1.0 Purpose

The purpose of this procedure is to establish critical control review point specifications for all products during manufacturing and packaging processes at Ion Labs, Inc.

2.0 Scope

This procedure applies to all manufacturing and packaging processes at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of any employee performing PQC or PQV activities for any critical control point to strictly follow this procedure.

3.2 It is the responsibility of the Food Safety and Regulatory Supervisor to assess, identify, and document Food Safety CCPs in the hazard analysis of the HACCP-HARPC (Food Safety Plan).

4.0 Definitions

4.1 **Critical Control Point (CCP)** – a point at which controls are applied and adherence to specification is determined prior to proceeding with the manufacturing or packaging process

4.2 **Food Safety CCP (FS-CCP)** – a point in the process where an identified food safety hazard can be prevented, eliminated, or reduced to acceptable levels

4.3 **Critical Control Point 1 – Blending (CCP 1)** – the point after the blending process of solid dosage powders

4.4 **Critical Control Point 2 – Compression & Encapsulation (CCP 2)** – the initial startup approval for the Compression or Encapsulation process

4.5 **Critical Control Point 3 – Packaging (CCP 3)** – Dosage delivery for scoops (or equivalent) used for powder products

4.6 **Critical Control Point 4 – Metal Detection (CCP 4)** – metal detection for tablets, capsules, powders, and liquids

4.7 **Critical Control Point 5 – Blister Packaging (CCP 5)** – the initial startup approval for the blister packaging process

4.8 **Critical Control Point 6 – Liquid Tank Sampling (CCP 6)** – the point after the blending process of liquid form products

4.9 **Critical Control Point 7 – Liquid Bottling Weight Verification (CCP 7)** – the initial startup approval for the liquid bottling process

4.10 **Critical Control Point 8 – Pouching (CCP 8)** – the initial startup approval for the pouch packaging process

4.11 **Critical Control Point 9 – Gummy Blend °Brix Record (CCP 9)** – Gummy base cooking verification

4.12 **Critical Control Point 10 – Deposition Checks (CCP 10)** – Gummy flow calibration and weight verification

4.13 **Critical Control Point 11 – Gummy Pre-Curing (CCP 11)** – Organoleptic testing and pH

4.14 **Critical Control Point 12 – Gummy Post-Curing (CCP 12)** – Water activity and content testing

4.15 **PQC** – Process Quality Check

4.16 **PQV** – Process Quality Verification

4.17 **QC** – Quality Control

4.18 **MBR** – Master Batch Record

4.19 **BPR** – Batch Production Record

4.20 **Brix** (°Bx) – The approximation of percent non-volatile content of a solution, based off the refractive index of a high sugar solution

4.21 **R&D** – Research and Development

5.0 References

5.1 C-707-F1, Form, CCP1 – Blending (Absence of Foreign Material and Bulk Density)

5.2 C-707-F2, Form, CCP2 – Compression Startup Check

5.3 C-707-F3, Form, CCP2 – Encapsulation Startup Check

5.4 C-707-F4, Form, CCP4 – Metal Detection (Manual)

5.5 C-707-F5, Form, CCP4 – Metal Detection (Inline)

5.6 C-707-F6, Form, CCP4 – Metal Detection (Insight Throat)

5.7 C-707-F7, Form, CCP3 – Dosage Delivery

5.8 C-707-F8, Form, CCP5 – Blister Packaging Startup Check

5.9 C-707-F9, Form, CCP6 – Liquid Tank Sampling

5.10 C-707-F10, Form, CCP7 – Liquid Weight Verification

5.11 C-707-F11, Form, CCP 8 – Pouch Packaging Startup Check

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

5.13 C-707-F13, Form, CCP10 – Gummy Blend Deposition Checks

5.14 C-707-F14, Form, CCP11 – Gummy Pre-Curing

5.15 C-707-F15, Form, CCP12 – Gummy Post-Curing

5.16 C-502, SOP, Record Storage, Retention, and Destruction

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

5.18 D-201, SOP, QC Laboratory Sample Logbook Recording

5.19 B-603, SOP, Insight Throat Metal Detector

5.20 B-629, SOP, Inline Metal Detector

5.21 B-630, SOP, Manual Metal Detector

5.22 A-106, SOP, Documentation Guidelines for cGMP Records

5.23 B-905, SOP, Quality Inspection Process

5.24 Food Safety Plans (HACCP-HARPC)

6.0 Procedure

6.1 PQC and PQV

6.1.1 A PQC is a process quality check. PQV is a process quality verification. Refer to SOPs A-106 Documentation Guidelines for cGMP Records and B-905 Quality Inspection Process for details on the requirements for a PQC and PQV.

6.2 Food Safety Plan (HACCP-HARPC)

6.2.1 A FS-CCP (Food Safety "FS" CCP) defines critical control preventative measures

that a product conforms to prior to continuing the next process stage.

6.2.2 FS-CCPs will be identified and documented in the Hazard Analysis only (for example: FS-CCP 4 Metal Detection).

6.2.3 FS-CCPs will be documented as CCP # on the Process Flow Diagram as referenced (for example CCP 4 Metal Detection). The Process Flow Diagram will include other process CCP's referenced.

6.3 The process may not continue until the requirements of the CCP have been met and verified.

6.4 All samples must be collected in a manner to prevent contamination. This requires the use of clean gloves and clean sampling instruments to remove samples from the container or equipment.

