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 Fail status for 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	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. Equipment ID EQP_GRAN_01 was involved. LIMS results indicated a Fail status for 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.

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 increased, with a peak value of 78.2°C recorded at 08:15. Immediate actions included stopping the process at 09:00 as per the Deviation Report.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 had an overdue calibration by 15 days. Thermocouple drift noted at +4°C in the Maintenance Log. W	Root cause analysis was conducted using equipment logs, maintenance
CONCLUSION	
The root cause was identified as an overdue calibration of EQP_GRAN_01, with a thermocouple drift of +4°C. Maintenance Log dated 20	

6. Scope of Review

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

7. Exceptions

The Inlet Air Temperature exceeded the specified range, leading to a deviation. LIMS results confirmed an assay failure.

8. CAPA

CAPA actions included recalibration of EQP_GRAN_01 under work order ID WO-2024-0456. New thermocouples were installed, and a requalification report was generated.

9. Impact Assessment

LIMS results showed a Fail status for the assay with a result of 95%, below the specification of 98-102%. The batch disposition is on HOLD.

10. Conclusion

The current batch status is on HOLD as per the Deviation Report. An OOS investigation reference was initiated due to the LIMS failure. Equipment EQP_GRAN_01 was recalibrated and returned to service.

11. Regulatory Compliance

Standard	Status
21 CFR Part 211	Under Review

Compliance Checklist

Standard	Description	Status
21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	■ Review

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 maintenance are recommended to prevent recurrence.