
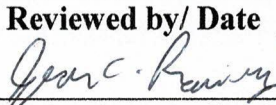
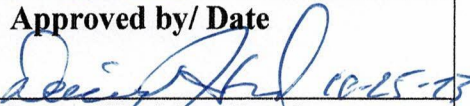
	Standard Operating Procedure Continuous Gummy Manufacturing Process		SOP Number B-911	Revision 0
			Effective Date 10/28/23	Page Page 1 of 14
Written by/ Date  10-23-23	Reviewed by/ Date  10-25-23	Approved by/ Date  10-25-23		
Title: Technical Product Manager - Gummies	Title: Gummy Production Manager	Title: VP of Quality & Regulatory Affairs		

1.0 Purpose

This procedure describes the standard operation of gummy manufacturing (named chewable gels per the United States Pharmacopeia), using the continuous cooking process.

2.0 Scope

This procedure applies to all GMP batches manufactured on Continuous Gummy Manufacturing Machines at Ion Nutritional Labs.

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 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 aligned with current practices.
- 3.3 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 **M300** – Continuous gummy manufacturing line rated for 300 kg per hour
- 4.6 **M40** – Continuous gummy manufacturing line rated for 40 kg per hour
- 4.7 **Batter** – The molten mixture of gummy materials at any state prior to depositing into the gummy mold and prior to setting into a chewable hydrogel state.
- 4.8 **CFA** – Color, Flavor and acid
- 4.9 **DI** – Dietary Ingredient, which is an ingredient added with a ‘per serving’ label claim on the finished product packaging
- 4.10 **Skid A** – Base Prep Skid, Responsible for automatic weighing and blending of base ingredients
 - 4.10.1 A-BTK01 – Blend tank on Skid A
 - 4.10.2 A-HTK01 – Hold tank on Skid A
- 4.11 **Skid B** – Pre-heat skid; brings blended base up to temperature before being sent through rising film cooker
 - 4.11.1 B-HTK01 – Hold tank that continuously receives heated batter from A-HTK01 and continuously feeds the rising film cooker
- 4.12 **Skid C** – Cooking Skid; rising film cooker with flash vessel, primarily responsible for most of the water evaporation during processing
- 4.13 **Skid D** – DI and CFA Skid; responsible for automatic weighing of cooked gummy base and blending with Dis, added by time-based calibration and responsible for adding color, flavor and acid in-line before being discharged into the hopper
 - 4.13.1 D-HTK01 – Hold tank that continuously receives cooked batter from Skid C and distributes to blend tanks

Standard Operating Procedure Continuous Gummy Manufacturing Process	SOP No B-911	Rev 0	Page 3 of 14
---	-------------------------	------------------	---------------------

4.13.2 **D-BTK 01 & 02** – Blend tanks where DIs are added and mixed into batter

4.13.3 **D-HTK02** – Hold tank that receives batter from D-BTK01 & 02, and continuously feeds the hopper of the depositor

4.14 **GDL** – Gummy Depositing Line

4.14.1 **E-HTK01** – Holding tank for mold release aid

4.15 **HMI** – User interface

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

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

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

4.19 **Simple Green** – Cleaning solution used by Ion Nutritional Labs

4.20 **PPE** – Personal Protective Equipment

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

4.22 **PDT** – Product Detail Tag

4.23 **NMT** – Not More Than

5.0 References

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

5.2 D-794, SOP, Use and Calibration of Brix Refractometers

5.3 D-827, SOP, Gummy pH Calibration and Verification

Standard Operating Procedure Continuous Gummy Manufacturing Process	SOP No B-911	Rev 0	Page 4 of 14
--	-------------------------	------------------	---------------------

- 5.4 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment
- 5.5 B-103, SOP, Small Parts Cleaning and General Sanitation
- 5.6 B-105, SOP, Preparation of Cleaning and Sanitizing Chemicals for Production
- 5.7 C-104, SOP, Master Batch Record and Issuance of Batch Production Record
- 5.8 C-707, SOP, Critical Control Point Specifications
- 5.9 E-803, SOP, Inspection of Palletized In-Process and Finished Product
- 5.10 G-201, SOP, Calibration Program
- 5.11 G-202, SOP, Calibration Verification of Digital Temperature Devices
- 5.12 G-207, SOP, Calibration Verification and Operation of Scales
- 5.13 D-794, SOP, Use and Calibration of Brix Refractometers
- 5.14 B-911-F1, Form, Gummy Inline Equipment Verification Log
- 5.15 C-104-F31, Form, Gummy Record
- 5.16 C-707-F13, Form, CCP 10 – Deposition Checks
- 5.17 C-707-F15, Form, CCP 12 – Post-Curing

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 when working with the kettles and mixing tanks. When working with the hot kettles, mixing tank, and pump/piping the PPE includes, but is not limited to, face shield, heat resistant gloves, Tyvek leggings, and rubber boots. The kettles, mixing tank, and pump is hot and may cause serious burns if

touched. The equipment involves fluids under pressure through the pump and has an inherent risk of these hot fluids spraying into the room. Protective eyewear is required when working near the equipment.