6.5 CCP1 – Blending (Absence of Foreign Material and Bulk Density)

6.5.1 After the blending process, the following should be performed:

6.5.1.1 A sieve test (sieve size 2.4mm or smaller) for absence of foreign material – collect approximately 20g samples from the top of the containers that represent (1) Beginning, (2) Middle, and (3) End of blend after transfer into holding containers. A visual inspection of the product on top of the container(s) will be conducted while a sieve test is performed.

Example: If there are five (5) containers, collect the sample from container 1, 3 and 5.

6.5.1.1.1 A blend with no foreign material will be approved.

6.5.1.1.2 If foreign material is found, check "Fail" on the form and contact QC and/or R&D.

6.5.1.2 Bulk Density Test – collect 100gm samples from container(s) that represent (1) Beginning, (2) Middle, and (3) End of blend after transfer into holding containers.

6.5.1.2.1 Tare a 100ml graduated cylinder and gently transfer, via a clean funnel, sufficient powder to fill 50ml to 60ml of powder with minimum shaking or vibrations.

6.5.1.2.2 Weigh the net weight of the powder transferred into the 100 ml graduated cylinder and record as weight.

6.5.1.2.3 Determine the volume by gently moving the graduated cylinder to create a flat surface for accurate line to determine measured volume using only whole numbers, and record as volume.

6.5.1.2.4 A blend will be approved if results meet the acceptance criteria.

6.5.1.2.5 If there are any problems, notify QC, R&D, and Production Management.

6.5.2 Document Performed By/Date (PQC) and Approved By/Date (PQV) on Form C-707-F1 CCP1 – Blending (Absence of Foreign Material and Bulk Density.

6.5.3 Upon completion and approval of form C-707-F1 CCP1 – Blending (Absence of Foreign Material and Bulk Density, the blend will be released to the next manufacturing stage.

6.6 CCP 2 – Compression Startup Check

6.6.1 CCP for tablets consists of performing individual tablet checks for weight, thickness, hardness, and friability.

6.6.2 Weigh 10 tablets individually, and determine the average weight. Each of the individual weights should be within the limits of 95% and 105% of the average weight (target weight).

6.6.3 Measure the thickness of 10 tablets individually and determine the average thickness. Each of the individual thickness results should be within the limits of 90% - 110% of the average.

6.6.4 If all of the tablets do not fall within the range limits, the equipment must be adjusted to ensure that the tablets meet the current product specification. Tablets must be consistent in size, color, and shape.

6.6.5 Friability testing - For tablets with a unit weight equal to or less than 650 mg, take a sample of whole tablets corresponding as near as possible to 6.5 g. For tablets with a unit weight of more than 650 mg, take a sample of 10 whole tablets. The tablets should be carefully dedusted prior to testing. Accurately weigh the tablet sample (initial weight), and place the tablets in the drum. Rotate the drum 100 times for non-chewable tablets and 50 times for chewable tablets, and remove the tablets. Remove any loose dust from the tablets and accurately weigh (final weight). Use the formula below:

$$\frac{\text{Initial Weight (\quad) – Final Weight (\quad) x 100 \%}}{\text{Initial Weight (\quad)}} = \underline{\qquad\qquad} \%$$

6.6.5.1 High limit is 1.0 % for non-chewable tablets. High limit for chewable tablets is 5.0%.

6.6.5.2 If there are any problems, notify QC, R&D, and/or Production Management.

6.6.6 Upon completion and approval of form C-707-F2 CCP2 – Compression Startup Check, the compression process may proceed.

6.7 CCP 2 – Encapsulation Startup Check

6.7.1 Weigh 10 intact capsules individually, and determine the average weight. Each of the individual weights should be within the limits of 95% and 105% of the average weight (target weight).

6.7.2 If all of the capsules do not fall within the range limits, notify the operator to make the necessary adjustments to the equipment to ensure that capsules meet the current product specification.

6.7.3 Capsules must be completely locked with consistent size, color, and powder quantity.

6.7.4 If the capsules meet the acceptance criteria, the operator may proceed with encapsulation startup.

6.7.4.1 If there is any problem, notify QC and/or R&D.

6.7.5 Upon completion and approval of form C-707-F3 CCP2 – Encapsulation Startup Check, the encapsulation process may proceed.

6.8 CCP 3 – Packaging (Dosage Delivery)

6.8.1 Some packages have components such as scoops, medicine droppers, and dosage cups, which indicate that a specific quantity of material is contained or dispensed therein. These components are to be checked prior to packaging the batch.

6.8.2 In each case, the average weight delivery must fall within 90% - 110% of the label claim delivery (or as required by customer specifications).

6.8.2.1 Direct Weighing (powders):

6.8.2.1.1 Dispense 10 dosage units into three tared containers and determine the average weight of the containers. The average

weight must be within the limits of 90% - 110% of the label claim delivery.

Example: Label claims each delivery contains 10.0gm

90% - 110% of 10.0gm (9.0gm - 11.0gm)

Dispense 10 dosage units into three tared containers

Container 1 weight: 107.0gm

Container 2 weight: 104.0gm

Container 3 weight: 105.0gm

Average weight: (107.0 + 104.0 + 105.0)/ 3 = 105.3gm

105.3gm/ 10 = 10.5gm

6.8.2.2 If there are any problems, notify QC, R&D, and/or Production Management.

6.8.3 Upon completion and approval of form C-707-F7 CCP3 – Dosage Delivery, the packaging process may proceed.

6.9 CCP 4 – Metal Detection (Tablets/Capsules/Powders/Liquids)

6.9.1 All tablets, capsules, powders, and liquids (unless otherwise noted) must pass through the metal detector without indication of containing metal.

