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Designation: F3375 – 19

Standard Test Method for Assessing Non-Metered Restricted Delivery Systems for Liquid Consumer Products[1]

This standard is issued under the fixed designation F3375; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers assessment of non-metered restricted delivery system characteristics so that they can be evaluated to a standard that signifies efficacy in limiting accessibility of liquid contents to young children.

1.2 This test method provides general test conditions for the determination of flow control of liquids by restricted delivery systems using mechanical testing to simulate methods that may be used to access liquid consumer products by young children.

1.3 The test parameters provided within this test method are estimates based on existing literature and experience. The estimated values are intended to allow comparison of performance characteristics across different restricted delivery systems.

1.4 This test method applies to liquids packaged in reclosable containers.

NOTE 1—Since there are many variables that may affect release of liquid (for example, rigidity of container, viscosity of liquid contents, or variation in test equipment), it is important that the entire restricted delivery system is tested together as intended for use while using the same or similar testing equipment. This test method does not address other product characteristics that might be affected by use of restricted delivery systems (for example, uniformity of active ingredient throughout duration of use).

1.5 *Units*—The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard.

1.6 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D7778 Guide for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *restricted delivery system, n*—packaging system designed to limit the amount of contents that can be accessed by young children (<6 years of age).

3.1.1.1 *Discussion*—For liquid consumer products, the restricted delivery system includes the liquid contents, container (for example, bottle), and any additional container components to limit flow (for example, components attached to the container orifice, including press-in bottle adapters).

4. Summary of Test Method

4.1 Three mechanical test procedures are used to assess efficacy of restricted delivery systems in limiting unintentional access to liquid consumer products by young children. Test procedures are intended to simulate methods that young children may use to access liquid products from containers. All components of the restricted delivery system are tested together and the amount of liquid released is recorded for each procedure.

4.1.1 *Deceleration*—To simulate shaking the container; "swing test."

4.1.2 *Application of Force*—To simulate squeezing the container; "squeeze test."

[1] This test method is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.30 on Mechanical Dispensers.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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4.1.3 *Application of Negative Pressure*—To simulate sucking from the container: "vacuum test."

5. Significance and Use

5.1 Despite child-resistant packaging requirements for most potentially harmful liquid consumer products, each year tens of thousands of young children are evaluated in emergency departments for potential poisoning from liquid consumer products. Products that use reclosable safety packaging rely on users to resecure the child-resistant closure fully after each use. If the closure is not fully secured or a child opens the closure, the entirety of the product contents is immediately accessible. Restricted delivery systems are a type of packaging for medications and other liquid consumer products designed to limit the amount of product that is accessible even after the primary closure is removed.

5.2 This test method can be used to provide quantitative assessment of restricted delivery systems for liquid consumer products. This test method outlines three types of mechanical test procedures to simulate methods young children may use when attempting to access liquid contents from a container. To evaluate the efficacy of restricted delivery systems, tests are conducted with the primary closure removed and under conditions approximating intended use of the products. Instruction for use for the intended product should be used when preparing the samples for testing; for example, storage temperature, shaking of product, and use of associated dispensing devices when applicable.

6. Apparatus

6.1 *Deceleration (*Fig. 1*)*—The apparatus should permit the container to be dropped in a controlled pendulum swing in a 90° downward arc to a sudden stop. The apparatus should be sufficiently rigid to handle swings of containers intended for liquid consumer products without excessive motion or vibration and with minimal friction. The apparatus should permit the container to be securely loaded in an upright position before testing and ending in a fully inverted position after the 90° swing. The upright container should be firmly attached to the apparatus by a rod of 25 ± 1 cm [10 ± 0.25 in.] to approximate the forearm length of a child (see Fig. 2).

6.2 *Application of Force (*Fig. 3*)*—The apparatus should have an upright post that allows a 1.0 cm [0.375 in.] diameter rod (cantilever) to be hinged to it. The rod should be 41.1 cm [16.2 in.] long from hinge to hang point and allow a 1.0 kg [2.2 lb] weight to be hung from the non-hinged end. The rod should be sufficiently rigid to resist flexing when the weight is hung from the end. The weight should be a one-piece design to help facilitate with the continuous application of force during the test. The container should be positioned under the rod at a distance 10.2 cm [4 in.] from the hinged end of the rod. The container should be either seated in a groove or block to keep it from moving out of position during the test. The rod should be aligned with the midpoint of the container for the application of "squeezing." Midpoint is defined as the position halfway between the base of the container and shoulder where the body of the container meets the neck of the container. Note that the compression strength of a bottle may be impacted by the material distribution and the parting line on the container, i.e. where the two halves of the mold meet, for this reason the position of the parting line should either be noted or positioned consistently during testing to reduce variation.