6.3 Preparing the Batch

- 6.3.1 Verify the gummy room has been identified with the correct PDT as required by 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 temperature for NMT 75°F and humidity NMT 60%.
- 6.3.5 Ensure that a daily scale performance check is complete and documented as outlined in SOP G-207 Calibration Verification and Operation of Scales. Document in the scale's logbook.
- 6.3.6 Ensure the load cells are operational as outlined in G-207. Document verification on B-911-F1.
- 6.3.7 Check the scale calibration sticker to ensure that the scale calibration has not expired. Report expired calibration to QC personnel. Do not use equipment with an expired calibration.
- 6.3.8 Ensure load cell sets are within their calibration schedule. If they are past due for calibration, notify supervisor.

- 6.3.9 Ensure pH meters are cleaned and calibrated. If they are outside of calibration schedule, calibrate according to SOP D-827 Inline pH Meters. Document on B-911-F1
- 6.3.10 Ensure inline refractometers are within their calibration schedule. If they are past due, calibrate according to SOP D-794 Use and Calibration of Brix Refractometers. Document on B-911-F1
- 6.3.11 Perform Daily check for ambient temperature on thermometers. Document on B-911-F1. If results do not reflect ambient conditions, discard and replace with calibration verified probe.
- 6.3.12 Verify boilers are in operation.
- 6.3.13 Ensure the air-line is connected to the GDL and Skid-D, and air is flowing.
- 6.3.14 Adjust oil sprayers.
- 6.3.14.1 Ensure appropriate release aid is filled in E-HTK01. An oil/wax based coating may be loaded here and used for dual purpose as a release aid and coating.
- 6.3.14.2 Using the DL-HMI, turn on the mold drive and oil sprayers.
- 6.3.14.3 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.
- 6.3.15 QC Inspectors must inspect GM-1 and all components. Upon satisfactory cleaning inspection, the room and equipment cleaning logs must be completed indicating the room was clean prior to commencing manufacturing. The QC inspector will inspect the following areas to make sure they are visually clean:

6.3.15.1 The molds of the machine

6.3.15.2 The blue product belt

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

6.3.15.4 The 2 bristle spinners on the underside of the machine

6.3.15.5 Inside all tanks

6.3.15.6 Inside both depositor hoppers

6.3.16 Production must bring all components of the total batch into GM-1 and check all materials needed for the batch are present, correct, and released or approved for At Risk use by the QC Laboratory.

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

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

6.3.18.1 This manufacturing process has both batch and continuous sections. The base blend is batched to approximately 175 kg for the M300 and 85 kg for the M40. The blended base is cooked continuously through skids B & C to reach a target brix as defined in the BPR. The cooked base is then aliquoted to approximately 50 kg and combined with DIs in a batch blend. After blending the batter is sent to a final hold tank where it is continuously pumped out and combined inline with CFA before reaching the depositor.

6.4 Prepare premixes as described in the BPR.

6.5 Load raw materials and premixes in their respective locations as described in the BPR.

6.6 Turn on warming jacket circulation for all skids and verify they are circulating. Set circulation temperature as described in the BPR.

6.7 Base Batter Preparation (Skid A)

6.7.1 Ensure the correct recipe parameters are loaded onto the HMI of Skid A as defined in the BPR.

6.7.2 Ensure valves are set to flow from A-BTK01 to A-HTK01

6.7.3 Run the program by selecting RUN on the Operation screen of the HMI.

Note: This will weigh each component of the base batter, blend them for a defined amount of time and heat them to a defined temperature before sending the base to a hold tank to be called from Skids B & C. Skid A will run continuously until stopped or there is no more room in its hold tank.

6.8 Preheat and Cooking (Skids B & C)

6.8.1 Open the water valve and run water to waste.

6.8.2 Warm up the skids by opening the steam valve and set the Batter Temperature on the HMI to 75 degrees. Gradually ramp to desired higher temperature.

6.8.3 After skid has reached temperature, close the water valve and run most of the water in B-HTK through the system.

6.8.4 Immediately call for batter from A-HTK01 and transition from running water through the system to batter.

6.8.5 Ensure flow rate from B-HTK01 through the cooker match the target flow rate as described in the BPR. Flow rates can be checked by following the procedure in CCP¹⁰ – Gummy Start Up of C-707 Critical Control Point Specifications. Ensure flow rate from A-HTK01 to B-HTK01 is sufficient to not run out or overflow.

6.8.6 Monitor the brix of solution and adjust the following parameters until target brix is reached.

- 6.8.6.1 Pre-heater Batter Temp – Higher temperature results in higher brix
- 6.8.6.2 Cooker Batter Temp – Higher temperature results in higher brix
- 6.8.6.3 Output Power Ratio – Higher power results in higher brix
- 6.8.6.4 Vacuum on/off – Vacuum on results in higher brix
- 6.8.6.5 Vacuum Pressure – Lower pressure results in higher brix
- 6.8.6.6 Valve Set Position – Lower set position results in higher brix, may result in more air bubbles in batter
- 6.8.7 Once target brix is reached, record brix value and settings on the BPR and change flow from waste to D-HTK01.

