⟨755⟩ MINIMUM FILL

Change to read:

SCOPE

The following tests and ▲acceptance criteria▲ (USP 1-Dec-2020) apply to articles such as creams, gels, lotions, ointments, pastes, powders, aerosols, ▲foams,▲ (USP 1-Dec-2020) and sprays that are packaged in containers. To minimize the impact of entrained air for products labeled by volume, the fill determination is performed by mass from which the volume is calculated by use of the density of the preparation.

PURPOSE

The test for minimum fill ensures that the amount of material filled into the product conforms to the labeled amount.

Change to read:

PROCEDURE FOR DOSAGE FORMS OTHER THAN AEROSOLS,▲SPRAYS, AND FOAMS▲ (USP 1-DEC-2020)

For Containers Labeled by Weight

Select a sample of 10 filled containers, and remove any labeling that might be altered in weight during the removal of the container contents. Thoroughly cleanse and dry the outside of the containers by a suitable means, and weigh individually. Quantitatively remove the contents from each container, cutting the latter open and washing with a suitable solvent, if necessary, taking care to retain the closure and other parts of each container that were present during the initial weighing. Dry and reweigh each empty container, together with its corresponding parts. Determine the net weight of the contents of the container by difference.

For Containers Labeled by Volume

Proceed as indicated above for products labeled by weight, but convert the mass to volume using the density of the preparation. A suggested approach to determine the density of the materials is as follows:

1. Tare a 100-mL volumetric flask containing 50.0 mL of liquid that is miscible with the formulation.
2. Add approximately 25 mL of a representative sample of the product and gently swirl the contents to mix.
3. Reweigh the flask.
4. From a buret, add an accurately measured amount of the miscible liquid 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 miscible fluid necessary to adjust the contents of the flask to 100 mL

Other methods of determining the density may be employed depending on the formulation (e.g., substantially nonaqueous formulations). Similarly, if the container contents are less than 25 mL, smaller graduated vessels may be used, with the quantities of miscible liquid adjusted accordingly.

Alternatively, pour the contents of 10 containers into 10 suitable graduated cylinders, and allow to drain completely. Record the volume of the contents of each of the 10 containers.

Acceptance Criteria

This test meets the acceptance criteria either at *Stage 1* or *Stage 2*:

Stage 1:

1. The average net content of the 10 containers is NLT the labeled amount, and the net content of any single container is NLT 90% of the labeled amount where the labeled amount is 60 g or 60 mL or less, or NLT 95% of the labeled amount where the labeled amount is more than 60 g or 60 mL. If these criteria are not met, and the net content of NMT 1 container is less than 90% of the labeled amount where the labeled amount is 60 g or 60 mL or less, or ▲less than▲ (USP 1-Dec-2020) 95% of the labeled amount where the labeled amount is more than 60 g or 60 mL, proceed to *Stage 2*.

Stage 2:

1. Determine the content of 20 additional containers.

2. The average content of the 30 containers is NLT the labeled amount, and the net content of NMT 1 of the 30 containers is less than 90% of the labeled amount where the labeled amount is 60 g or 60 mL or less, or less than 95% of the labeled amount where the labeled amount is more than 60 g or 60 mL.

Change to read:

PROCEDURE FOR AEROSOLS, SPRAYS, AND ▲FOAMS▲ (USP 1-DEC-2020)

Select a sample of 10 filled containers, and remove any labeling that might be altered in weight during the removal of the container contents. Thoroughly cleanse and dry the ▲outside▲ (USP 1-Dec-2020) of the containers by suitable means, and weigh individually. Remove the contents from each container by employing any safe technique (e.g., chill to reduce the internal pressure, remove the valve, and pour). Remove any residual contents with suitable solvents, then rinse with a few portions of methanol. Retain as a unit the container, the valve, and all associated parts, and heat them at 100° for 5 min. Cool, and again weigh each of the containers together with its corresponding parts. The difference between the original weight and the weight of the empty aerosol container is the net fill weight. Determine the net fill weight for each container tested.

Acceptance Criteria

The requirements are met if the net weight of the contents of each of the 10 containers is NLT the labeled amount.