⟨698⟩ DELIVERABLE VOLUME

PURPOSE

The following tests are designed to provide assurance that oral liquids will, when transferred from the original container, deliver the volume of dosage form that is declared on the label.

Change to read:

SCOPE

These tests are applicable to products that are dispensed by pouring from the container. The tests apply whether the products are supplied as liquid preparations or liquid preparations that are constituted from solids upon the addition of a designated volume of a specific diluent. ▲When the container includes a flow restrictor or orifice reducer (e.g., a coupler for an oral syringe), the volume for this test should be discharged according to the labeling advice. These tests▲ (USP 1-Dec-2020) are not required for an article packaged in single-unit containers when the monograph includes the test for *Uniformity of Dosage Units* ⟨905⟩.

DENSITY DETERMINATION

Because of the tendency of oral liquids to entrain air when shaken or transferred, a more accurate method for determining the delivered volume is to first determine the delivered mass, and then, using the density of the material, to convert the mass to delivered volume. In order to do that, a determination of the density of the material is required. The following is one method to determine density:

1. Tare a 100-mL volumetric flask containing 50.0 mL of water.
2. Add approximately 25 g of well-shaken product, and gently swirl the contents to mix.
3. Reweigh the flask.
4. From a buret, add an accurately measured amount of water to bring the flask contents to volume while gently swirling the contents of the flask. Record the volume taken from the buret.
5. Calculate the density of the sample:

$$\text{Result} = W/V$$

W = weight of the material taken (g)
V = 50.0 minus the volume, in mL, of the water necessary to adjust the contents of the flask to volume

Other methods of determining the density may be employed depending on the formulation (e.g., substantially nonaqueous formulations).

TEST PREPARATIONS

For the determination of deliverable volume, select NLT 30 containers, and proceed as follows for the dosage form designated.

Oral Solutions and Oral Suspensions

Shake the contents of 10 containers individually.

Powders That Are Labeled to State the Volume of Oral Liquid That Results When the Powder Is Constituted with the Volume of Diluent Stated in the Labeling

Constitute 10 containers with the volume of diluent stated in the labeling, accurately measured, and shake individually.

Change to read:

PROCEDURE

The deliverable volume can be determined by weight as follows:

1. Discharge the container contents into a suitable tared container (allowing drainage for NMT 5 s for single-▲unit▲ (USP 1-Dec-2020) containers and NMT 10 min for multiple-unit containers).
2. Determine the mass of the contents.
3. Calculate the volume using the density.

Alternatively, the following by-volume procedure may be used:

1. Under conditions of use or as instructed in the labeling, carefully discharge the contents of each container into separate dry graduated cylinders of a rated capacity not exceeding 2.5 times the volume to be measured and calibrated "to contain" (see *Volumetric Apparatus* ⟨31⟩). Care must be taken to avoid the formation of air bubbles during the process. In the absence of labeling instructions, support the containers at about a 30° angle to the horizontal, and gently discharge the contents into the graduated cylinder.
2. Allow each container to drain for a period not to exceed 10 min for multiple-unit containers and 5 s for single-unit containers, unless otherwise specified in the monograph.
3. When free from bubbles, measure the volume of each mixture.

ACCEPTANCE CRITERIA

Use the following criteria to determine compliance with this test.

For Multiple-Unit Containers (see *Figure 1*)

The average volume of liquid obtained from the 10 containers is NLT 100%, and the volume of no container is less than 95% of the volume declared in the labeling. If (A), the average volume is less than 100% of that declared in the labeling, but the volume of no container is less than 95% of the labeled amount, or if (B), the average volume is NLT 100% and the volume of NMT 1 container is less than 95%, but is NLT 90% of the labeled volume, perform the test on 20 additional containers. The average volume of liquid obtained from the 30 containers is NLT 100% of the volume declared in the labeling; the volume of liquid obtained from NMT 1 of the 30 containers is less than 95%, but NLT 90% of that declared in the labeling.

