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, as recorded on equipment EQP_GRAN_01. 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 currently on HOLD.

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

3. Executive Summary

Batch BTC0048 of Paracetamol Tablets 500mg at Unit-III Hyderabad experienced a deviation in the granulation process on 2024-10-12. The Inlet Air Temperature on equipment EQP_GRAN_01 exceeded the upper limit of 70°C, reaching 74.8°C. LIMS results showed an assay failure with a result of 95%, below the specification of 98%-102%, leading to an OOS reference. 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 on equipment EQP_GRAN_01. The operator ID was not recorded. The temperature progressively rose, with a peak value of 78.2°C recorded at 08:15. Immediate actions included stopping the process and notifying the maintenance team as per the Deviation Report.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
The probable cause was identified as a calibration issue with equipment EQP_GRAN_01. The calibration was overdue by 15 days, and	The root cause analysis involved reviewing maintenance logs and
CONCLUSION	
The root cause was determined to be an overdue calibration and thermocouple drift on equipment EQP_GRAN_01. Maintenance Log dat	

6. Scope of Review

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

7. Exceptions

The primary exception was the Inlet Air Temperature exceeding the upper limit, leading to a deviation in the granulation process.

8. CAPA

CAPA actions included recalibration of EQP_GRAN_01 under work order ID 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 95% is below the specification of 98%-102%, leading to an OOS reference. The batch disposition is currently 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 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: 85% — 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.