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, reaching 74.8°C against a specification of 60-70°C. Equipment ID EQP_GRAN_01 was involved. LIMS results indicate a failure in 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	60-70°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 in the granulation process exceeded the upper limit, reaching 74.8°C against a specification of 60-70°C, involving equipment ID EQP_GRAN_01. 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 at 2024-10-12 08:00 with the Inlet Air Temperature reaching 74.8°C. 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 at 08:30 as per the Deviation Report.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 had an overdue calibration by 15 days. The analysis involved reviewing equipment logs, maintenance rec	Root Cause Analysis (RCA) was conducted at +4°C in the Maintenance Log
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

The primary exception was the Inlet Air Temperature exceeding the specified range, leading to a process halt.

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 as per report RQ-2024-011.

9. Impact Assessment

LIMS results showed a failure in the assay test 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 status of batch BTC0048 is on HOLD. An OOS investigation is referenced due to the 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 maintenance are recommended to prevent recurrence.