



Standard Test Method for Evaluation of Drop Size by weight of Solutions and Suspensions¹

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1. Scope

1.1 This standard test method uses a simulated in-use study to measure the drop size by weight and to determine the number of drops per container for solutions and suspensions contained in a package system designed to deliver product drop-wise through a controlled size orifice by squeezing or compressing the package.

1.2 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.*

2. Terminology

2.1 Definitions:

2.1.1 *Average drop size per dosing interval*—The average weight of a drop of product dispensed from a given package within a given dosing interval.

2.1.2 *Average drop size per package*—The average weight of a drop of product dispensed from a given package considering all dispensed doses.

2.1.3 *Controlling orifice*—A dispensing plug which fits snugly enough in the mating bottle to form a seal, thereby forcing all fluid exiting the package to travel through the plug.

2.1.4 *Dosing interval*—The time period between product dosings. Testing may be performed “as per label directions,” which means testing is performed at time intervals defined by label directions (for example, once daily). Alternatively, testing may be performed “continuously,” meaning that a shorter time period between dosing intervals is used in order to expedite testing.

2.1.5 *Drop size*—The weight of a single drop of product dispensed from a package designed to deliver product through a controlling orifice.

2.1.6 *Unsolicited drops*—An amount of product that comes from the container without the user squeezing the container.

2.1.7 *Variable*—Different plugs, closures, bottles, or formulations.

2.1.8 *Volcanoing*—Spewing forth of the product upon initial opening of the container/closure system.

3. Summary of Test Method

3.1 Drop size tends to be highly subjective given all the potential variables, however, it is an essential element in describing the dosage delivered from a specific package. This test method is structured to mimic patient use of an solution or suspension that is delivered through a controlling orifice to determine an average drop size for the product. The average number of drops per container will then be calculated from the data collected.

4. Significance and Use

4.1 This test method may be used to measure the drop size and the number of drops per container for solutions and suspensions in a specific package system.

5. Apparatus

5.1 For drop size testing solutions and suspensions, the following equipment is required:

5.1.1 *Analytical balance*—accurate to ± 0.0001 gram.

6. Reagents and Materials

6.1 Bottles, plugs, and closures that are representative of the desired package system under investigation.

6.2 It is strongly recommended that actual product be used for this test. However, it is recognized that in some instances actual product may not be available. In this case a fluid that has similar viscosity and dispensing characteristics as the product under investigation should be used.

7. Hazards

7.1 Any remaining test product should be disposed of in a responsible manner.

7.2 The disposal requirements of the available MSDS for the product, or key ingredients of the product, or both should be observed in disposal.

8. Sampling, Test Specimens, and Test Units

8.1 Ten test samples are recommended for testing. A test sample is defined as a complete unit consisting of the bottle, plug, and closure intended for use; and the package should be

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