	✓ Pass
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Evidence Coverage Score: 95% — High Confidence

AI Insight: The investigation identified overdue calibration and thermocouple drift as the root causes of the temperature deviations. Prompt CAPA actions were implemented to address these issues.