6.9.2 System Suitability – Manual Metal Detector

6.9.2.1 Using a calibration sample kit as outlined in SOP B-630 Manual Metal Detector, pass the test samples individually through the machine. The samples contain metal and should be rejected.

6.9.2.2 Recover and remove each test sample after use.

6.9.2.2.1 If there are any problems, notify QC and/or Production Management.

6.9.2.3 Upon completion and approval of form C-707-F4 CCP4 – Metal Detection (Manual), the product may proceed with metal detection until completion.

6.9.3 System Suitability – Inline Metal Detector

6.9.3.1 Using a calibration sample kit as outlined in SOP B-629 Inline Metal Detector, pass the test samples individually through the center of the machine. The samples contain metal and should be rejected into the rejection plate on the conveyor.

Note: The sample must be allowed to fully reject into the rejection plate in order to confirm machine accuracy. Do not grab the sample form the conveyor.

6.9.3.2 Recover and remove each test sample after use.

6.9.3.2.1 If there are any problems, notify QC and/or Production Management.

6.9.3.3 Upon completion and approval of form C-707-F5 CCP4 – Metal Detection (Inline), the product may continue through the packaging process.

6.9.4 System Suitability – Insight Throat Metal Detector

6.9.4.1 Using a calibration sample kit as outlined in SOP B-603 Insight Throat Metal Detector, enter from the bottom and insert each test piece individually into the black pipe and center the probe in the middle of the pipe. Solid bars indicate that metal has been detected and there will be a

sound signal.

6.9.4.2 Recover and remove each test piece after use.

6.9.4.2.1 If there are any problems, notify QC and/or Production Management.

6.9.4.3 Upon completion and approval of form C-707-F6 CCP4 – Metal Detection (Insight Throat), the product may continue through the packaging process.

6.10 CCP 5 – Blister Packaging (Blister Packaging Startup Check)

6.10.1 Three (3) blister strips should be pulled from each blister drop. The following will be evaluated:

6.10.1.1 Blister Form and Seal - blister cavities are formed uniformly and the foil is sealed with the dots notably distinguished and even from each side of blister edge to cavity.

6.10.1.2 Blister Card Coding – ensure that the blister card has correct and legible coding, as required by the product's packaging profile.

6.10.1.3 Product Quality – verify blister count (all cavities are filled) and make sure that product in the blister is free from chips, breaks, and foreign material.

6.10.1.4 Push/Tear Test – push product through the foil and ensure that the component is dispensed easily and not damaged.

6.10.1.5 Blister Submersion Leak Test – wear gloves and perform a leak test by submersing three blister cards (one from each drop) into colored water

for minimum of one minute, then inspect for seal integrity by drying off the blister card and inspecting the blister seal for blue water penetration into the blister cavity and around the edge of the blister seal.

6.10.1.5.1 If there are any problems, notify QC and/or Production Management.

6.10.1.6 Upon completion and approval of form C-707-F6 CCP4 – Metal Detection (Insight Throat), the product may continue through the packaging process.

6.11 CCP 6 - Liquid Tank Sampling

6.11.1 Upon completion of mixing the liquid batch, a Mix Tank Laboratory Sample will be taken from the top of the tank and from the bottom of the tank.

6.11.2 Using a clean sterile 100ml green cap cup, for the C-707-F8 "Bulk" Liquid Tank Sample collection, collect approximately 100ml of product from the top and 100ml from the bottom of the mixing tank. Cover the container with the green cap and tighten.

6.11.3 Identify the mix tank samples with the following information:

6.11.3.1 Product Name

6.11.3.2 Batch Number

6.11.3.3 Circle if sample is from the top or bottom of the mixing tank

6.11.3.4 Initials and Date of collecting employee

6.11.4 Forward the Mix Tank Sample to the QC laboratory and document the sample as per SOP D-201 QC Laboratory Sample Logbook Recording. Indicate that the sample is from CCP-6 Bulk Liquid Mix Tank (top or bottom).

6.11.5 Reference Form C-707-F9 CCP-6 Liquid Tank Sampling for documenting visual and QC Laboratory test results.

6.11.6 Once the laboratory sample is completed by the QC Laboratory and is acceptable, the blend will be released to be transferred to the liquid filler and/or holding tank.

6.12 CCP 7- Liquid Weight Verification

6.12.1 CCP 7 defines Critical Control Point to determine that the product volume weight, in grams, conforms to specifications for meeting label claim.

6.12.2 Target weight is based on the theoretical formulated dose weight of 1oz applying the established product density.

6.13 Determining the Average Fill Bottle Weight

6.13.1 Set the fill volume to target weight. Once the machine is set, fill ten consecutive bottles without cap or seal and check the weight of each bottle, Document the weights on Form C-707-F10 in the "Weight" section.

6.13.2 Add the ten bottle weights and divide by ten to determine the average fill weight. If volume is below desired product weight, adjust fill volume and reweigh ten more bottles and document.

6.13.3 If the fill weight is within specification, circle, "Pass". If bottle weights cannot be achieved, circle "Fail" and inform a Production supervisor and QC.

6.13.4 If there are any comments, document them in the comments section.

6.13.5 Document Performed By/Date (PQC) and Approved By/Date (PQV) on Form C-707-F10.

6.13.6 Packaging of the product may begin once form C-707-F10 has been approved.

6.14 CCP 8 – Pouching Startup

6.14.1 Pouch Seal - A visual check will be made that the pouch is sealed on both sides with a notch cut into one side.

6.14.2 Pouch Coding - ensure that the pouch has the correct coding as specified in the product's packaging profile.

6.14.3 Product Quality - verify pouch count (if applicable) and ensure that product in the pouch is correct and free from chips, breaks, and foreign material.

