



# OFFICIAL METHOD

## Determination of Net Contents

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**Health Products and Food Branch**

## **I. APPLICATION**

This method shall be used to determine the contents of packages as referred to in Section C.01.061 of the *Food and Drug Regulations*.

## **II. SAMPLING**

Select ten packages of the same declared net contents judged to be representative of the lot, batch or unit of production. Remove and discard any outer wrapper and carry out all tests using the immediate container, subsequently referred to as the container.

## **III. PROCEDURE**

### **A. For Contents Declared by Weight**

#### *1. For other than aerosol type containers*

- (a) Weigh the ten unopened containers.
- (b) Remove the contents from each container and closure (collapsible tubes must be slit in order to ensure that the contents are completely removed from the inside surfaces).
- (c) Wash and thoroughly dry the containers and closures.
- (d) Weigh the empty containers and closures.
- (e) Subtract the weight of the empty containers and closures from that of the ten unopened containers.
- (f) Express the difference in the units of weight declared on the label.

#### *2. For aerosol-type containers*

- (a) Weigh the ten full containers.
- (b) Empty each container through the valve.
- (c) Open each container with tube cutters employing any safe technique -- e.g. chill to reduce the internal pressure.

- (d) Wash and thoroughly dry each container, valve and all associated parts.
- (e) Weigh the containers, valves and all associated parts.
- (f) Subtract the weight of the ten empty containers, valves and associated parts.
- (g) Express the difference in the units of weight declared on the label.

**B. For Contents Declared by Volume**

*1. If the preparation can be readily poured:*

- (a) Transfer the contents at approximately 22°C of each of the ten containers into one or more clean, dry graduated cylinders. The fluid should occupy at least 40% of the rated capacity of each cylinder.
- (b) Record the total volume of fluid from the ten containers.
- (c) Express the results in the units of volume declared on the label.

*2. If the preparation cannot be readily poured.*

- (a) Weigh the ten unopened containers.
- (b) Transfer a representative portion of the contents at approximately 22°C to a weighed vessel of known volume to fill the vessel level with the top and in such a way that no air is trapped.
- (c) Weigh the vessel and contents.
- (d) Calculate the density of the contents by dividing the difference in the weight of the full and empty vessel by the volume of the vessel.
- (e) Remove the contents from each container and closure (collapsible tubes must be slit in order to ensure that the contents are completely removed from the inside surfaces).
- (f) Wash and thoroughly dry each container and closure.
- (g) Weigh the empty containers and closures.

- (h) Calculate the volume of the contents of the containers by dividing the difference in weight of the full and empty containers by the density of the contents.
- (i) Express the results in the units of volume declared on the label.

**C. For Contents Declared by Number**

- (a) Count the number of units in each container.

**IV. INTERPRETATION OF RESULTS**

**A. For Contents Declared by Weight**

The lot is acceptable if the average weight of the contents of the ten containers tested is not less than the weight shown on the label.

**B. For Contents Declared by Volume**

The lot is acceptable if the average volume of the contents of the ten containers tested is not less than the volume shown on the label.

**C. For Contents Declared by Number**

The lot is acceptable if:

- (a) the average number of dosage units in the ten containers tested is not less than the number of dosage units shown on the label; and
- (b) no container contains less than the number of dosage units shown on the label except as provided in the table below; and
- (c) where the drug is a controlled drug or a narcotic as defined in the *Narcotic Control Act*, no container contains more than the number of dosage units shown on the label except as provided in the table.

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<b>Labelled Number of Dosage Units Per Package</b>	<b>Permitted Variation from the Labelled Number</b>
50 or less	0
More than 50, but less than 101	1
101 or more	The greater of 1 unit or 0.75% of the labelled number rounded up to the next whole number

The method described above, being comprised of four pages and identified as DO-31, DETERMINATION OF NET CONTENTS and dated December 7, 1988, is hereby designated the "official method" referred to in Section C.01.061 of the *Food and Drug Regulations*.