

⟨2091⟩ WEIGHT VARIATION OF DIETARY SUPPLEMENTS

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INTRODUCTION

The following tests provide limits for the permissible variations in the weights of individual tablets, capsules, ▲or chewable gels▲ (USP 1-Dec-2019) expressed in terms of the allowable deviation from the average weight of a sample. Separate procedures and limits are described herein for capsules, uncoated tablets, coated tablets, ▲and chewable gels▲ (USP 1-Dec-2019) that are intended for use as dietary supplements.

CAPSULES

Capsules meet the requirements of the following test with respect to variation in weight of contents.

Hard Shell Capsules

Weigh 20 intact capsules individually, and determine the average weight. The requirements are met if each of the individual weights is within the limits of 90% and 110% of the average weight.

If not all of the capsules fall within the aforementioned limits, weigh the 20 capsules individually, taking care to preserve the identity of each capsule, and remove the contents of each capsule with the aid of a small brush or pledget of cotton. Weigh the emptied shells individually, and calculate for each capsule the net weight of its contents by subtracting the weight of the shell from the respective gross weight. Determine the average net content from the sum of the individual net weights. Then determine the difference between each individual net content and the average net content: the requirements are met if (a) NMT 2 of the differences are greater than 10% of the average net content and (b) in no case is the difference greater than 25%.

If more than 2 but NMT 6 capsules deviate from the average between 10% and 25%, determine the net contents of an additional 40 capsules, and determine the average content of the entire 60 capsules. Determine the 60 deviations from the new average: the requirements are met if (a) NMT 6 of the 60 capsules have differences that are greater than 10% of the average net content and (b) in no case does the difference exceed 25%.

Soft Shell Capsules

Proceed as directed under *Hard Shell Capsules*, but determine the net weight of the contents of individual capsules as follows. Weigh the intact capsules individually to obtain their gross weights, taking care to preserve the identity of each capsule. Then 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. Allow the occluded solvent to evaporate from the shells at room temperature over a period of about 30 min, taking precautions to avoid uptake or loss of moisture. Weigh the individual shells, and calculate the net contents. The requirements are as stated under *Hard Shell Capsules*.

TABLETS

Tablets conform to the criteria given in *Table 1*.

Uncoated Tablets and Film-Coated Tablets

Weigh 20 whole tablets individually, and calculate the average weight. The requirements are met if the weights of NMT 2 of the tablets differ from the average weight by more than the percentage listed in *Table 1*, and no tablet differs in weight by more than double that percentage.

Coated Tablets (Other Than Film-Coated Tablets)

Weigh 20 whole tablets individually, and calculate the average weight. If the coated tablets do not conform to the criteria in *Table 1*, place 20 tablets in a beaker of water at 37° and swirl gently for NMT 5 min. Examine the cores for evidence of disintegration and repeat the procedure for a shorter time if disintegration has begun. Dry the cores at 50° for 30 min. Accurately weigh 20 individual tablet cores, and calculate the average weight.

The requirements are met if the weights of NMT 2 of the tablets differ from the average weight by more than the percentage listed in *Table 1* and no tablet differs in weight by more than double that percentage.

Acceptance Criteria

Table 1. Weight Variation Tolerances for Uncoated Tablets, Film-Coated Tablets, and Coated Tablets (Other Than Film-Coated Tablets)

| Average Weight of Tablet (mg) | Difference (%) |
|-------------------------------|----------------|
| 130 or less | 10 |
| From 130 through 324 | 7.5 |
| More than 324 | 5 |

Add the following:

▲CHEWABLE GELS

Chewable gels meet the requirements of the following test with respect to weight variation. Individually weigh an equal number of units of each color and shape to obtain a total of NLT 20 and NMT 30 individual weights, and calculate the average weight.

The requirements are met if no individual weight deviates from the average weight by more than 7.5%. If more than 1 unit exceeds the specified limit, the test fails.

If 1 unit falls outside of the limits, repeat the procedure with an additional set of NLT 20 and NMT 30 individual chewable gels. The requirements are met if none of the units tested in the second set differ from their average weight by more than 10%.▲ (USP 1-Dec-2019)