6.15 CCP 9 – Gummy Blend Brix Record

6.15.1 Obtain a small sample of the blend with a clean utensil and deposit it on the prism of a clean Brix meter.

6.15.2 Close the Brix meter cover and press firmly to get a thin layer of the blend over the prism.

6.15.3 Look through the eyepiece of the brix meter in a well-lit area, ensuring to hold the Brix meter level.

6.15.4 Record the reading where the blue and white areas meet.

6.15.5 This measurement must be repeated in reproducible duplicates.

Note 1: Reference SOP D-794 Use of an Analog Brix Meter for more details regarding the use and calibration of an analog brix meter.

Note 2: The measurement is dependent on temperature. As the product cools the °Bx will increase. Allow the mixture to cool enough so that the °Bx is constant and use that as the recorded value.

6.16 CCP 10 – Gummy Start Up

6.16.1 The desired flow rates in kilograms or grams per minute is indicated in the batch record.

6.16.2 Perform flow calibration of the liquid dosing pumps via weigh by difference method as described on form C-707-F13 Deposition Checks.

6.16.3 Perform flow calibration of the batter dosing pump via direct weight method as described on form C-707-F13 Deposition Checks.

6.16.4 Adjust the flow rate and repeat calibration as necessary in order to reach the desired flow rate. Record flow rates and settings used in the BPR.

6.16.5 Obtain the desired deposit weight range from the product profile in the BPR.

6.16.6 Deposit at least 5 rows of gummies and then stop depositing. The first rows will be under filled while the system primes.

6.16.7 Weigh one gummy from each well of a single mold individually and determine the average weight. Each of the individual weights should be within the limits 90% - 110% of the average weight.

6.16.8 If there is high variance in the gummy weight, adjust the depositors individually and repeat step 6.16.7. If the gummies are uniformly too high or too low, adjust the deposit length using the computer interface of the machine and repeat step 6.16.7.

6.16.9 Inspect the organoleptic properties of the gummies for consistency in size, color, smell, and general appearance.

6.16.10 Inspect the gummies for foreign material.

6.16.11 Record all results on form C-707-F13 Deposition Checks, located in the BPR.

6.17 CCP 11 – Gummy Pre-Curing

6.17.1 Upon startup and approximately every hour while running, bring 3 gummies to the QC laboratory for organoleptic and pH testing.

6.17.2 The gummies must be labeled with the date they were made, the batch number, and the time they were sampled. They must be accompanied by form C-707-F14

Pre-Curing, located in the BPR.

6.17.3 The results will be compiled by the QC Laboratory and retrieved by Production personnel before the batch is released for packaging operations.

6.18 CCP12 – Gummy Post-Curing

6.18.1 After approximately 24 hours of drying and approximately every 12 hours after, a gummy sample will be delivered to the QC Laboratory for water activity and water content testing.

6.18.2 The gummies are grouped according to the day in which they were manufactured. At least 5 gummies per day of running are necessary for the tests.

6.18.3 The gummies must be labeled with batch number, the sub-batches ran on that day, the time they were placed in the drying room, and the time they were removed from the drying room for analysis. They must be accompanied by form C-707-F15 Post-Curing, located in the BPR.

6.18.4 The results will be compiled by the QC Laboratory and retrieved by Production personnel before the batch released for packaging operations.

6.19 Manufacturing of batches may not proceed without meeting the acceptance criteria of the CCPs or adequate justification for not meeting criteria.

6.20 Documentation Maintenance

6.20.1 CCP forms will be included as a part of each MBR as required by the product form and issued with each BPR. Records will be maintained following SOP C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCN	By
0	08/06/10	New	-	-
1	12/12/10	Added CCP2 for Tablets and Capsules	-	-
2	03/22/11	Added CCP3 for Packaging	-	-
3	04/26/11	Made some minor changes	-	-
4	08/08/11	Changes in the forms	-	-
5	10/18/11	Added CCP4 for Metal Detection	-	-
6	06/21/12	Made SOP and Forms more detailed	-	-
7	05/31/13	Changed the logo, added bulk density test in CCP1, organized and clarified the SOP and forms	-	-
8	08/26/13	Changes on the forms, removed 5.8.5, changed % limits to whole numbers	13-728	V. Iltcheva
9	02/11/14	Revised entire procedure, added record for blister packaging, removed C-707-F2A	14-0142	V. Iltcheva
10	04/09/14	Added 4.7, 5.7, 5.10	14-0309	V. Iltcheva
11	09/22/14	Corrected some format issues.	14-0748	K. Burris
12	05/11/15	Added CCP 7 & CCP 8 for liquids with detailed information.	15-0203	M. Wienke
13	06/15/16	Updated CCP 8 for liquids to reflect product specific weight specification	16-0600	L. Titolo
14	09/10/18	Complete rewrite to reflect new ERP requirements. Obsolete processes removed. All forms revised and renumbered per ERP System. Added new forms.	18-0302	K. Burris
15	01/06/21	Added critical control point testing for gummy process. Added information on food safety and quality critical control points.	CC-20-0784	P. Wilson
16	03/13/23	Procedure rewrite to remove QC from requirements and replace with PQV requirements.	CC-23-0133	K. Burris

ION Nutritional Labs	Batch Record **CCP 1 – Blending (Absence of Foreign Material and Bulk Density)**		
	Form: C-707-F1	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. Absence of Foreign Material

Sieve ID: _____

Instructions: Collect approximately 20g samples from the top drums that represent (1) Beginning, (2) Middle and (3) End of blend after transfer into holding containers. A visual inspection of the product on top of the drum(s) will be conducted while a sieve test is performed.

