1.0 Purpose

The purpose of this procedure is to define the process of selecting and executing a finished product sampling plan. This procedure provides guidance for selecting the samples for identity, purity, strength, and composition testing.

2.0 Scope

This procedure applies to all products that have been manufactured and/or packaged by Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Management to implement and maintain this procedure.

3.2 It is the responsibility of QC personnel to strictly follow the procedure.

3.3 It is the responsibility of the QC Laboratory to test samples that have been submitted, using in-house testing or outside testing if required.

3.4 It is the responsibility of QC Laboratory Management to define any deviations from the default reserve and stability reserve sampling procedures.

4.0 Definitions

4.1 **Finished Product** – Final Dosage form of any Dietary supplement, OTC drug product, pet product, or cosmetic

4.2 **MBR** – Master Batch Record

4.3 **DC** – Document Control

4.4 **BPR** – Batch Production Record

5.0 References

5.1 D-201-F1, Form, QC Laboratory Sample Log Book

5.2 E-702-F1, Form, Master Sampling Plan

5.3 E-702-F2, Form, Special Sampling Request

5.4 E-702-F3, Form, Confirmation of Sample Collection

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

5.6 21 CFR Part 111.83

5.7 21 CFR Part 211.170

6.0 Sampling for Identity, Strength, and Composition Testing

6.1 The sampling requirements outlined in this procedure apply to all products manufactured at Ion Labs and can only be superseded if the Product Profile details an alternative sampling and testing plan that is supported by scientific justification.

6.2 Collect laboratory samples for all finished product release testing, with the exception of microbial analysis (reference section 7.0), from the final finished product dosage form, i.e. processing step just prior to packaging. Alternatively, conduct testing on a composite sample of beginning, middle, and end of packaging.

6.3 As samples are collected, complete form E-702-F3 Confirmation of Sample Collection. An entry is to be made and signed for at each collection time point.

6.4 Each BPR will contain form E-702-F1 Master Sampling Plan, which outlines the required samples for each stage of manufacturing. These sampling plans are product specific and will be built at time of MBR creation.

6.5 Tablets and Capsules

6.5.1 For each day and shift of manufacturing, tablets and capsules will be sampled throughout the compression/encapsulation process and composited into an HDPE bottle with closure. Sampling can occur at any point in each shift.

6.5.2 Collection bottles will be labeled to contain the following information:

6.5.2.1 Product name

6.5.2.2 Batch number

6.5.2.3 Initials of QC and date

Note: If multiple tablet or encapsulation machines are running the same batch number simultaneously, combine samples from each room into the same bottle so a composite sample is made from all rooms.

6.6 Bulk Powder

6.6.1 Bulk powder finished product samples will be collected from the beginning, middle, and end of packaging, i.e. bottles, canisters, or stick packs. Laboratory testing will be completed by compositing these samples.

6.6.2 Collection bottle(s) will be labeled to contain the following information:

6.6.2.1 Product name

6.6.2.2 Batch number

6.6.2.3 Initials of QC and date

6.7 Liquids

6.7.1 Mix tank lab samples will be taken from the top and bottom of the tank, upon completion of mixing the liquid batch. Approximately 100ml of product from the top and 100ml of the product from the bottom of the Tank will be collected using a clean sterile 100ml green cap cup. The bottles will be identified as CCP 6 samples with following information:

6.7.1.1 Product Name

6.7.1.2 Batch Number

6.7.1.3 Circle if sample is from the Top or Bottom of the Mixing Tank

6.7.1.4 Initials and date sample was taken

6.7.2 Liquid laboratory finished product release testing will be sampled from the liquid blend tank into an appropriate container(s).

6.7.3 Collection bottle(s) will be labeled to contain the following information:

6.7.3.1 Product name

6.7.3.2 Batch number

6.7.3.3 Initials of QC and date

6.8 Chewable Gels (Gummies)

6.8.1 Chewable Gel finished product samples will be collected from the beginning, middle, and end of packaging. Laboratory testing will be completed by compositing these samples.