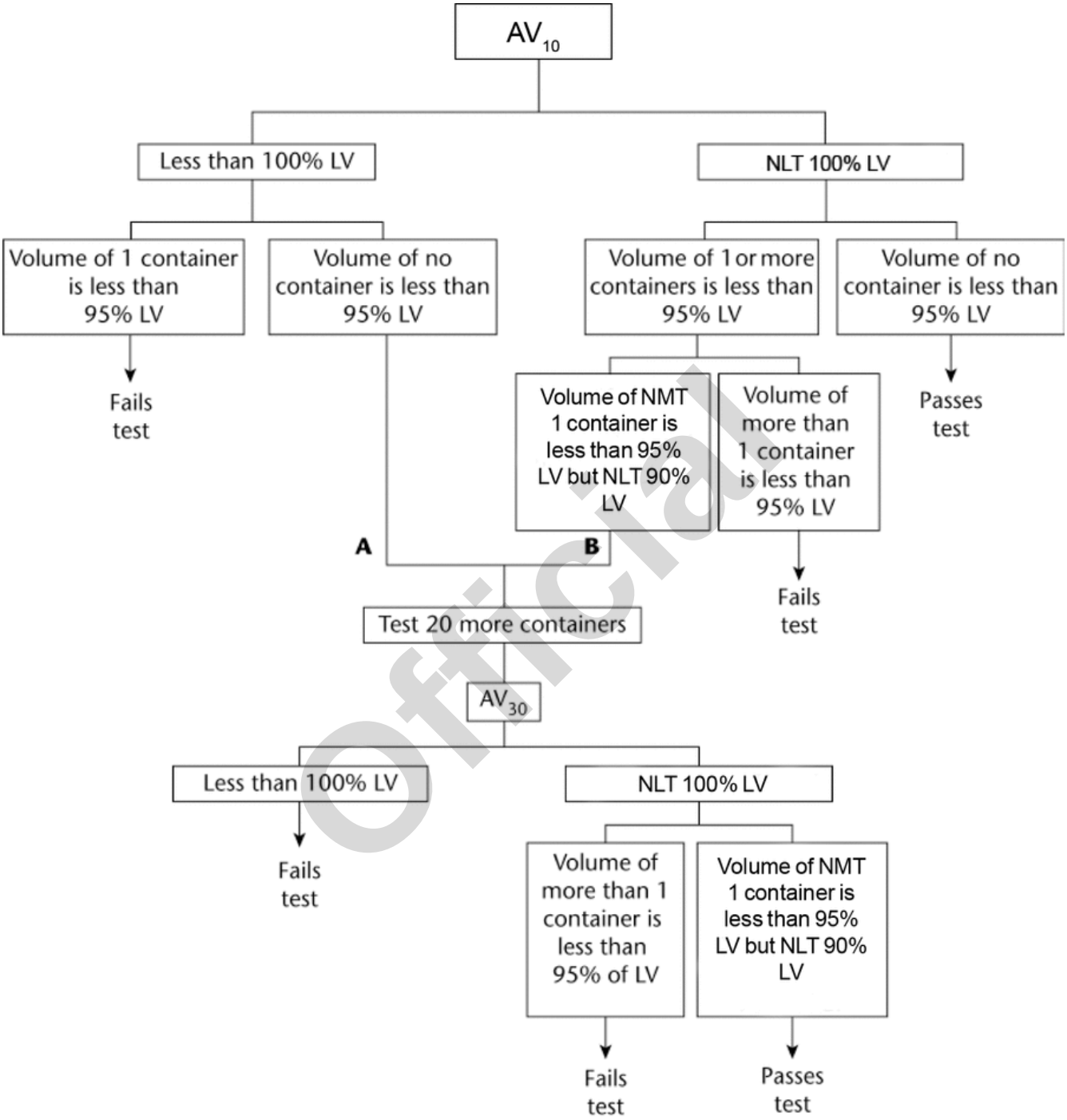

Figure 1. Decision scheme for multiple-unit containers (AV = average volume; LV = labeled volume).

For Single-Unit Containers (see *Figure 2*)

The average volume of liquid obtained from the 10 containers is NLT 100%, and the volume of each of the 10 containers lies within the range of 95%–110% of the volume declared in the labeling. If (A), the average volume is less than 100% of that declared in the labeling, but the volume of no container is outside the range of 95%–110%, or if (B), the average volume is NLT 100% and the volume of NMT 1 container is outside the range of 95%–110%, but within the range of 90%–115%, perform the test on 20 additional containers. The average volume of liquid obtained from the 30 containers is NLT 100% of the volume declared in the labeling; the volume obtained from NMT 1 of the 30 containers is outside the range of 95%–110%, but within the range of 90%–115% of the volume declared on the labeling.