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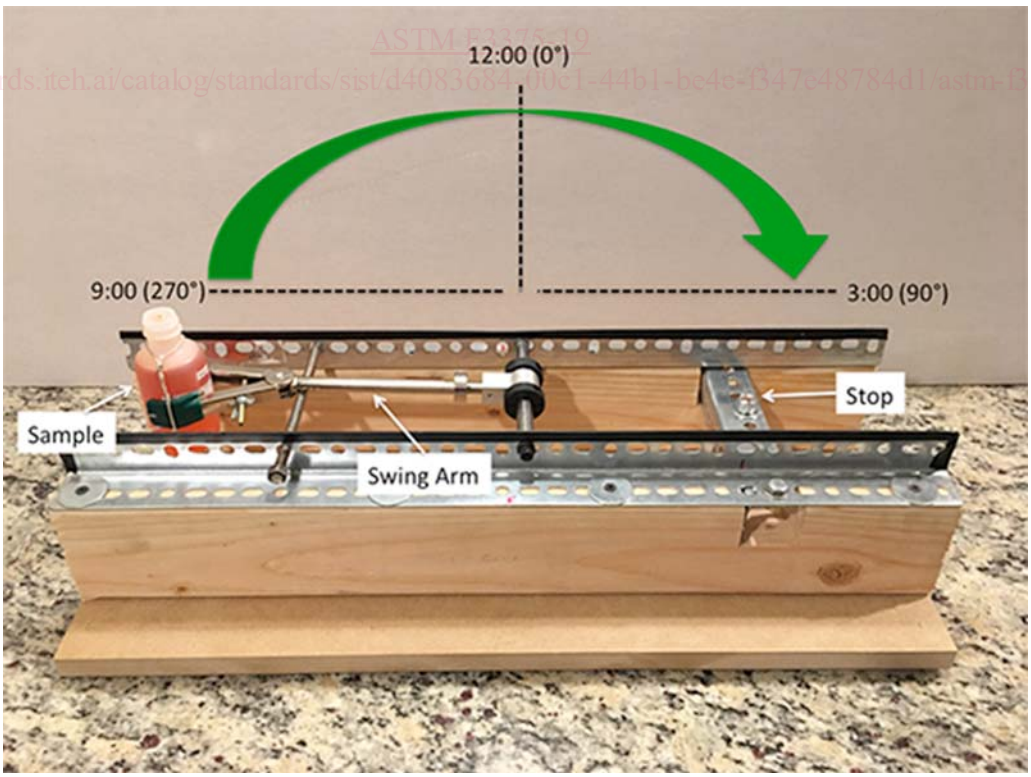

