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⟨603⟩ TOPICAL AEROSOLS

INTRODUCTION

Topical aerosol products contain the drug in solution or in suspension, packaged under pressure, and released upon activation of an appropriate valve system. The topical aerosol products should follow the product quality test requirements described in general test chapters *Inhalation and Nasal Drug Products—General Information and Product Quality Tests* ⟨5⟩, *Microbial Enumeration Tests* ⟨61⟩, *Tests for Specified Organisms* ⟨62⟩, *Minimum Fill* ⟨755⟩, and *Leak Rate* ⟨604⟩. The topical aerosols include dermatological foams and sprays. Topical aerosol foams should include a physical appearance of both the foam and also of the collapsed foam.

DELIVERY RATE AND DELIVERED AMOUNT

Perform these tests only on containers fitted with continuous valves.

Delivery Rate: Select NLT four aerosol containers; shake, if the label includes this directive; remove the caps and covers; and actuate each valve for 2–3 s. Weigh each container accurately, and immerse in a constant-temperature bath until the internal pressure is equilibrated at a temperature of 25° as determined by constancy of internal pressure, as directed under the *Pressure Test* below. Remove the containers from the bath; remove excess moisture by blotting with a paper towel; shake, if the label includes this directive; actuate each valve for 5.0 s (accurately timed by use of a stopwatch); and weigh each container again. Return the containers to the constant-temperature bath, and repeat the foregoing procedure three times for each container. Calculate the average *Delivery Rate*, in g/s, for each container.

Delivered Amount: Return the containers to the constant-temperature bath, continuing to deliver 5 s actuations to waste, until each container is exhausted. [Note—Ensure that sufficient time is allowed between each actuation to avoid significant canister cooling.] Calculate the total weight loss from each container. This is the *Delivered Amount*.

PRESSURE TEST

Perform this test only on topical aerosols fitted with continuous valves.

Select NLT four aerosol containers, remove the caps and covers, and immerse in a constant-temperature bath until the internal pressure is constant at a temperature of 25°. Remove the containers from the bath, shake, and remove the actuator and water, if any, from the valve stem. Place each container in an upright position, and determine the pressure in each container by placing a calibrated pressure gauge on the valve stem, holding firmly, and actuating the valve so that it is fully open. The gauge is of a calibration approximating the expected pressure and is fitted with an adapter appropriate for the particular valve stem dimensions. Read the pressure directly from the gauge.

MINIMUM FILL

Topical aerosols meet the requirements for aerosols in *Minimum Fill* ⟨755⟩.

LEAKAGE TEST

Proceed as directed in *Leak Rate* ⟨604⟩.

NUMBER OF DISCHARGES PER CONTAINER

Perform this test only on topical aerosols fitted with dose-metering valves, at the same time as, and on the same containers used for, the test for *Delivered-Dose Uniformity*. Determine the number of discharges or deliveries by counting the number of priming discharges plus those used in determining the spray contents, and continue to fire until the label claim number of discharges. The requirements are met if all the containers or inhalers tested contain NLT the number of discharges stated on the label.

Change to read:

DELIVERED-DOSE UNIFORMITY

The test for *Delivered-Dose Uniformity* is required for topical aerosols fitted with dose-metering valves. For collection of the minimum dose, proceed as directed in ▲*Inhalation and Nasal Drug Products: Aerosols, Sprays, and Powders—Performance Quality Tests* ⟨601⟩, *A. Delivered-Dose Uniformity*/*A.1 Inhalation Aerosols and Inhalation Sprays*▲ (CN 1-May-2021), and ▲*A.3 Inhalation Powders*▲ (CN 1-May-2021), as described in ⟨601⟩, except modify the dose sampling apparatus so that it is capable of quantitatively capturing the delivered dose from the preparation being tested.

Topic/Question	Contact	Expert Committee
<603> TOPICAL AEROSOLS	Kahkashan Zaidi Principal Scientific Liaison	GCDF2020 General Chapters - Dosage Forms 2020

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