Acceptance Criteria: Foreign Particulate _____ Fail _____ Pass

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

2. Blend Uniformity

Balance ID # _____ Calibration Due Date _____

Instructions: Collect approximately 100gm samples from drum(s) that represent (1) Beginning, (2) Middle and (3) End of blend after transfer into holding containers.

Method:
1. Tare a 100 ml graduate cylinder and gently transfer via a funnel sufficient powder to fill 50 ml to 60 ml of powder with minimum shaking or vibrations.
2. Weigh the net weight of powder transferred into 100 ml graduated cylinder, record as weight (a).
3. Determine volume by gently moving graduated cylinder to create a flat surface for accurate line to determine measured volume using only whole numbers, record as volume (b).

Calculations: Percent of Average = Individual Density Value/ Average Density Value x 100 Acceptance Criteria: All samples 95% to 105% of Average Value

Results: Loose Bulk Density

Sample	a. Weight (gm)	b. Volume (ml)	Density (a/ b)	Percent of Average
1. Beginning				
2. Middle				
3. End				
Average				

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

CONFIDENTIAL: For Ion Nutritional Labs use only

Issued By: _____ Date: _____

ION Nutritional Labs	Batch Record **CCP 2 – Compression Startup Check**		
	Form: C-707-F2	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

Equipment Name	ION ID Number	Calibration Due Date	Equipment Name	ION ID Number	Calibration Due Date
Hardness Tester			Balance		
Thickness Gauge			Friabulator		

Tablet Testing: Weigh 10 tablets individually, and determines the average weight. Each of the individual weights should be within the limits of 95% - 105% of the average weight. Measure the thickness on 10 tablets individually and determine the average thickness. Each of the individual thickness should be within the limits of 90% - 110% of the average thickness. Tablets must be consistent (size, color, shape).

Friability: For tablets with a unit weight equal to or less than 650 mg, take a sample of whole tablets corresponding as near as possible to 6.5gm. For tablets with a unit weight of more than 650mg, take a sample of 10 whole tablets. The tablets should be carefully dedusted prior to testing. Accurately weigh the tablet sample (initial weight), and place the tablets in the drum. Rotate the drum 100 times for non-chewable tablets and 50 times for chewable tablets, and remove the tablets. Remove any loose dust from the tablets, and accurately weigh (final weight).

Tablet #	Thickness	Weight	Hardness	Friability
1				
2				
3				**Acceptance Criteria**: High limit is 1.0% for non-chewable tablets. High limit for chewable tablets is 5.0%.
4				
5				
6				
7				
8				
9				Initial Weight (_____) – Final Weight (_____) x 100% = _____%
10				Initial Weight (_____)
Average				
Low Limit				
	Average - 10%	Average - 5%	kp	
High Limit				
	Average + 10%	Average + 5%	kp	

Comments	

Determination (circle one) **Pass** **Fail**

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

CONFIDENTIAL: For Ion Nutritional Labs use only

Issued By: _____ Date: _____

ION Nutritional Labs	Batch Record **CCP 2 – Encapsulation Startup Check**		
	Form: C-707-F3	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. Individual Capsule Testing

Balance ID # _____ Calibration Due Date _____

Instructions: Weigh 10 intact capsules individually, and determine the average weight. Each of the individual weights should be within the limits 95% - 105% of the average weight. Capsules must be completely locked with consistent size, color, and powder quantity.

Capsule #	Weight	Capsule #	Weight
1		6	
2		7	
3		8	
4		9	
5		10	

Average	
Low Limit (Average – 5%)	
High Limit (Average + 5%)	

Capsules completely locked with consistent size, color and powder quantity _____Yes _____ No

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

ION Nutritional Labs	Batch Record **CCP 4 – Metal Detection (Manual)**		
	Form: C-707-F4	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

MANUAL METAL DETECTOR Equipment ID # _____

STEPS	Pass/Fail
Verify cleaning log book for room/ equipment is completed.	
Check the operation of the machine by passing the required test samples through the machine (Good/Bad). Do NOT proceed if a test sample containing metal is not rejected, notify maintenance for repairs. Proceed if test sample is rejected. Test samples not containing metal should not be rejected.	
Recover and remove test samples.	

Determination (circle one) **Pass** **Fail**

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

STEPS	Pass/Fail
Place a clean catch container under both the passing chute and reject chute.	
Add product to the hopper feeding metal detector.	
Continue until the entire batch is processed.	

Note: Collect and record any rejected product to packaging waste

Acceptance Criteria: All tablets and capsules for packaging must pass through the metal detector without triggering the reject mechanism.

Determination (circle one) **Pass** **Fail**

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

	Batch Record **CCP 4 – Metal Detection (Inline)**		
ION Nutritional Labs	Form: C-707-F5	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

INLINE METAL DETECTOR Equipment ID # _____

STEPS	Pass/Fail
Verify cleaning log book for room/ equipment are complete.	
With the display of the machine showing a bar graph with empty rectangles (no metal detected) the machine is ready to test.	
Pass a test sample through the center of the machine. The sample do not contain metal and should not activate the machine, bar graph will show empty rectangles (no metal detected).	
Pass a test sample through the center of the machine. The sample contains metal and should activate the machine to alert that metal is present, bar graph will show filled rectangles when metal is present. The sample should be discarded to the rejection plate on the conveyor.	
Recover and remove the samples.	

