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 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 95%, below the specification of 98%-102%, leading to an OOS reference. The batch disposition is 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	74.8°C	70°C
Product Bed Temperature	1 hour	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 exceeded the upper limit of 70°C, reaching 74.8°C 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 95%, below the specification of 98%-102%, leading to an OOS reference. The batch disposition is on HOLD as per the Deviation Report.

4. Deviation Description

The first deviation was recorded at 08:00 on 2024-10-12 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 granulation process and notifying the QA department 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 noted at +4°C during the breakdown	Root cause analysis was conducted using fishbone diagram and review
CONCLUSION	
The root cause was identified as an overdue calibration of Equipment ID EQP_GRAN_01, with a thermocouple drift of +4°C. Maintenance	

6. Scope of Review

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

7. Exceptions

Temperature deviations were noted in the granulation process, specifically with the Inlet Air Temperature and Product Bed Temperature exceeding their upper limits.

8. CAPA

CAPA actions included recalibrating Equipment ID EQP_GRAN_01, replacing the thermocouple, and conducting a requalification as per Maintenance Log WO-2024-0456.

9. Impact Assessment

LIMS results show a failure in the assay with a result of 95%, below the specification of 98%-102%, leading to an OOS reference. The batch disposition is on HOLD.

10. Conclusion

The current batch status is on HOLD as per the Deviation Report. An OOS investigation is referenced due to the LIMS failure. Equipment was 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 maintenance are recommended to prevent recurrence.