

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, reaching 74.8°C against a specification of 60-70°C. Equipment ID EQP_GRAN_01 was involved. LIMS results showed 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 during granulation exceeded the upper limit, reaching 74.8°C, while the specification was 60-70°C. Equipment ID EQP_GRAN_01 was involved. LIMS results indicated 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 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 thermocouple deviation was recorded at +4°C, as per Maintenance Log.	The investigation involved reviewing equipment data, calibration records, and maintenance logs.
CONCLUSION	
The root cause was identified as an overdue calibration of EQP_GRAN_01, with a thermocouple drift of +4°C. Maintenance Log dated 2024-08-15.	

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, impacting the product quality.

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 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 reference has been initiated 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
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21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	✗ Fail
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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.