Determination (circle one) **Pass** **Fail**

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

STEPS	Pass/Fail
Start packaging and continue until the entire batch is processed.	

Note: Collect and record any rejected product to packaging waste

Acceptance Criteria: All product for packaging must pass through the metal detector without triggering the reject mechanism.

Determination (circle one) **Pass** **Fail**

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

	Batch Record **CCP 4 – Metal Detection (Insight Throat)**		
ION Nutritional Labs	Form: C-707-F6	CCR No. CC-23-0133	Revision: 2

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

INSIGHT THROAT METAL DETECTOR Equipment ID # _____

STEPS	Pass/Fail
Verify cleaning log books for room/ equipment are complete.	
With the display of the machine showing a hollow bars (no metal detected) the machine is ready to test.	
Insert the metal test probe into the black pipe and center the probe in the middle of the pipe. Solid bars indicate that metal has been detected and there will be a sound signal.	
Remove the metal test probe.	

Determination (circle one) **Pass** **Fail**

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

STEPS	Pass/Fail
Start filling process and continue until the entire batch is processed.	

Note: Collect and record any rejected product to packaging waste

Acceptance Criteria: All powder for packaging must pass through the metal detector without triggering the reject mechanism.

Determination (circle one) **Pass** **Fail**

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

ION Nutritional Labs	Batch Record **CCP 3 – Dosage Delivery**		
	Form: C-707-F7	CCR No. CC-23-0133	Revision: 2

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. Dosage Delivery Verification

Label Claims each delivery contains _____

High Limit (label claims delivery + 10%) _____

Low Limit (label claims delivery – 10%) _____

Scale ID: _____

Calibration Due: _____

Direct Weighing

Dispense 10 dosage units (scoops) into 3 tared containers

Container	Weight
1	
2	
3	
Average for 10 dosage units	
Average/10 (for 1 dosage unit)	

Acceptance Criteria: Average weight is 90% - 110% of label claim delivery

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC)/Date: _____

Approved By (PQV)/Date: _____

ION Nutritional Labs	Batch Record **CCP 5 – Blister Packaging (Startup Check)**		
	Form: C-707-F8	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. Individual Blister Testing

Instructions: Pull 3 Blister strips, one from each drop for performing test 1- 4 and 3 additional Blister strips for performing test 5

Note: While standing at the end of the blister drop section of the machine, drop one will start from the left side drop, drop two will be the center drop, drop three will be the right side drop. The following tests will be performed on each drop

1. Blister Form and Seal- A visual check will be made that the blister cavities are formed uniformly and the foil is sealed with the dots notably distinguished and even from each side of blister edge to cavity.
2. Batch # / Exp. or Best by Date - ensure the Blister Pack has the correct and readable Batch #/ Exp. or Best by Date.
3. Product Quality – verify Blister count (all cavities are filled) and make sure that product in the blister is free from chips, breaks, and foreign material.
4. Push/Tear test, push tablets/ capsules through the foil and ensure the component is dispensed easily and not damaged.
5. Blister Submersion Leak Test

Note: The blue dye solution utilized for the leak test is 30 mls of Methylene Blue Solution to 4 liters of water. Wear latex gloves and perform leak test by submersing 3 blister strips (one from each drop) into colored water for minimum of one minute; inspect for seal integrity by drying off the blister strip and inspecting the blister seal for blue water penetration into the blister cavity and around the edge of the blister seal. Discard blister strips and latex gloves and document it in the Batch Record.

Circle one P – pass; or F – fail

Blister Strip	Blister Form and Seal	Batch# /Shelf Life Date	Product Quality	Push/Tear Test	Submersion Leak Test
1	**P / F**	**P / F**	**P / F**	**P / F**	**P / F**
2	**P / F**	**P / F**	**P / F**	**P / F**	**P / F**
3	**P / F**	**P / F**	**P / F**	**P / F**	**P / F**

Determination - All parameters were met: (circle one) **Pass** **Fail**

Comments	

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

ION Nutritional Labs	Batch Record **CCP 6 – Liquid Tank Sampling**		
	Form: C-707-F9	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. Visual inspection of blended product for Foreign Particulate

Circle one: TOP of Tank / BOTTOM of Tank

Instructions: Collect two tank lab test samples, one from the top and one from the bottom of the tank. Label the container with CCP 6 – Liquid Tank Sample.

Acceptance Criteria: If foreign material found check Fail and contact QC/R&D. If no foreign material found check Pass. Foreign Particulate _____ Fail _____ Pass

2. QC Laboratory Organoleptic, pH, Density, Viscosity

Instructions: Perform the following test and indicate Pass or Fail and the specific value following the test results where indicated.

