Designation: D3481 – 06 (Reapproved 2011)

Standard Test Method for Manual Shelling Two-Piece Child-Resistant Closures That Are Activated by Two Simultaneous Dissimilar Motions[1]

This standard is issued under the fixed designation D3481; 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 the measurement of the force required to separate (or "shell") the snap-fitted outer cap from the inner cap of Type IA, IB, or IC child-resistant closures.

1.2 This test method does not measure the force required to separate parts of a child-resistant closure system that were originally "screwed-on" instead of "snapped-on" (for example, pull a cap over or through continuous or multi-start threads when the cap was originally screwed on).

1.3 The values stated in SI units are to be regarded as the standard. The inch-pound units given in parentheses are for information only.

1.4 *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 determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D3474 Practice for Calibration and Use of Torque Meters Used in Packaging Applications

D3475 Classification of Child-Resistant Packages

E105 Practice for Probability Sampling of Materials

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

2.2 *Other Documents:*

ISO Bulletin 2233 Packaging—Complete, Filled, Transport Packages—Part 2: Conditioning for Testing[3]

3. Terminology (see Classification D3475)

3.1 *Definitions:*

3.1.1 *Type IA child-resistant closure*—a two-piece continuous thread closure requiring a random push down while turning; no orientation of the push down force is necessary.

3.1.2 *Type IB child-resistant closure*—a two-piece continuous thread closure requiring a localized squeeze force while turning; the force must be applied to a designated location on the closure skirt.

3.1.3 *Type IC child-resistant closure*—a two-piece continuous thread closure requiring a random squeeze while turning; no orientation of the squeeze force is necessary.

4. Summary of Test Method

4.1 This test method measures the force required to pry the outer cap off the inner cap using a fixture having a contact point under the tip of the skirt of the outer cap and leverage being placed on that point and the top of the cap. This procedure is used where a pivotal prying force can be successfully used to separate the components of the closure system. Either a torque wrench or a torque meter can be used as a measuring device.

5. Significance and Use

5.1 This test method of applying force may be used as a standard test to compare the characteristics of a given design of container/child-resistant closure system with a standard or to compare the characteristics of container/child-resistant closure systems differing in construction.

5.2 It may be used to simulate certain manipulations that may be expected to occur in protocol testing[4] (such as, prying with the teeth or objects in the room, biting, and pulling with the teeth).

5.3 This test method may be used to establish performance specifications.

6. Apparatus

6.1 *Testing Machine(s):*

[1] This test method is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical, Medical, and Child Resistant Packaging.

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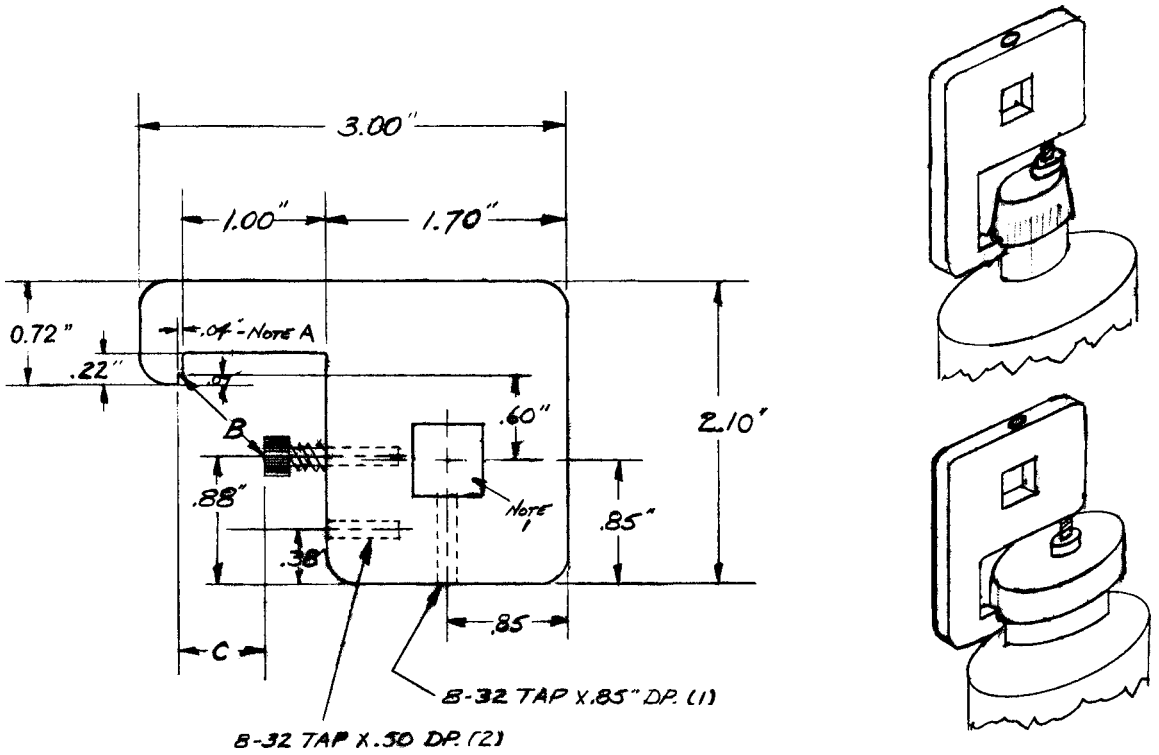
[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Consumer Product Safety Commission's Poison Prevention Packaging Act, 1970.



Metric Equivalents

in.	mm
3.00	76.2
1.00	25.4
1.70	43.2
0.50	12.7
0.22	5.6
0.04	1.0
0.07	1.8
0.88	22.4
0.38	9.7
0.60	15.2
0.85	21.6
2.10	53.3

Note A—0.040 in. (1.0 mm) or outer shell thickness.
Note B—Maximum 1¾ in. (34 mm)
Note C—Height adjusted with cap screw shown.
Note 1—¼, ½ , or ¾-in. square hole to fit a standard torque wrench post.
Note 2—Tool made of ¼-in. metal bar stock.

