



**Unplanned Deviation Investigation Form**

Form: C-201-F2      CCR No. CC-23-0469      Revision: 1

Deviation #

**Section II – Unplanned Deviation Investigation**

**Deviation Overview** (Completed by the Investigator)

<b>Deviation Title</b> Short description	Black Maca Gummies SGM00551 Batch 240516 - Release product at 0.6790 water activity
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**Investigation Activities** (Completed by the Investigator)

The following activities were used to conduct this investigation (check all that apply):

- Interviews (list interview personnel interviewed and key findings below)
- Document reviews (list documents reviewed and key findings below)
- Observations – (list observations and key findings below)
- Testing / Inspection (list activities and results below)
- Five (5) Whys review (list questions and answers below)
- Other (specify below)


Add detail information to the impact assessment selected above as applicable.

- Attached     Discussed here

Water activity data will be attached for reference. The average Aw of the samples collected during the production dehydration period was 0.666 Aw. The tests were conducted between 06/07/24 - 06/12/24. However, release testing resulted in an average water activity of 0.63 This release testing was conducted on 06/12/24 at 6:00am for packaging release. We have noticed recently that gummies left in our drying rooms at ambient temperature will increase in water activity over time in seasons of high humidity.

Based on the investigation, the key findings are as follows:

1. Water Activity Testing conducted on 06/07/24 at 7:25am results of 0.71, failing the acceptable range of 0.62 to 0.67. Tested again on 06/10/24 at 7:31 am results of 0.69, failing the acceptable range, Tested 06/11/24 at 7:15am - 0.66 passing the acceptable range, Tested 06/11/24 at 11:30 am - 0.65 passing the acceptable range, Tested 06/12/24 at 6:00am - 0.63 passing the acceptable range. Dehydration room's drying setpoints was lowered to 85 F from 100F. Set points control the Relative Humidity levels within the Dehydration room was rased to 60% RH.
2. Packing of the product commenced on 06/12/24 at 6:00 am. batch packaging completed 06/12/24 in the pm.

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**Causes and Root Cause Identified (Completed by the Investigator)**

List likely causes of this deviation and identify the most likely root cause. See SOP QS-111 for Root Cause Analysis

Attached  Discussed here

The Dehydration room's drying set points were set lower to 85F, end of 1st shift 06/11/24, and not raised. Due to the Dehydration room's drying setpoints being turned down and the Relative Humidity levels increased within the Dehydration room. Caused the rate of moisture migration in the gummies or water activity equilibrium to rise. The Dehydration rooms are not pressurized thus allowing ambient weather conditions to enter the rooms. Leading to increasing rate of overall WA testing results.

**Investigation Summary and Conclusions (Completed by the Investigator)**

Summarize this deviation investigation and conclusions.

Attached  Discussed here

Despite being outside of our specified water activity range, the water activity of this lot should still be safe from microbial growth. Drying beyond 0.6790 is strictly for organoleptic purposes. Based on assessment from Patrick Wilson, 240516 was deemed organoleptically acceptable. Understanding the rates of change of water activity is a topic we are internally studying right now. With time and more data collection, we will better understand how our different gummy formulas change their water activity at different temperature and humidity conditions.

**Approval Signatures**

Note: Quality should not approve this investigation unless it is thorough enough for Quality to complete form C-201-F3 to close this investigation. Specifically, Quality will need to make Impact and Quality assessments as well as determine CAPA. This investigation must provide details necessary for these determinations.

Name	Title	Signature	Date
Completed By: (Investigator) Gabriel Dominguez	Gummy Manager		
Approved By: (Quality)			