6.9 DI & CFA (Skid D)

- 6.9.1 Refer to BPR for HMI settings and target quantities of DIs.
- 6.9.2 Calibrate Liquid and Powder dosing feed systems as described in CCP¹⁰ – Gummy Start Up of C-707 Critical Control Point Specifications.
- 6.9.3 Enable both D-BTK01 and D-BTK02 on the HMI, then run the program.

Note: This program will run continuously, alternating between blending tanks. First, batter is added to the target weight as programmed into the HMI. Once weight is reached the batter valve is closed, the mixer starts, and the DI dosing systems turn on simultaneously. After blending for the programmed time, the mixer will turn off and the blended batter will discharge into D-HTK02. If there is not enough batter to fill a tank to target weight, the system will not move forward with the program.

6.9.4 Adjust flow rates for the aqueous acid, color, flavor or other ingredient as instructed in CCP10 – Gummy Start Up of C-707 Critical Control Point Specifications. Record values reached and settings used in the BPR.

6.10 Depositing

6.10.1 Turn on heating elements for depositor.

6.10.2 Place the clean pan under depositors.

6.10.3 Open the appropriate manual valves to allow flow from D-HTK02 to waste.

6.10.4 Using the GDL-HMI, adjust the flow rate for the gummy solution as instructed in CCP¹⁰ – Gummy Start Up of C-707 Critical Control Point Specifications. Record parameters used in the BPR.

6.10.5 Before flowing to hopper, it is necessary to do a “set check”.

6.10.5.1 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 D-HTK02 to decrease waste. Gelled gummy may not be added back to HTK02.

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

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

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

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

- 6.10.6 With all flows turned on, switch the manual valve from waste to hopper.
- 6.10.7 Collect enough molten gummy in the hopper to cover the depositors, then proceed to the next step.
- 6.10.8 Using GDL-HMI, 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.
- 6.10.9 Gummy Weight Check
- 6.10.9.1 When the hopper reaches 3/4th full, use the GDL-HMI to engage the mold drive, mold jump, and depositors to begin depositing gummies into molds.
- 6.10.9.2 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.
- 6.10.9.3 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-HMI. If adjustments were made go back to step 6.9.9.2 If not proceed to the next step.
- 6.10.10 Turn on all flows, engage the mold drive and lift, turn on the conveyor belt and brushes using the GDL-HMI and begin depositing.
- 6.10.11 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.

6.10.12 Production must perform and record average weight checks every 20 minutes as described on form C-104-F31 Gummy Record.

6.11 Coating

6.11.1 Fill M-HTK01 with appropriate coating as described in the BPR.

Note: If using oil and waxed based coating, the coating may be sprayed onto gummies as they come off the line, as well as sprayed onto gummies while they tumble.

6.11.2 Gummies will automatically flow from depositor into the tumbler via conveyor belts. The flow of gummies through the depositor should be adjusted to maintain a good cascade.

6.11.3 From the coater, gummies are either automatically weighed via the tray weighing system or manually collected onto trays.

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

6.11.4 The trays are either loaded onto carts manually or via co-bots.

6.12 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.

6.12.1 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.

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

6.12.3 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.

6.12.4 When the product has reached appropriate dryness specifications, carts are weighed on a tared scale to determine batch yield.

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

6.12.6 Calculate yields.

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

6.13 Cleaning

6.13.1 Prepare cleaning agents as outlined in SOP B-105 Preparation of Cleaning and Sanitizing Chemicals for Production.

6.13.2 Follow SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to ensure proper cleaning and sanitization are performed for each type of equipment and that these activities are properly documented.

6.13.3 Refer to SOP B-103 Small Parts Cleaning and General Sanitation to follow appropriate cleaning steps for small parts and utensils.

6.13.4 Detailed cleaning instructions and disassembly specific to individual pieces of equipment will be reflected in the individual equipment procedures.

6.14 Continuous Gummy Manufacturing Batch Records

6.14.1 Due to the nature of the continuous gummy manufacturing lines, the gummy batch forms referenced in SOP C-104 Master Batch Record and Issuance of Batch

Production Record and SOP C-707 Critical Control Point Specifications will not apply. Forms for this line will be created for each product and will be assigned numbers unique to that product. There will be no templates for these forms attached to the procedures referenced here.

6.14.2 Unique MBR numbers will be assigned using the following format:

6.14.2.1 CGM-Formula Number-Batch Size

6.14.2.2 Example: CGM-SGM00474-1100.63KG

6.14.2.3 These MBRs will be revision-controlled and will follow all requirements as outlined in SOP C-403 Change Control Procedure.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	09/24/23	New procedure.	N/A	P. Wilson