FIG. 1 Cap Holding Fixture

6.1.1 *Torque Meter*—[5] with a scale that will read with the maximum point reading accuracy within the torque range expected to be measured (for example, use a 0 to 25 T.I.P. torque meter for readings under 25 T.I.P., not a 0 to 100 T.I.P. torque meter).

6.1.2 *Torque Wrench,* of accepted design and capacity.

6.2 *Attachments, Fixtures,* etc. (see Fig. 1):

6.2.1 *Cap Holding Fixture* with one contact point under the lip of the outer cap skirt and the other point contacting the top of the cap. The distance between the two contact points should be 34 mm or approximately 1 3/8 in. (in accordance with page 19 of the Krogman study[5]) or to the farthest side of the cap if less than 34 mm.

[5] A digital torque instrument, if used, will have an appropriate design and scale capacity for the container/closure system to be evaluated. Torque results will be available in either electronic display or printout format.

TABLE 1 Special Atmospheres

Environment	Temperature, °C (°F)	Relative Humidity, %
Cryogenic	−55 ± 3 (−67 ± 6)	...
Frozen food storage	− 18 ± 2 (0 ± 4)	...
Refrigerated storage	5 ± 2 (41 ± 4)	85± 5
Temperature high humidity	20 ± 2 (68 ± 4)	85± 5
Tropical	40 ± 2 (104 ± 6)	85 ± 5
Desert	60 ± 3 (140 ± 6)	15 ± 2

6.2.2 *Device* for attaching the above tool to a torque wrench or torque meter.

6.2.3 *Bottle,* standard size, with corresponding finish to the closure(s) being tested.

7. Sampling

7.1 The number of samples will depend on the desired purpose for which the test is being conducted. However, for a given set of samples, sufficient measurements should be taken in accordance with established statistical sampling procedures in order to obtain consistent results.[6]

7.1.1 Refer to Practices E105 and E122 for more specific information.

7.2 Performance normally should be based on a test of not less than ten representative specimens of a given type selected at random.

8. Test Specimens

8.1 Use child-resistant closures and corresponding containers that are within their respective specifications.

9. Calibration

9.1 Follow Practice D3474 for calibrating the torque meter.[7]

10. Conditioning

10.1 Preconditioning is not necessary unless it is required to simulate a particular storage environment.

10.2 If special conditions are not required, components may be stored for a minimum of 24 h at 23 ± 2°C (73.4 ± 3.4°F) and 50 ± 5 % relative humidity.

10.3 The atmosphere conditions in Table 1 may be used when special conditioning is appropriate. Other atmosphere conditions may be used as appropriate.

11. Procedure

11.1 Apply all closures to be tested to the appropriate containers at a specified and uniform torque.

NOTE 1—Specifying the application torque level is necessary for test consistency as the physical relationship/interlocking between the inner and outer closure can change at different application torque levels.

11.2 Attach the cap holding fixture to the torque meter or torque tester and slide fixture over the widest part of the cap (the diameter).

11.3 Apply torque in the following manner:

11.3.1 When a table model torque meter is used, the test container should be parallel to the table (that is, it should be in a horizontal position and not canted). Grasp the test container at the base with the thumb and forefingers (not with the entire hand) to avoid the application of "english" or twisting forces while applying torque.

11.3.2 When a torque wrench is used, grasp the test container firmly in the hand or in a holding fixture in a vertical position (perpendicular to the floor). Apply direct upward pressure with the torque wrench. Do not cant or cock the wrench when pressure is applied.

11.4 Apply torque at a slow, steady rate that allows the total testing time to range between 15 and 30 s for each closure.

11.5 The end point of the test should be the lifting of the outer cap to a position where the plane of the top surface of the outer cap forms a 45° angle with the bottom plane of the bottle.

11.6 Record test results and procedures used to obtain results.

12. Report

12.1 The report shall include the following:

12.1.1 Name, number, and date of procedure used,

12.1.2 Gross description of container/child-resistant closure system under test; its complete structural specifications; kind of material; size and style of closure and bottle finish including thread type; manufacturer and lot number; date of receipt or other identification of the specific batch being evaluated,

12.1.3 Description of the exact test equipment and procedures that were used to obtain the test results,

12.1.4 Detailed record of the test on each container/child-resistant closure system, including damage, together with any observations that may assist in correctly interpreting the results or aid in improving the design of the system,

12.1.5 Table showing the maximum torque and lifting force for each test, and

12.1.6 Statement that the test was made in accordance with ASTM Test Method D3481.

13. Precision and Bias

13.1 *Precision*—The repeatability standard deviation has been estimated for three packages based on testing conducted in one laboratory. One package had a within-laboratory standard deviation of 1.6 lb or 11.1 % of the average. The second package was 1.4 lb or 7.8 % of the average. The third package was 5.1 lb or 24.3 % of the average. A log-normal distribution might also be considered for evaluation of data from this test method. Other packages may have different repeatability values. The reproducibility of this test method is being determined.

13.2 *Bias*—No justifiable statement can be made on the bias of this test method since a true value cannot be established by an accepted referee method.

[6] Krogman, W. M., *The Manual and Oral Strengths of American White and Negro Children, Ages 3 to 6 Years*, School of Medicine, University of Pennsylvania, 1971.

[7] Follow calibration procedure of manufacturer if a digital torque instrument is to be used.

14. Keywords

14.1 shelling; two simultaneous dissimilar motions; Type IA child-resistant closure; Type IB child-resistant closure; Type IC child-resistant closure