1.0 Purpose

This procedure describes the standard operation of gummy manufacturing (named chewable gels per the Unites States Pharamacopeia).

2.0 Scope

This procedure applies to all GMP batches manufactured on Gummy Machine 1 (GM-1) at Ion Labs Inc.

3.0 Responsibility

3.1 It is the responsibility of Production (Gummy) personnel to strictly follow this procedure.

3.2 It is the responsibility of the QC Inspectors to follow the quality steps outlined in this procedure.

3.3 It is the responsibility of the Department Manager/Supervisor to implement this procedure and to ensure that the procedure is being followed. The Department Manager/Supervisor is also responsible for maintaining this procedure and ensuring that it is kept up to date with

3.4 It is the responsibility of Operations to maintain the sanitation of the equipment in accordance with this procedure.

4.0 Definitions

4.1 **BPR** – Batch Production Record

4.2 **CCP** – Critical Control Point

4.3 **QC** – Quality Control

4.4 **GMP** – Good Manufacturing Practices

4.5 **GM-1** – Gummy Machine 1

4.6 **Batter** – Gummy base containing pectin, sugar, syrup, buffer and water. The dry premix of these ingredients (minus syrup and water) may also be referred to as batter.

4.7 **CMS** – Cooking and Mixing System

4.7.1 **CM-PLC** – Cooking and Mixing Control Panel

4.7.2 **Kettle 1** – Hemispheric kettle closest to control panel

4.7.3 **Kettle 2** – Hemispheric kettle furthest from control panel

4.7.4 **Open Switch** – Switches that control the stoppers on the Kettles, i.e. Open 1 and Open 2 for Kettles 1 and 2 respectively.

4.7.5 **Tank 3** – Cylindrical tank furthest from control panel which contains no heating element

4.7.6 **Tank 4** – Cylindrical tank closest to control panel which contains heating elements

4.7.7 **Pump 1** – Transfer pump from Kettle 1 and 2 to Tank 3

4.7.8 **Pump 2** – Transfer pump from Tank 3 to Tank 4

4.7.9 **Pump 3** – Transfer pump from Tank 4 to the gummy hopper

4.7.10 **Water Pump** – Circulates water in the heated jackets of kettle 4 and piping.

4.7.11 **Hot 1** – On/Off switch for heating elements for Kettle 1

4.7.12 **Hot 2** – On/Off switch for heating elements for Kettle 2

4.7.13 **Hot 3** – On/Off switch for heating elements in Tank 4

4.8 **GDL** – Gummy Depositing Line

4.8.1 **DL-PLC** – Depositing Line Control Panel

4.8.2 **Clean Pan** – Stainless steel pan used to purge the depositors so that waste does not purge onto molds.

4.9 **Tumbler** – Cylindrical machine for tumble coating the gummies

4.10 **Drying Trays** – Ventilated trays for drying gummies

4.11 **Dry Room** – Temperature and humidity controlled room for curing the gummies to a set water content

4.12 **Simple Green** – Cleaning solution used by Ion Labs

4.13 **PPE** – Personal Protective Equipment

4.14 **AQL** – Acceptable quality level; a statistical measurement of the maximum acceptable number of defective goods in a particular sample size

5.0 References

5.1 A-108, SOP, Good Manufacturing Practices and Personal Hygiene

5.2 D-794, SOP, Use and Calibration of an Analog Brix Meter

5.3 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

5.4 E-803, SOP, Inspection of Palletized In-Process and Finished Product

5.5 C-104-F31, Form, Gummy Coating Record

5.6 C-104-F32, Form, Gummy Record

5.7 C-707-F12, Form, CCP 9 – Gummy Blend Brix Record

5.8 C-707-F13, Form, CCP 10 – Deposition Checks

5.9 C-707-F14, Form, CCP 11 – Pre-Curing

5.10 C-707-F15, Form, CCP 12 – Post-Curing

5.11 B-111-F5, Form, Area Group 4 Cleaning Form

6.0 Procedure

6.1 All Personnel must follow GMP as per SOP A-108 Good Manufacturing Practices and Personal Hygiene.

6.2 All Personnel must wear appropriate PPE. The jackets on the equipment are hot and may cause serious burns if touched. The equipment involves fluids under pleasure and as such there is always an inherent risk of these fluids spraying into the room. Some fluids contain concentrated weak acids, which are eye irritants. Protective eyewear is necessary when working near the equipment, and heat gloves are recommended when working with the hot kettles and piping.

