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. The Product Bed Temperature also deviated, reaching 78.2°C. Equipment ID EQP_GRAN_01 was involved. LIMS results indicate a failed assay with a result of 2.3% LOD, which is within specification, but further investigation is required. The batch is currently 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
Product Bed Temperature	45 minutes	78.2°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 reached 74.8°C, exceeding the limit of 60-70°C, and the Product Bed Temperature reached 78.2°C. Equipment ID EQP_GRAN_01 was involved. LIMS results showed a Loss on Drying (LOD) of 2.3%, which is within the specification of 1.5-3%. The batch disposition is currently on HOLD.

4. Deviation Description

The first deviation was recorded at 08:00 on 2024-10-12 with the Inlet Air Temperature reaching 74.8°C. The operator ID was not recorded. The temperature progressively increased, with the Product Bed Temperature peaking at 78.2°C at 08:15. Immediate actions included stopping the granulation process at 08:30 as per the Deviation Report.

05. Root Cause Analysis

PROBABLE CAUSE	METHODOLOGY
Equipment ID EQP_GRAN_01 had a calibration overdue by 15 days. Thermocouple drift was noted at +4°C during the maintenance inspe	Root cause analysis was conducted by reviewing equipment logs, mainte

CONCLUSION
The root cause was identified as overdue calibration and thermocouple drift in EQP_GRAN_01. Maintenance Log dated 2024-10-10 conf

6. Scope of Review

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

7. Exceptions

Temperature deviations were noted in the granulation process, specifically with the Inlet Air and Product Bed Temperatures exceeding specified limits.

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 indicate that the product was impacted. The assay for Loss on Drying (LOD) was 2.3%, which is within specification, but the batch is on HOLD pending further investigation.

10. Conclusion

The batch BTC0048 is currently on HOLD. An OOS investigation is referenced due to the temperature deviations. Equipment EQP_GRAN_01 has been 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: Ensure regular calibration schedules are adhered to prevent future deviations.