	Unplanned Deviation Initiation Form		
	Form: C-201-F1	CCR No. CC-23-0469	Revision: 1

Deviation #

Section I – Unplanned Deviation Information

Deviation Overview (Completed by the Initiator)

Initiator's Name:	Gabriel Dominguez	Department:	Gummy Department
Observer's Name:	N/A	Department:	N/A
Deviation Title (Short description)	Release product at 0.6790 water activity		

Description of the Deviation: (Include details like who, what, when, where, and why associated with the deviation. As applicable include sequence of events, background information, cross references to protocols, etc. Include details like room numbers, lot numbers, material names and numbers, product names and numbers, etc.)


Most recent specification for water activity release of Black Maca Gummies is 0.62 to 0.66 Aw.

For Black Maca Gummies SGM00551 Batch 240516 the result is 0.6790 aw.

Drying below 0.75 Aw is for organoleptic purposes only and not required to limit growth of microbial organisms. These gummies were assessed organoleptically by Patrick Wilson and deemed acceptable.

Deviation Details (Completed by the Initiator)

Date & Time (if known) deviation occurred:	
Date / Time deviation initiated:	06/20/24 2:30pm
<input type="checkbox"/> N/A <input checked="" type="checkbox"/> Reason for a delay between date of occurrence and initiation if greater than 2 business days Packaging Samples to lab for final release testing/evaluation.	
Deviation Type: <input checked="" type="checkbox"/> Deviation from Procedure <input type="checkbox"/> Non-conforming material/product/result/data <input type="checkbox"/> Deviation within facility/services/environment <input type="checkbox"/> Deviation from regulations <input type="checkbox"/> Adverse trend detected <input type="checkbox"/> Other, Specify:	Specify what was deviated from: (procedure number, specification, standard, equipment function, etc.) Water activity release specifications

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What may be affected by the deviation? (Completed by the Initiator)

Item	Detail
<input type="checkbox"/> Equipment ID	
<input checked="" type="checkbox"/> Process/Specification	
<input checked="" type="checkbox"/> Product (SKU/Name/Batch#)	Black Maca Gummies SGM00551 Batch 240516
<input type="checkbox"/> Material (Item#/R#)	
<input type="checkbox"/> Standard	
<input type="checkbox"/> Other	

Discuss potential impact of this deviation including process, products, materials, etc.
 (Note: Impact may change after investigation is completed)
 Product samples of Black Maca texture are a bit softer with a heavy sheen. Possible that too much R#51254 oil & R#51226 polishing was added in the demolding process interfering with the dehydration process.

Initial Action(s) Taken (Completed by the Initiator)

<i>Notifications (check all that apply)</i>			<i>Quarantine / Tag Out / Hold</i>
<input type="checkbox"/> QA	<input type="checkbox"/> QC Lab	<input type="checkbox"/> Executive Management	<input type="checkbox"/> N/A
<input type="checkbox"/> QC Inspectors	<input checked="" type="checkbox"/> R&D		<input type="checkbox"/> Yes (explain below)
<input type="checkbox"/> QC Doc Control	<input checked="" type="checkbox"/> Prod. Management	<input type="checkbox"/> Other (specify below)	<input type="checkbox"/> No (explain below)

Describe immediate action taken to correct the deviation or nonconformance and to provide detail for boxes above.
 Production has noticed recently that gummies left in our drying rooms at ambient temperature will increase in water activity over time in seasons of high humidity. This lot of Black Maca was Wa tested five different times ranging from 0.71 to 0.63. Production has recently started targeting the lower to middle ranges of our Wa specifications before release. Also, releasing a max of three carts in the production area at a time to limit the time each cart is allowed to stay in ambient temperatures.

Deviation Assignment (Completed by the Initiator and/or Quality)

Lead Investigator Role Assigned to	Gabriel Dominguez	Deviation Due Date	06/20/24
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Approval Signatures

Name	Title	Signature	Date
Completed By: (Initiator) Gabriel Dominguez	Gummy Manager		
Assignment Accepted By: <input checked="" type="checkbox"/> N/A if same as completed by			
Approved By: (Quality)			