6.8.2 Packaged containers will be labeled to contain the following information:

6.8.2.1 Product name

6.8.2.2 Batch number

6.8.2.3 Initials of QC and date

7.0 Sampling for Purity Testing (Microbial Testing)

7.1 For all products, laboratory samples intended for microbial analysis will be taken from beginning, middle, and end of packaging. These samples will then be composited in the laboratory and evaluated for microbial contamination.

7.2 For products packaged as bulk, microbial analysis will be performed on the final dosage form as a composite of beginning, middle, and end of manufacturing process.

7.3 The bottle will be identified as micro sample with the following information:

7.3.1 Product name

7.3.2 Sampling timeframe (beginning, middle, or end)

7.3.3 Batch number

7.3.4 Initials of QC and date

8.0 Reserve and Stability Reserve Sampling

8.1 Sampling points – sampling will be staggered between the beginning, middle, and end of the process.

8.1.1 For bottled and blistered products, samples will be taken during the final packaging process. For bulk packaged products, samples will be taken during the bulk packaging operation. The default reserve quantity for any product is six bottles, two beginning, two middle and two end samples.

8.1.2 Reserve samples will be held in the same container/closure in which the packaged and labeled product is distributed.

8.1.3 Reserve samples will be taken in the following manner:

8.1.3.1 Bottling – six reserve samples will be pulled during the bottling process. If bottles will be further packaged into secondary or tertiary packaging, reserve samples must be packaged and submitted to the lab in same manner.

8.1.3.2 Blister packaging – six reserve samples will be pulled during the final pack out of blisters (ex. Cartoning process).

8.1.3.3 Bulk packaging (capsules/tablets) – a minimum of 60 capsules/tablets will be placed in six 200cc HDPE containers with closures.

8.1.3.4 Bulk packaging (powders) – during the filling of the containers, six reserve samples will be pulled.

8.1.4 The bottles will be identified as reserve samples with the following information:

8.1.4.1 Product name

8.1.4.2 Batch number

8.1.4.3 Initials of QC and date

8.1.5 Deviation from the default reserve sampling procedure:

8.1.5.1 The default number of six reserve samples can be reduced to a number no less than three bottles when sufficient dosage exists in a reserve sample to justify a reduced number of packages. The reserve quantity must meet the requirements of 21 CFR 111.83 and CFR 211.170.

8.2 Stability Reserve Quantities

8.2.1 The default stability reserve quantity for any product is nine bottles/cartons, three beginning, three middle and three end samples.

8.2.2 Stability reserves will be held in the same container/closure assembly in which the packaged and labeled dietary supplement is distributed.

8.2.3 The bottles/cartons will be identified as stability samples with the following information listed on the bottle:

8.2.3.1 Product name

8.2.3.2 Batch number

8.2.3.3 Initials of QC and date

8.2.4 Deviation from the default stability reserve sampling procedure:

8.2.4.1 Stability reserves must consist of at least twice the quantity necessary to complete all tests or examinations to determine whether or not product meets specifications across the entire stability test cycle.

8.2.4.2 The default number of nine bottles/cartons can be reduced to a number no less than one bottle per stability test interval.

Example 1: 2kg powder with 2 year stability; Test intervals at 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months for a two year best by date: a minimum of four stability samples are required.

Example 2: 180ct bottle, 1 gram dosage with 3 year stability; test intervals at 3 months, 6 months, 9 months, 12 months, 18 months, 24 months, 30 months, and 36 months for a three year best by date: A minimum of six stability samples are required.

8.2.5 Justification for reduced stability reserves will be listed in the exemption section of the product profile.

8.2.6 Formulations can be bracketed or matrixed for stability testing.

8.2.6.1 The bracketing or matrixing program must be defined in the exemption section of each product profile contributing to the specific bracketing or matrixing program.

8.2.6.2 Bracketed or matrixed batch reserves will be accounted for by QC chemists to determine the required number of reserve samples needed to meet stability objectives.