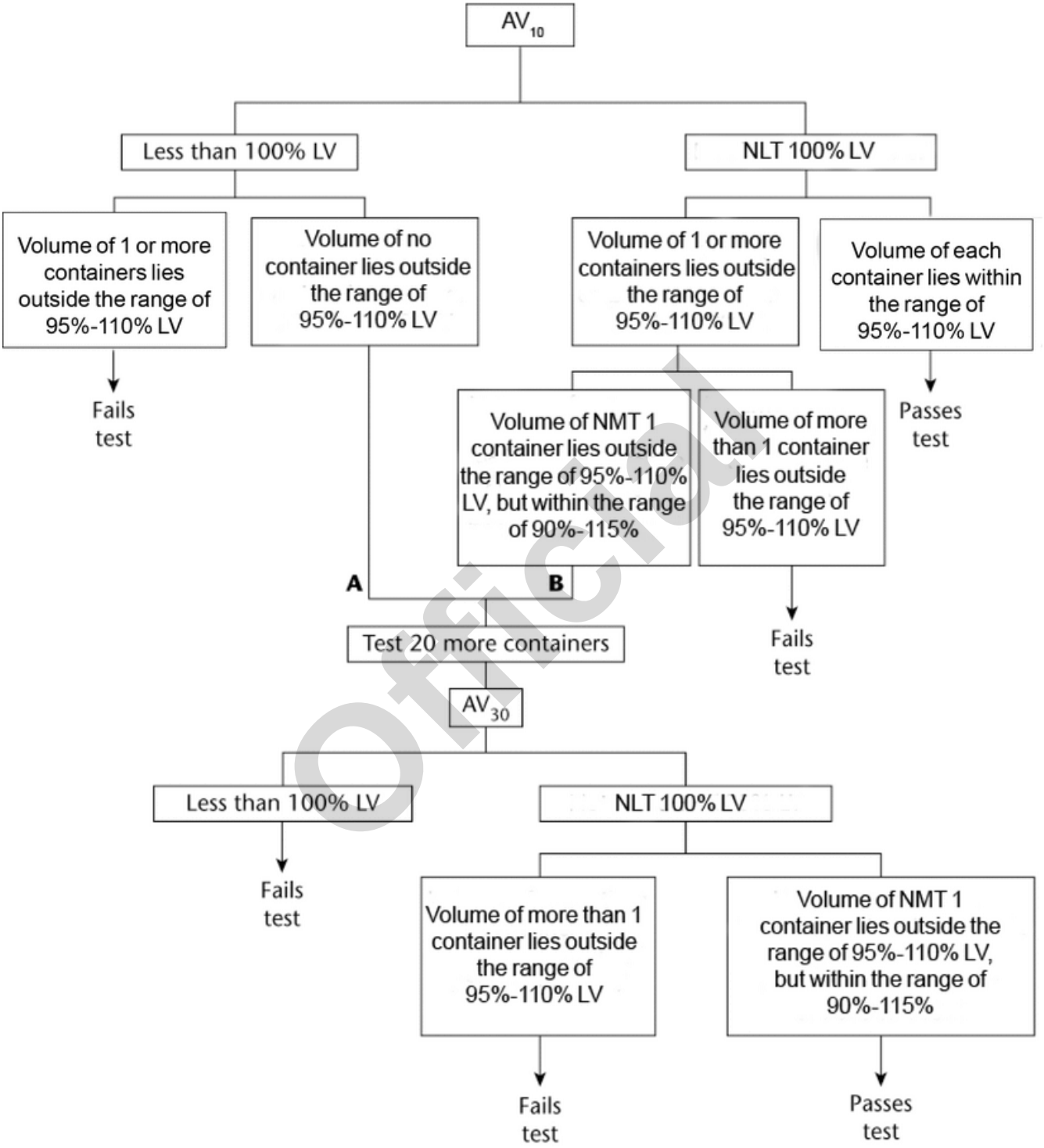

Figure 2. Decision scheme for single-unit containers (AV = average volume; LV = labeled volume).