FIG. 1 Example Apparatus for Deceleration (Swing) Test

FIG. 2 Pendulum Arm Dimensions

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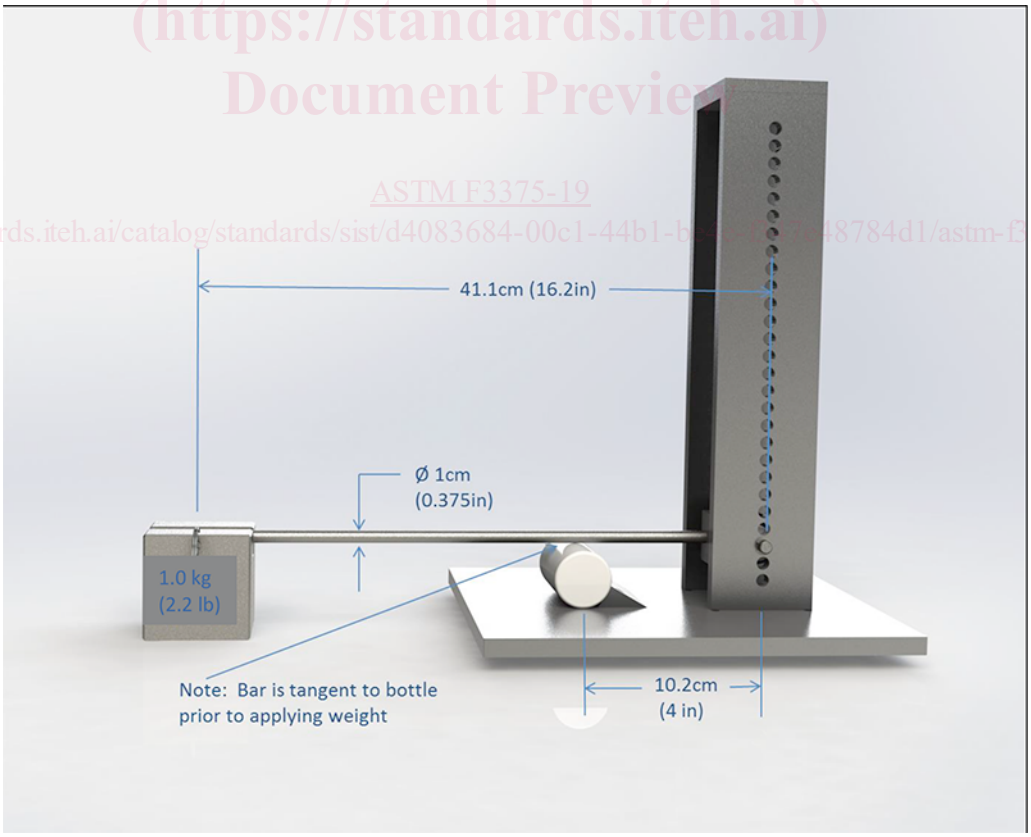

FIG. 3 Example Critical Parameters for Application of Force (Squeeze) Apparatus

6.3 *Application of Negative Pressure (*Fig. 4*)*—The apparatus should consist of a vacuum source (56-113 L/min or 2-4 ft^3/min), vacuum chamber (3-28 L or 0.1-1.0 ft^3), inverted sample holder, collection vessel, vacuum regulator, and gauge

