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 failed 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	Manufacturing

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 against a specification of 60-70°C on equipment 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 operator ID not recorded. The Inlet Air Temperature progressively rose, reaching a peak of 74.8°C at 08:00. Immediate actions included stopping the process at 09:00 as per the Deviation Report. The deviation was noted in the Equipment Log with a status of DEVIATION.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 had an overdue calibration by 15 days. The analysis indicates that the thermocouple drift was observed at +3°C in the Maintenance Log dated 2024-10-10 con	Root Cause Analysis (RCA) was conducted using historical equipment logs, maintenance records, and
CONCLUSION	
The root cause was identified as overdue calibration and thermocouple drift on EQP_GRAN_01. Maintenance Log dated 2024-10-10 con	

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 during granulation.

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 on HOLD.

10. Conclusion

The current batch status is on HOLD as per the Deviation Report. An OOS investigation is referenced due to the failed LIMS assay. Equipment EQP_GRAN_01 has been returned to service post-maintenance.

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: Ensure timely calibration of equipment to prevent deviations and maintain product quality.