1.0 Purpose

The purpose of this procedure is to provide instruction for the measurement of weight variation in all tableted, encapsulated, or chewable gel products that require weight variation at Ion Labs.

2.0 Scope

This procedure applies to all tableted, encapsulated, or chewable gel products manufactured at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of trained QC personnel to follow this procedure.

3.2 It is the responsibility of QC Laboratory Management to implement this procedure and keep procedure updated with current practices.

3.3 It is the responsibility of QC Laboratory Management to ensure that the procedure is followed.

4.0 Definitions

4.1 **SD** – Standard Deviation

4.2 **RSD** – Standard Deviation expressed as a percentage of the mean

4.3 **Chewable Gel** – Gummy vitamin product.

4.4 **QC** – Quality Control

5.0 References

5.1 D-707, SOP, Use of Balances in the QC Laboratory

5.2 D-712-F1, Form, Weight Variation Form

5.3 USP <2091> Weight Variation of Dietary Supplements

6.0 Procedure

Note: This procedure requires an understanding of SOP D-707 Use of Balances in the QC Laboratory.

6.1 Equipment

6.1.1 Analytical balance with printer

6.2 Measuring weight variation in uncoated tablets

6.2.1 Weigh individually 20 whole tablets and calculate the average weight.

6.2.2 Acceptance criteria: The requirements are met if the weights of not more than 2 of the tablets differ from the average weight by more than the percentage listed in Table 1, and there is no tablet that differs in weight by more than double the percentage, unless otherwise stated in product profile.

6.3 Measuring weight variation in coated tablets

6.3.1 Weigh individually 20 whole tablets and calculate the average weight.

6.3.2 Acceptance criteria: The requirements are met if the weights of not more than two of the tablets differ from the average weight by more than the percentage listed in Table 1, and there is no tablet that differs in weight by more than double that percentage, unless otherwise stated in product profile.

6.3.3 If the coated tablets do not conform to the criteria, place 20 tablets in 37°C Millipore water and gently swirl for up to 5 minutes. Repeat for a shorter period

if any core disintegration has begun.

6.3.4 Dry un-disintegrated cores at 50°C for 30 minutes.

6.3.5 Weigh the 20 cores individually and calculate the average weight.

6.3.6 Determine if the requirements meet the acceptance criteria.

6.3.7 In place of removing the coating from tablets, a representative sample of uncoated tablets from the corresponding batch can be used to assess weight variation.

Formulation Weight of Tablet Measured	Acceptance % Difference
130mg or less	10
130mg – 324mg	7.5
324mg +	5

Table 1 Weight Variation Tolerances for Uncoated and Coated Tablets, unless otherwise stated in product profile

6.4 Measuring weight variation in Hard Capsules

6.4.1 Weigh individually 20 whole capsules and calculate the average weight.

6.4.2 Acceptance Criteria: The requirements are met if each of the individual weights is within the limits of 90% and 110% of the average weight.

6.4.3 If not all of the capsules fall within the Acceptance Criteria uniquely identify 20 capsules and weigh them individually documenting the weight with the capsule identifier.

6.4.4 Remove the contents of each capsule with the aid of a small brush or cotton swab.

6.4.5 Weigh the identified shell and subtract the shell weight from the corresponding gross weight.

6.4.6 Calculate the average fill weight per capsule.

6.4.7 The requirements are met if not more than two of the net weight differences are greater than 10% of the average net content and in no case is the difference greater than 25%, unless otherwise stated in product profile.

6.4.7.1 If the requirements are not met because more than two but not more than 6 capsules deviate from the average between 10% and 25%, determine the net contents of an additional 40 capsules.

6.4.7.2 Combine the original net data for the first 20 capsules with the additional 40 capsules for a total of 60 capsules and calculate the net weight mean.

6.4.7.3 The requirements are met if not more than 6 of the 60 capsules exceed 10% of the average net content and in no case does the difference exceed 25%.

6.5 Measuring Weight Variation in Soft Capsules

6.5.1 Proceed as directed in Section 6.4 Hard Capsules.

6.5.2 If the soft capsules do not meet the Acceptance Criteria then uniquely identify 20 soft capsules and weigh them individually documenting the weight with the soft capsule unique identifier.

6.5.3 Cut open the capsules by means of a suitable clean, dry cutting instrument such as scissors or a sharp open blade and remove the contents by washing with a suitable solvent.

6.5.4 Allow the occluded solvent to evaporate from the shells at room temperature over a period of no less than 30 minutes, taking precautions to avoid uptake or loss of moisture.

6.5.5 Continue evaluation from Section 6.4 Hard Capsules.

6.6 Measuring Weight Variation of Chewable Gels

6.6.1 Weigh an equal number of units from each color and shape individually to obtain a total of NLT 20 individual weights, and calculate the average weight.

6.6.2 The requirements are met if no individual weight differs from the average weight by more than 7.5%.

6.6.3 If 1 unit falls outside of the limits, repeat the procedure (6.6.1) with an additional set of NLT 20 chewable gels. The requirements are met if none of the units tested differ from the average weight by more than 10%.

6.7 Documenting Results

6.7.1 Only the official electronic form D-712-F1 Weight Variation may be used. All calculations will be performed using this electronic form which has all formulas. All Formulas are locked using a security passcode and the form traceable to user for modification and data entry.

6.7.2 The analyst will enter all weights into the electronic form. The form will be printed and taped into the laboratory notebook with the corresponding balance ticket.

6.7.3 The electronic form will be saved F:\Laboratory\Weight Variation Test in the correct folder for the year it was done. The file will be named with the Lot Number and Notebook Reference.

6.7.3.1 i.e. "240898 NB 318-95". 240898 is the lot number and NB 318-95 is the notebook reference.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	07/29/10	New	-	-
1	12/02/10	Updated SOP content	-	-
2	03/31/11	Updated SOP format	-	-
3	02/21/13	Updated with new format, updated forms to new format	13-105	B. Johns
4	02/03/14	Changed SOP title, removed HPLC test methods, added use of pre-coated tablets for assessment, clarified criteria on form.	14-0120	B. Johns
5	09/16/16	Biennial review: Updated format. Incorporated requirements of using electronic form including security requirements.	16-0825	B. Johns
6	04/14/20	Scheduled review: Updated responsibility and scope. Updated to include all forms of products produced at ION.	CC-20-0271	J. Maignan
7	09/30/22	Added process for chewable gels. Updated form D-712-F1 to include a product type and dynamically acceptable adjust ranges.	CC-22-0389	J. Nicholson
8	03/25/25	Add "Unless otherwise stated in product profile" to sections 6.2.2, 6.3.2, 6.4.7 Removed Attachment 1 and made Table 1 Updated Section 6.7 to reflect current practices	CC-25-0025	M. Maples