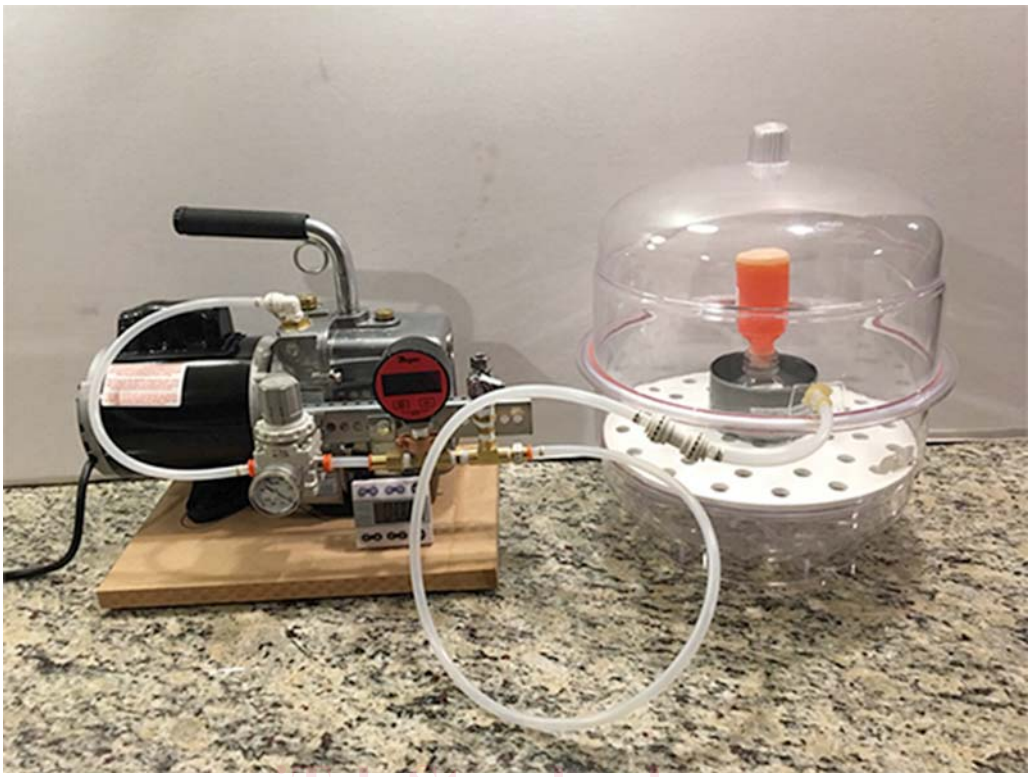

FIG. 4 Example Apparatus for Negative Pressure (Vacuum) Test

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(digital is preferred) (see Fig. 5). The sample holder and collection vessel may be combined into a single unit. A means of pressure equilibration between the vacuum chamber and the collection vessel (that is, vent hole) shall be provided (see Fig. 6). The apparatus should allow for the application of negative pressure for a specified time and the immediate release of the

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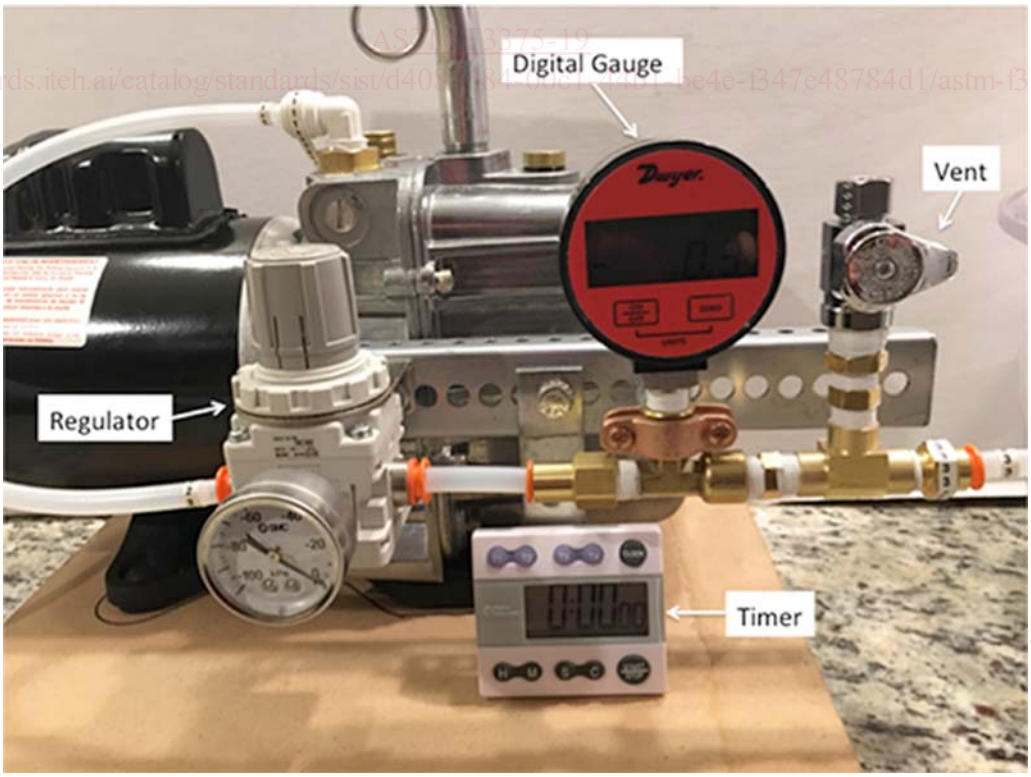

FIG. 5 Example Vacuum and Gauge Setup for Negative Pressure Test

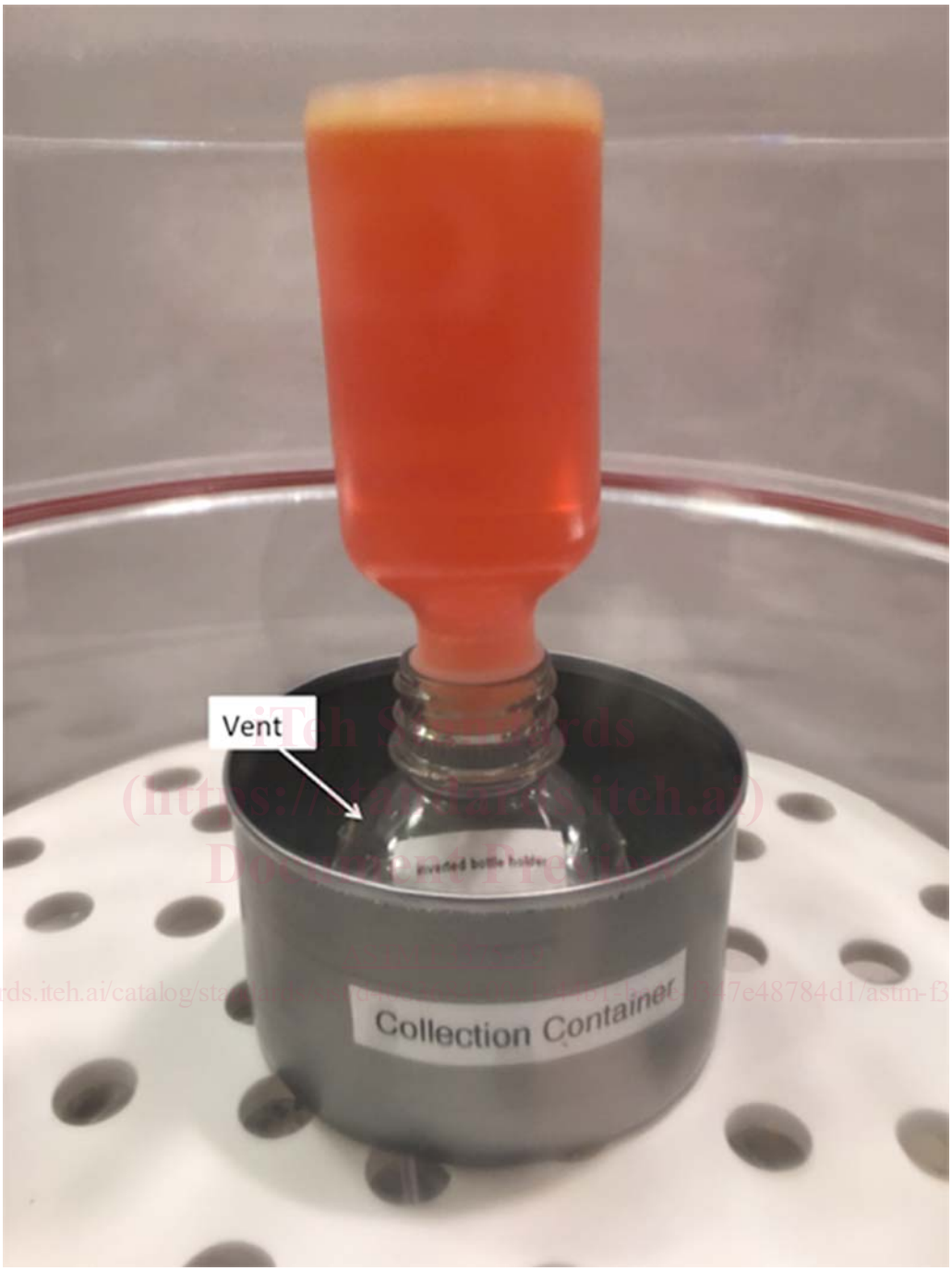

FIG. 6 Example Inverted Container Holder and Collection Container

vacuum after the test period. The vacuum gauge shall be laboratory quality with a full-scale range from 0 to 100 kPa [0 to 29.5 in. Hg] with minimum graduations no greater than 0.1 kPa [0.03 in. Hg] and accuracy to within 2 %.

7. Reagents

7.1 Tests should be conducted with the liquid product for which the specific restricted delivery system is intended to be used or a liquid of similar viscosity and other flow characteristics to the liquid product for which the delivery system is intended to be used.

8. Test Conditions

8.1 *Temperature*—Tests should be conducted within the temperature range recommended for proper storage of the liquid contents. Test samples should be allowed to come to equilibrium to the ambient test conditions and the temperature should be recorded.

8.2 *Fill Capacity*—The deceleration and application of negative pressure tests should be conducted both with containers having one dose of liquid contents removed and containers having half of the product removed based on the label claim

capacity. The one dose removed should be based on the smallest dose listed in the dosing instructions for the product. The application of force test should only be conducted with containers with the one dose of liquid removed. Removal of product (one dose and half) should be via the intended dosing device when applicable.