6.3 Preparing the batch

6.3.1 Verify the gummy room has the correct product name and batch number that matches with the BPR.

6.3.2 Ensure that a major cleaning has been performed on the room according to procedures detailed in section 6.8.

6.3.3 Ensure that the drying room is clean and set to the temperature and relative humidity specified in the BPR.

6.3.4 Set up the gummy depositing room for ventilation and dehumidification.

6.3.5 Ensure that all scales are properly calibrated and log books are filled out. If any scale is past due for calibration, decommission and inform QC and Analytical Development.

6.3.6 Calibrate the refractometer according to SOP D-794 Use and Calibration of an Analog Brix Meter.

6.3.7 Ensure the air-line is connected to the GDL and air is flowing.

6.3.8 Adjust oil sprayers.

6.3.8.1 Using the DL-PLC, turn on the mold drive and oil sprayers.

6.3.8.2 Manually adjust the spray using the individual valves on each sprayer to evenly coat the molds.

Note: Using a clean piece of cardboard allows you to more easily see the quantity of oil coming from each sprayer and adjust accordingly.

6.3.9 QC Inspectors must inspect GM-1 and all components. Upon satisfactory cleaning inspection the room and equipment cleaning logs must be signed indicating the room was clean prior to commencing manufacturing. The QC inspector will inspect the following areas to make sure they are visually clean:

6.3.9.1 The molds of the machine

6.3.9.2 The blue product belt

6.3.9.3 The blue product belt tray (located in-between the belt)

6.3.9.4 The 2 bristle spinners on the underside of the machine

6.3.9.5 Inside kettle 1, 2 and Tank 3 and 4

6.3.9.6 Inside the depositor hopper

6.3.10 Production must bring all components of the total batch into GM-1 and check all materials needed for the batch are present and correct.

6.3.11 QC Inspectors must verify all materials are present and correct.

6.3.12 Once materials are verified, utilize the BPR to begin weigh-out.

6.3.12.1 This manufacturing process is semi-continuous. The total batch weights will be broken down into sub-blends of up to 150 kg each. This batch break-down is detailed in the manufacturing weigh & mix instructions. A standard weigh sheet will be used to document total batch usages.

6.3.12.2 Purified water is to be taken fresh daily from Ion Labs purified water system. Purified water taps are available in the liquids manufacturing suites L-1 through L-5. Follow standard procedures for obtaining purified water, i.e. flush the tap for a specified amount of time before filling the transfer container. Only use clean containers/vessels to transfer water. Do not hold water for longer than is necessary to process the batch and all water is to be used same day.

6.3.12.3 It is recommended to heat a large quantity of purified water at the start of the batch and store it in a clean insulated container for later use.

6.3.13 Consult CCP-10 of the batch record for the desired flow rates of the acid and flavors. Calibrate the flow rates according to the instructions on form C-707-F13 CCP 10 – Deposition Checks.

6.4 Blending

6.4.1 Heat the necessary quantity of water to ~95 °C using one of the kettles, then transfer into an insulated container for later use.

6.4.2 Turn on the Water Pump and Hot 3 (set to 78 °C) to begin warming the jackets on Tank 4 and the transfer lines.

6.4.3 Prepare premixes as described in the BPR.

6.4.4 Prepare batter as described in BPR (Time to reach Brix will be ~1-2 hrs).

6.4.5 Transfer batter to tank 3 and add in actives as described in BPR.

6.4.6 Transfer batter to tank 4 as described in BPR.

6.5 Depositing

6.5.1 Turn on heating elements for depositor.

6.5.2 Place the clean pan under depositors.

6.5.3 Open the appropriate manual vales to allow flow from Tank 4 to waste.

6.5.4 Adjust flow rates for the aqueous acid and flavor as instructed on form C-707-F13 CCP 10 – Deposition Checks. Record parameters used in the BPR.

6.5.5 Using the DL-PLC, adjust the flow rate for the gummy solution (Pump 3) as instructed on form C-707-F13 CCP 10 – Deposition Checks. Record parameters used in the BPR.

6.5.6 Turn on CFA mixer 1 using the DL-PLC.

6.5.7 Before flowing to hopper, it is necessary to do a "set check".

6.5.7.1 With the valve still set to waste, turn on all flows (acid, flavor, and gummy solution) and collect the gummy solution in a clean bucket.

Note: Gummy solution collected in this bucket may be added back to Tank 4 to decrease waste.

6.5.7.2 Periodically sample the gummy mixture directly from the output and observe how it sets.

6.5.7.3 When the solution appears to be gelling, take a small sample a fill, several pre-oiled molds.

6.5.7.4 Place the mold in the cooling tunnel and wait at least 3 minutes.

6.5.7.5 Remove the mold and eject the gummy. If properties are acceptable then you may begin pumping to the hopper.

6.5.8 With all flows turned on, switch the manual valve from waste to hopper.

6.5.9 Collect enough molten gummy in the hopper to cover the depositors, then proceed to the next step.

6.5.10 Using DL-PLC, briefly run the depositing pistols in "clean" mode to ensure all depositing heads are working and any water in the line is purged into the clean pan. Once verified, turn off depositing and remove the clean pan.