9.0 Special Sample Requests

9.1 Any requests for product samples outside of the scope of this procedure will be conducted using form E-702-F2 Special Sample Request.

9.1.1 Special sample requests must be completed and submitted to DC prior to batch record completion.

9.1.2 Special Sample Request forms will be included with the Master Sampling Plan located in the batch record.

9.1.3 Details on special sample request form include:

9.1.3.1 Sample Type Requested

9.1.3.2 Number of dosage/ bottles requested

9.1.3.3 Requested by and date

9.1.3.4 Collected by and date

9.1.4 Once collected, all special sample request containers will be submitted to the requestor.

10.0 Sample Logging Procedure

10.1 QC will submit the samples to the QC Laboratory and log them on form D-201-F1 QC Laboratory Sample Log Book.

11.0 Documentation

11.1 Forms associated with this procedure will be filed in the applicable BPR and maintained as outlined in SOP C-502 Record Storage, Retention, and Destruction..

12.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	11/13/12	New	-	-
2	04/12/13	Changed SOP number. Added "bulk packaged – in kg" to sections 5.1.1, 5.1.2, and 5.1.3. Added section 5.2.	-	-
3	12/04/13	Changed the content to reflect times of when samples are taken, quantity taken, and bottles used for bulk samples	13-1119	M. Wienke
4	03/18/14	Added note in section 6.1. Updated SOP format. Changed from two bottles taken to three in section 6.1.1	14-0228	M. Wienke
5	05/05/14	Added deviation section for finished product retains and stability retains. Added reference to D-703 and D-712.	14-0387	B. Johns
6	09/01/16	Biennial review – widen scope to OTC, cosmetics, pet product	16-0786	E. Hasanbasic
7	11/29/16	Updated for liquid process sampling, added cartons, clarified blistering process sampling	16-1092	E. Hasanbasic
8	05/05/21	Scheduled review: complete procedure rewrite. Added attachment 1. Added form E-702-F1.	CC-21-0175	K. Burris
9	12/20/22	Clarified finished product testing. Added Chewable gels to scope.	CC-22-0474	J. Sassman

ION LABS	Master Sampling Plan		
	Form: E-702-F1	CCR No. CC-22-0474	Revision: 1

Product Name		Customer Name	
Batch Number		Product SKU	

Sample Type*	Sample Quantity	Collection Stage

** All collected samples will be labeled as outlined above and delivered to appropriate location.*

Comments:

ION LABS	Special Sampling Request		
	Form: E-702-F2	CCR No. CC-22-0474	Revision: 0

Product Name	
Batch Number	
Sample Request Purpose	

Sample Type Requested (Select One)	Number of Dosages/ Bottles Requested	Requested By/Date	Collected By/ Date
☐ Powder Blend ☐ Inner Capsule ☐ Outer Capsule ☐ Uncoated Tablet ☐ Coated Tablet ☐ Liquid Blend ☐ Packaged Product ☐ Other:			
☐ Powder Blend ☐ Inner Capsule ☐ Outer Capsule ☐ Uncoated Tablet ☐ Coated Tablet ☐ Liquid Blend ☐ Packaged Product ☐ Other:			
☐ Powder Blend ☐ Inner Capsule ☐ Outer Capsule ☐ Uncoated Tablet ☐ Coated Tablet ☐ Liquid Blend ☐ Packaged Product ☐ Other:			
☐ Powder Blend ☐ Inner Capsule ☐ Outer Capsule ☐ Uncoated Tablet ☐ Coated Tablet ☐ Liquid Blend ☐ Packaged Product ☐ Other:			

Comments:

ION LABS	Confirmation of Sample Collection		
	Form: E-702-F3	CCR No. CC-22-0474	Revision: 0

Product Name		Customer Name	
Batch Number		Product SKU	

Sample Type*	Date/ Shift Collected	Collection Stage**	Collection Room	Collected By/Date

** For example, composite or microbial* ***For example, capsule, coated tablet, blend drop, packaging (B, M, E)*

Comments: