

## Corrective and Preventive Action (CAPA) Report

### CAPA Report Details

CAPA ID: CAPA-2025-031

Initiated Date: 2025-03-18

Initiated By: QA Analyst – Priya Nair

Department: Quality Control

Related Batch: Corn Batch #C-4456

Related Document: QC-PRO-GRAIN-022 (Moisture & Protein Protocol)

### 1. Issue Summary

During routine QC testing of Corn Batch #C-4456, the moisture result reported was 14.7%, which is above the acceptable limit of 13.0% as per protocol.

Additionally, the result was released without verification from the QA supervisor and was entered late into the ELN system.

### 2. Immediate Containment

- Affected batch was placed under HOLD status within 2 hours of detection.
- Downstream processing and packaging were halted.
- Customers and warehouse teams were notified of the issue.

### 3. Root Cause Analysis

Primary Cause: Oven temperature was operating at 95°C due to calibration drift, causing under-drying and artificially high moisture.

Secondary Cause: The balance used had not undergone calibration within the bi-weekly interval.

Tertiary Cause: Technician failed to follow ELN entry and release approval protocol.

### 4. Corrective Actions

- Oven recalibrated and verified using certified temp probes.
- Analytical balance recalibrated and signed off by Instrumentation Officer.
- Technician re-trained on moisture SOP and ELN procedure (Training Record TR-NAIR-2025).

- All high-moisture lots from March 14–18 re-tested and documented.

## **5. Preventive Actions**

- Implemented automated calibration reminders via ELN system.
- Mandatory dual sign-off added for all moisture release entries.
- Monthly technician audits initiated for QC compliance checklists.

## **6. Effectiveness Check**

QA monitored 15 subsequent batch results post-CAPA closure; all were within specified range (avg. 12.3%).

Follow-up audit scheduled for April 15, 2025, to validate long-term resolution.

## **7. Closure**

Closed By: QA Supervisor – Henry Walker

Closure Date: 2025-03-28

Status: Verified and Closed

All CAPA records must be retained for a minimum of 3 years for audit readiness.