Test	Specification	Result	Pass / Fail	By/Date
Organoleptic - Odor				
Organoleptic - Color				
Organoleptic - Appearance/Clarity				
pH				
Density				
Viscosity				

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC – QC Laboratory)/Date: _____ Approved By (PQV – QC Laboratory)/Date: _____

CONFIDENTIAL: For Ion Nutritional Labs use only

Issued By: _____ Date: _____

ION Nutritional Labs	Batch Record **CCP 7 – Liquid Weight Verification**		
	Form: C-707-F10	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. Weight Verification

Balance ID # _____ Calibration Due Date _____

Instructions: Press Clear button on scale to zero out scale. Set fill Volume and weigh check the first filling increment of 10 containers to ensure proper fill volumes are maintained. Then take 10 consecutive filled containers, without cap or seal, and record below in the Weight section. Add the 10 volume weights and divide by 10 to reach an average weight. (Note: average weight of bottles has been predetermined)

Min Product Weight (g) _____ Target Weight (g) _____ Max Product Weight (g) _____

Filled Bottle Number	Weight	Filled Bottle Number	Weight
1		6	
2		7	
3		8	
4		9	
5		10	

Average	
Low Limit (Average – 2.5%)	
High Limit (Average + 2.5%)	

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

CONFIDENTIAL: For Ion Nutritional Labs use only

Issued By: _____ Date: _____

	Batch Record **CCP 8 – Pouching (Startup Check)**		
ION Nutritional Labs	Form: C-707-F11	CCR No. CC-23-0133	Revision: 2

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

Instructions: Pull 4 pouches (1 pouch from each drop) and perform the following tests:

1. Batch # / Expiration Date - ensure the pouch has the correct and readable Batch #/ Expiration Date.
2. Product Quality – verify pouch count/fill and make sure that product in the pouch is correct, free from chips, breaks, and/or foreign material.
3. Pouch Seal - Submersion Leak Test

   Note: The blue dye solution utilized for the leak test is 30 mls of Methylene Blue Solution to 4 liters of water. Wear latex gloves and perform leak test by submersing each pouch into colored water for minimum of one minute; inspect for seal integrity by drying off the pouch and inspecting for blue water penetration on the inside of the pouch. Discard pouches and latex gloves and document results in the Batch Record.

Circle one P – pass; or F – fail

Pouch Number	Pouch Seal	Batch# /Shelf Life Date	Product Quality
1	**P / F**	**P / F**	**P / F**
2	**P / F**	**P / F**	**P / F**
3	**P / F**	**P / F**	**P / F**
4	**P / F**	**P / F**	**P / F**

Determination - All parameters were met: (circle one) **Pass** **Fail**

Comments	

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

ION Nutritional Labs	Batch Record **CCP 9 – Gummy Blend Brix Record**		
	Form: C-707-F12	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**°Brix Range**	

1. Record °Brix for Each Sub-Blend in Kettles 1 & 2

Before moving the gummy blend from the kettles to tank 3, test the °Brix to ensure the blend meets the required specification. Obtain a small sample of the blend with a clean utensil and deposit it on the prism of a clean Brix meter. Close cover and press firmly to get a thin layer of the blend over the prism. Look through the eyepiece of the brix meter in a well-lit area, preferably with an incandescent light. Ensure to hold the brix meter level. Record the reading where the blue and white areas meet. This measurement must be repeated in reproducible duplicates. If °Brix is too low, continue heating the blend, re-testing periodically. If the °Brix is too high, immediately turn off the heat and pump to tank 3. Then contact R&D. R&D may calculate water to be added to bring the Brix back into an acceptable range.

Note: The measurement is dependent on temperature. As the product cools the °Bx will increase. Allow the mixture to cool enough so that the °Bx is constant and use that as the recorded value.

Sub Blend	1	2	3	4	5	6	7	8	9
°Brix									
Date									
Time									
Initials									

Sub Blend	10	11	12	13	14	15	16	17	18
°Brix									
Date									
Time									
Initials									

Comments	

PQV: _____

ION Nutritional Labs	Batch Record **CCP 9 – Gummy Blend Brix Record**		
	Form: C-707-F12	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**°Brix Range**	

2. Record °Brix for Each Sub-Blend Mix in Tank 4

Periodically test the °Brix to ensure the blend meets the required specification. Obtain a small sample of the blend with a clean utensil and deposit it on the prism of a clean Brix meter. Look through the eyepiece of the brix meter in a well-lit area, preferably with an incandescent light. Ensure to hold the brix meter level. Record the reading where the blue and white areas meet. This measurement must be repeated in reproducible duplicates. If °Brix is out of specification, contact R&D. R&D may provide additional heat to raise the °Brix, or additional water to lower the °Brix.

Note: The measurement is dependent on temperature. As the product cools the °Bx will increase. Allow the mixture to cool enough so that the °Bx is constant and use that as the recorded value.

Sub Blend	1	2	3	4	5	6	7	8	9
°Brix									
Date									
Time									
Initials									

Sub Blend	10	11	12	13	14	15	16	17	18
°Brix									
Date									
Time									
Initials									

Comments	

PQV: _____

	Batch Record **CCP 10 – Gummy Deposition Checks**		
ION Nutritional Labs	Form: C-707-F13	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. Flow Calibration

Instructions: Ensure the flow of each subcomponent is calibrated according to table 1 according to the following procedure.

Liquid Dosing Pumps (weigh by difference):
Fill a vessel with purified water and submerge the sink filter of the applicable dosing pump into the water. Determine the appropriate flow setting by comparing the required flow rate designated in the Mix Instructions with the example flow settings in Table 1. Turn on the applicable pump and set it to the applicable flow setting. Open the release knob on the back of the pump and then slowly close it ensure proper flow. Allow the pump to flow enough so that the lines are full of liquid. Obtain a suitable vessel for the subcomponent. Fill the vessel with the subcomponent and tare the vessel (record the tare weight in case the scale is accidentally reset). Remove the sink filter from the water and place it into the vessel containing the applicable subcomponent. Obtain a stopwatch and have it on standby. Simultaneously start the stopwatch and dosing pump. Stop the dosing pump after a minimum of 2 minutes. Remove the sink filter from the vessel and do your best to allow the material that clings to the outside of the sink filter to drip back into the vessel. Weigh the vessel and determine the amount of material that was pumped by taking the difference of the initial weight and the weight after pumping. Determine the flow rate by dividing the amount of material pumped by the time spent pumping. Remember that 60 secs = 1 min, e.g. a time of 1:15 = 1.25 minutes. Compare the measured flow rate to the required flow rate listed in Table 1 and adjust the setting on the pump as necessary. Repeat this procedure until the measured flow rate is correct.