6.5.11 Gummy Weight Check

6.5.11.1 When the hopper reaches 3/4th full, use the GDL-PLC to engage the mold drive, mold jump, and depositors to begin depositing gummies into molds.

6.5.11.2 Allow at least 6 depositing strokes and observe consistency in gummies before stopping depositing and turning off all flows to not overfill the hopper. Allow the filled molds to enter the cooling tunnel and then disengage the mold drive.

6.5.11.3 Perform weight checks on the gummies as instructed on form C-707-F13 CCP 10 – Deposition Checks. Record information in the BPR. If necessary, adjust the depositing length of the pistons. This can either be done manually on individual depositors by turning them with a wrench, or uniformly using the GDL-PLC. If adjustments were made go back to step 6.5.11.2. If not proceed to the next step.

6.5.12 Turn on all flows, engage the mold drive and lift, turn on the conveyor belt and brushes using the GDL-PLC and begin depositing.

6.5.13 Begin collecting gummies on drying trays. They must be single layer and gummy to gummy contact should be limited. Trays can be stacked on top of each other on carts.

6.5.14 Notify QC that they must start collection and documentation of the batch.

6.5.15 QC must perform weight variation of the batch as described on form C-104-F32 Gummy Record. During this time, the operator must also bring a sample of 3 gummies and the print out of C-707-F14 CCP 11 – Pre-Curing from the BPR to the QC lab for analysis.

6.5.16 QC laboratory personnel must perform the required analysis as described on form C-707-F14 CCP 11 – Pre-Curing. They must store the recorded data for production to later retrieve and add back into the BPR.

6.5.17 Production must perform and record average weight checks every 20 minutes as described on form C-104-F32 Gummy Record.

6.6 Coating

6.6.1 Fill the tumbler with an appropriate amount of coating to start the run.

Note: If using oil and waxed based coating, the coating may be sprayed onto gummy trays as they come off the line, as well as sprayed onto gummies while they tumble. Make at least 4 complete passes with the spray gun per tray.

6.6.2 Turn the tumbler on and set the direction so that there is no net flow out of the tumbler.

6.6.3 Dump the trays of gummies into the tumbler and allow them to coat. The net flow should be adjusted so that the average gummy spends approximately 5 minutes in the tumbler.

6.6.4 Enough Gummies should be added to the coater to maintain a good cascade.

6.6.5 If using oil and wax based coating, keep at least 5 buffing pads inside the coater to help buff the wax into the gummies.

6.6.6 When the gummies have been sufficiently coated, change the direction of the tumbler so that it flows onto a separate drying tray.

6.6.7 Move the drying tray onto the cart and spread the gummies so there are single layer and gummy to gummy contact is minimized. Repeat section 6.6 until finished, adding additional coating material as required.

Note: Gummies should not be doubled or excessively touching each other while drying. This is crucial for manufacturing non-sticky gummies.

6.7 Drying

Note: The Drying Room should be turned on at the start of the run to allow it to equilibrate to the temperature and humidity settings. Standard temperature for drying is 40 °C.

6.7.1 Move the carts filled with coated gummies into the drying room and label them with your initials, product name, batch number, and time / date they were entered into the room.

6.7.2 After approximately 24 hours of drying and approximately every 12 hours thereafter, production personnel must bring at least 4 gummies to the QC Lab for them to perform analysis as instructed on form C-707-F15 CCP 12 – Post-Curing.

6.7.3 QC Laboratory personnel must perform the required analysis as described on form C707-F15 CCP 12 – Post-Curing. They must store the recorded data for production to later retrieve and add back into the BPR. QC Laboratory personnel must also notify production when specifications are met.

6.7.4 When the product has reached appropriate dryness specifications, carts are weighed on a tared scale to determine batch yield. Notify QC at this stage so they can perform AQL.

6.7.5 Label each cart with product name, product number, batch number, weight of product and date.

6.7.6 Calculate yields.

Note: Coating waste is separated from batch waste. Wet sugar from coating is considered coating waste.

6.8 Cleaning

6.8.1 Reference SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment for cleaning procedures specific to gummy manufacturing. Document the cleaning on form B-111-F5 Area Group 4 Cleaning Form or appropriate Redzone data sheets.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	08/03/21	New procedure.	N/A	P. Wilson
1	05/17/22	Revised AQL and drying requirements. Updated logo and formatting. Corrected document references.	CC-22-0205	P. Wilson