

	Standard Operating Procedure Packaging Component Sampling Procedure		SOP Number E-701	Revision 9
			Effective Date 04/11/25	Page 1 of 5
Written by/ Date  03/11/25		Reviewed by/ Date AJS 03/17/25		Approved by/ Date  03/18/25
Title: Warehouse Manager		Title: QC Lab Manager		Title: QA/QC Director

1.0 Purpose

The purpose of this procedure is to define the procedure for sampling and inspection of all packaging components which come in contact with finished product.

2.0 Scope

This procedure is applicable for sampling and inspection of all finished product packaging components at Ion Labs including but not limited to bottles, caps, scoops, desiccants and space filler.

3.0 Responsibility

- 3.1 It is the responsibility of Quality Control Management or designee to implement and maintain this procedure, and to review and approve written specifications for packaging material.
- 3.2 It is the responsibility of the warehouse Sampler and QC personnel to strictly follow the procedure.
- 3.3 It is the responsibility of Quality Control to maintain and engineering to distribute all current written specifications and supporting documentation for packaging components.
- 3.4 Quality Control is responsible for reviewing and approving all packaging component specifications.
- 3.5 It is the responsibility of the Warehouse Sampler to ensure the correct Specification/Form is used while performing the inspection and it is the responsibility of the QC personnel that current specifications are retained for use.

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4.0 Definitions

- 4.1 **Packaging Component** – Any component intended for packaging related activity in the manufacture of a dietary supplement, pet product, or cosmetic.
- 4.2 **R#** - Receiving number; a unique number assigned to a component upon receipt
- 4.3 **QC** – Quality Control
- 4.4 **IPA** – 70% Isopropyl Alcohol
- 4.5 **COC** – Certificate of Compliance

5.0 References

- 5.1 Packaging Component Specification
- 5.2 E-701-F1, Form, Packaging Component Inspections
- 5.3 E-703-F1, Form, Sampling Log
- 5.4 C-201, SOP, Deviation and Investigation Procedure
- 5.5 21 CFR Part 111, Guidance, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

6.0 Procedure

- 6.1 All sampling is to be performed in designated sampling rooms or booths.
- 6.2 Prior to bringing any material into the sampling room:
 - 6.2.1 Ensure the room and any equipment in that room is clean and free of any debris

and all previously inspected material is removed.

6.2.2 Spray the surfaces with IPA, wipe clean, and ensure surfaces are dry.

6.2.3 Ensure gloves, lab coat/frock, hair net, safety glasses, beard cover (as applicable), and face mask are worn to prevent contamination of self and/or material when sampling.

6.3 Only one R# is to be sampled in the room/booth at any time.

6.4 Visually inspect that packaging containers are intact and packaging components being sampled appear free from contaminants.

6.5 Utilize Form E-701-F1 Packaging Component Inspection Form when sampling a packaging component.

6.6 Compare the supplier COC, Certificate of Quality, or equivalent against the container label (e.g. product description, lot number, part number) and ensure that they match.

6.7 . Collect 5 representative samples from 5 individual containers. If less than 5 containers of a lot are received, collect 5 samples at random from <5 cases received.

6.8 Inspect packaging components visually for contamination.

6.9 The containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their contents.

6.10 Each container from which a sample was taken should be marked, indicating that the container was sampled.

6.11 Retain 3 samples from the representative samples in a sealed container marked with the item and R# and date sampled. The retains are maintained for at least one year following the sampling date.

6.12 All sampling and inspection activities will be fully documented on Form E-701-F1 Packaging Component Inspection Form, recording required information as applicable, but

not limited to:

- Component name
- Manufacturer/vendor
- Date received
- Manufacturer/vendor's lot#
- Color, size, material type

6.12.1 Specifications are received from the vendor/manufacturer and are uploaded into Ion Labs ERP system. These specifications will autopopulate onto Form E-701-F1 and should include but not limited to color and size, which are essential for release.

6.12.2 The written specification should be reviewed at time of use and confirmed to be current.

6.12.2.1 If a written specification is not present or current, one should be created.

6.13 After completion of E-701-F1 Packaging Component Inspection Form, submit the form, along with the attached COC, to Quality Management or designee for review and approval.

6.14 Quality management/designee will review and approve/reject the results of the inspection conducted on the packaging material and sign the form.

6.14.1 If the inspection fails, Quality Management should place the failing material onto QC Hold until a disposition decision has been made.

6.14.2 Document pass or fail for each inspection on Form E-703-F1 Sampling Log.

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7.0 Revision History

Revision	Date	Description of Changes	CCR	By
1	12/17/12	Original	-	-
2	02/27/13	Changed SOP number, added in section 5.2.2 reference to SOP C-708, removed section 5.2.12	13-137	V.Iltcheva
3	03/05/14	Complete revision	14-0202	V.Iltcheva
4	03/24/15	Revise to include OTC and written specifications per FDA and NSF requirements	15-0073	D. Popp
5	01/04/19	Scheduled review: updated procedure and forms to reflect current processes. Changed responsibilities.	19-0019	K. Burris
6	11/27/19	Revised to be in line with current practice. Revised E-701-F-1/F2/F3. Obsoleted E-701-F4/F5/F6	19-0757	J. Sassman
7	10/06/22	Updated to reflect changes to form E-701-F1. Updated logo and format. Clarified procedure throughout. Updated responsibilities.	CC-22-0328	J. Nicholson
8	01/08/25	Updated responsibilities, sample plan, minimum unit sampling requirements	CC-25-0009	J. Murphy