Batter Dosing Pump (weigh directly):
Obtain a suitable vessel for the batter and tare it (record the tare weight in case the scale is accidentally reset). Obtain a stop watch and have it on standby. Obtain a secondary container to catch material that is not being weighed, to limit wasted batter. Place a floor pan under the output to aid in clean up. Determine the appropriate flow setting by comparing the required flow rate designated in the Mix Instructions with the example flow settings in Table 1. Turn on the pump and set it to the applicable flow setting. Allow the pump to discharge the water in the lines onto the floor pan, and wait until there is a steady flow of batter. Immediately switch flow to the tared vessel and simultaneously start the stop watch. Collect material for a minimum of 2 minutes, then switch flow from the tared vessel to the secondary container. Weigh the tared vessel to determine the amount that was pumped. Determine the flow rate by dividing the amount of material pumped by the time spent pumping. Remember that 60 secs = 1 min, e.g. a time of 1:15 = 1.25 minutes. Compare the measured flow rate to the required flow rate as designated in the Mix Instructions and adjust the setting on the pump as necessary. Repeat this procedure until the measured flow rate is correct. The material in the secondary container and the tared vessel is to be added back into Tank 4.

	Batch Record **CCP 10 – Gummy Deposition Checks**		
ION Nutritional Labs	Form: C-707-F13	CCR No. CC-23-0133	Revision: 1

Table 1: Example Flow Settings

Batter		**Flavors**		**50% Aqueous Acid**	
Example Flow Setting	Flow Rate	Example Flow Setting	Flow Rate	Example Flow Setting	Flow Rate

Table 2: Measured Flow Settings

Batter		**Flavors**		**50% Aqueous Citric Acid**	
Flow Setting	Flow Rate	Flow Setting	Flow Rate	Flow Setting	Flow Rate

Comments	

	Batch Record **CCP 10 – Gummy Deposition Checks**		
	Form: C-707-F13	CCR No. CC-23-0133	Revision: 1

2. **Individual Gummy Weight Check** Balance ID # _____ Calibration Due Date _____

Instructions: Weigh one gummy from each well of a single mold individually and determine the average weight. Each of the individual weights should be within the limits 90% - 110% of the average weight. Gummies must be consistent in size, color, and general appearance.

#	Weight (g)	#	Weight (g)	#	Weight (g)	#	Weight (g)	#	Weight (g)	#	Weight (g)	#	Weight (g)	#	Weight (g)
1		6		11		16		21		26		31		36	
2		7		12		17		22		27		32		37	
3		8		13		18		23		28		33		38	
4		9		14		19		24		29		34		39	
5		10		15		20		25		30		35		40	

Average	
Low Limit (Average – 10%)	
High Limit (Average + 10%)	

3. **Organoleptic Inspection of Pre-Cured Gummies**

Instructions: Collect five (5) gummies into one sample container, pre-cure gummies should be collected in the middle of the sub-batch.

Gummies consistent in size, color, smell and general appearance? _____Yes _____ No
Gummies absent of foreign particulate matter? _____Yes _____ No

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC)/Date: _____ Approved By (PQV)/Date: _____

ION Nutritional Labs	Batch Record **CCP 11 – Pre-Curing**		
	Form: C-707-F14	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. QC Laboratory Organoleptic / pH

Instructions: QC Laboratory will perform the following tests and indicate Pass or Fail and the specific value following the test results where indicated. These samples will be tested once every hour while running.

Test	Specification	Result	Pass / Fail
Organoleptic - Odor			
Organoleptic - Color			
Organoleptic - Appearance/Shape			
pH	≤ 4.5		

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC – QC Laboratory)/Date: _____

Approved By (PQV – QC Laboratory)/Date: _____

ION Nutritional Labs	Batch Record **CCP 12 – Post-Curing**		
	Form: C-707-F15	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. QC Laboratory Water Activity

Instructions: QC Laboratory will perform the following test and indicate Pass or Fail and the specific value following the test results where indicated. Samples will be tested after the first 24 hours, and then approximately every 12 hours until the specified parameters are met.

Test	Specification	Result
Water Activity	≤ 0.75 A_w	

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC – QC Laboratory)/Date: _____ Approved By (PQV – QC Laboratory)/Date: _____

ION Nutritional Labs	Batch Record **CCP 12 – Post-Curing**		
	Form: C-707-F15	CCR No. CC-23-0133	Revision: 1

Customer Name			
Product Name		**Product SKU**	
Batch Number		**Room ID**	
Test Date		**Test Time**	

1. QC Laboratory Water Activity

Instructions: QC Laboratory will perform the following test and indicate Pass or Fail and the specific value following the test results where indicated. Samples will be tested after the first 24 hours, and then approximately every 12 hours until the specified parameters are met.

Test	Specification	Result
Water Activity	≤ 0.75 A_w	

Determination (circle one) **Pass** **Fail**

Comments	

Performed By (PQC – QC Laboratory)/Date: _____ Approved By (PQV – QC Laboratory)/Date: _____