9. Test Parameters

9.1 *Deceleration: Rod Length, Arc, and Number of Cycles (*Fig. 1*)*—For the deceleration test, a container will be dropped in a pendulum swing to an inverted position to simulate the shaking of the container by a young child. The container will be slowly rotated from a 9:00 o'clock (270°) position to a 12:00 o'clock (0°) position, taking approximately 5 s, until gravity takes over the rotation to a sudden stop at the 3:00 o'clock (90°) position while achieving a downward swing of 90°. See Fig. 7 for positions.

9.1.1 The container is left inverted for 5 s before returning the container to an upright position at the 9:00 o'clock (270°) position. This is repeated for a total of five consecutive swings with each swing taking approximately 10 s to complete.

9.2 *Application of Force: Magnitude of Force and Number of Cycles (*Fig. 3 *and* Fig. 8*)*—To simulate the force with which a young child might squeeze a container, the application of 39 ± 1.5 N [8.8 lb ± 5.4 oz] should be used for the squeeze test. The test consists of one "squeeze" over a period of 5 s. The "squeeze" time is measured from the time the force is initially applied until it is removed at 5 s. The weight of the lever should be completely applied, that is, supported by the test container, within 1-2 s of the start of the test. This test is only performed once per container.

9.3 *Application of Negative Pressure: Magnitude of Negative Pressure and Duration (*Fig. 4 *and* Fig. 5*)*—To simulate the negative pressure that a young child might exert when drinking/sucking from a container, 21 ± 0.4 kPa [6.2 ± 0.12 in. Hg] of vacuum should be applied to an inverted container. The vacuum is applied to the inverted container for a total of 30 s and then immediately released. The target vacuum shall be achieved within the 30 s test period and the acceptable limits, that is, 21 ± 0.4 kPa [6.2 ± 0.12 in. Hg]. This test is only performed once per specimen.

10. Sample Selection and Preparation

10.1 The number of test specimens shall be chosen to permit an adequate determination of representative performance.

10.2 Test specimens should be representative of the intended commercial components/products.

10.3 The primary closure and any tamper-evident seal(s) should be removed before testing. Record the initial weight (in grams) of each container after the primary closure and tamper-evident seal(s) have been removed.

11. Procedure

11.1 *Deceleration:*

11.1.1 Remove either one dose of liquid or half of the intended contents from the container using the method of intended use (for example, drawing into oral syringe, squeezing into dosing cup).

11.1.2 Record the weight of the container after the specified amount of liquid has been removed. If the restricted delivery system uses a self-sealing mechanism, allow time for resealing and record the time from when the dose was removed to when the sample was first tested.

11.1.3 Slowly, taking approximately 5 s, rotate the container to the 12:00 o'clock (0°) position until gravity takes over the rotation of the container to a sudden stop at the 3:00 o'clock (90°) position (see Fig. 1).

11.1.4 Leave the container inverted for 5 s before returning the container to the 9:00 (270°) upright position.

11.1.5 This is repeated for a total of five consecutive swings with each cycle taking approximately 10 s to complete.

11.1.6 After the five swings are completed, detach and wipe any product that might be on the exterior of the container system. Weigh the container and compare the post-test weight to the pre-test weight (after one dose of liquid or half of the intended contents was removed) to determine the amount of liquid released.

11.2 *Application of Force:*

11.2.1 Remove one dose of liquid contents from the container using the method of intended use (for example, drawing into oral syringe, squeezing into dosing cup).

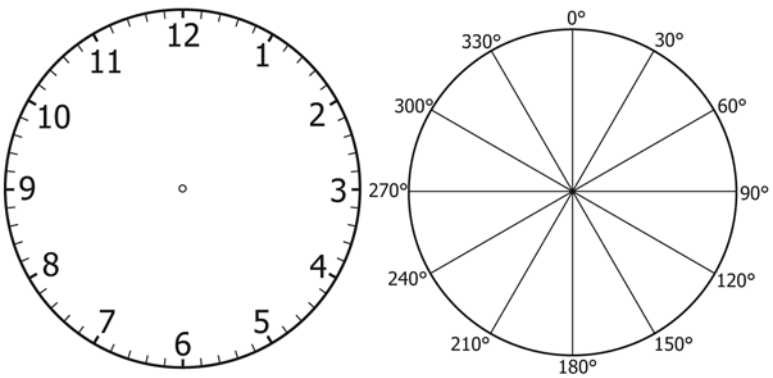

FIG. 7 Rotation Position