Testing method recommendations for gel candies/mini-cup jelly products

Date: 7-29-2026

**Please note, this recommendation is intended to provide supplemental general information to private laboratories on methods of analysis and test portion sizes of certain candies, such as mini-cup jelly candies, that may present a risk of choking. This document does not outline all the analytical method or worksheet requirements for packages being submitted for FDA review. **

Please refer to the current FDA Laboratory Manual, Volume III, Section 7 for comprehensive information on private laboratory package requirements and the review process:
https://www.fda.gov/media/73540/download

Sample Collection:
Samples should consist of at least six subsamples for official analysis. Each subsample should contain at least 1 lb. If there are multiple flavors, sizes and/or shapes in the retail container, then each subsample should contain at least one jelly cup of each type.

Analytical Protocol:
Test for the characteristics listed in IA 33-15 (i.e., packaging, size, shape, consistency, solubility, and slipperiness). Test at least one candy in each subsample. If there are multiple flavors, sizes and/or shapes in a subsample, then test at least one candy of each type.

The recommended protocol is found in FDA laboratory information bulletin (LIB) 4686A, *Comparison of consistency, solubility, and texture of foods to determine choking risk: a novel method and single-lab validation study*. Photos and figures are provided below to support analysis.

The following information should be included in the analytical package:

- Photos of product inside and outside of the cup, with a ruler in the photo for reference. If the product units vary in size, shape, or flavor, provide a representative photo for each product variation.
- The size of the product both inside and outside of the packaging.
  - Measurements should be made with a certified set of calipers.
  - Measurements should be in millimeters (mm) rounded to one digit past the decimal place.
- Size range (min and max) and average size of the six subsamples.
- A description of the product shape. If the shape varies between subsamples, be sure to note all product shapes.
- The coefficient of friction or a qualitative description of product slipperiness if it cannot be determined quantitatively.
- The outcome of solubility and consistency testing. A sample of U.S. style gelatin should be used as a control and should reach room temperature before consistency testing.

While the notice of detention may mention filth, the purpose of the testing is to obtain the information detailed in IA 33-15. Traditional filth testing (e.g., insects, rodent hairs) is not needed, unless specified.

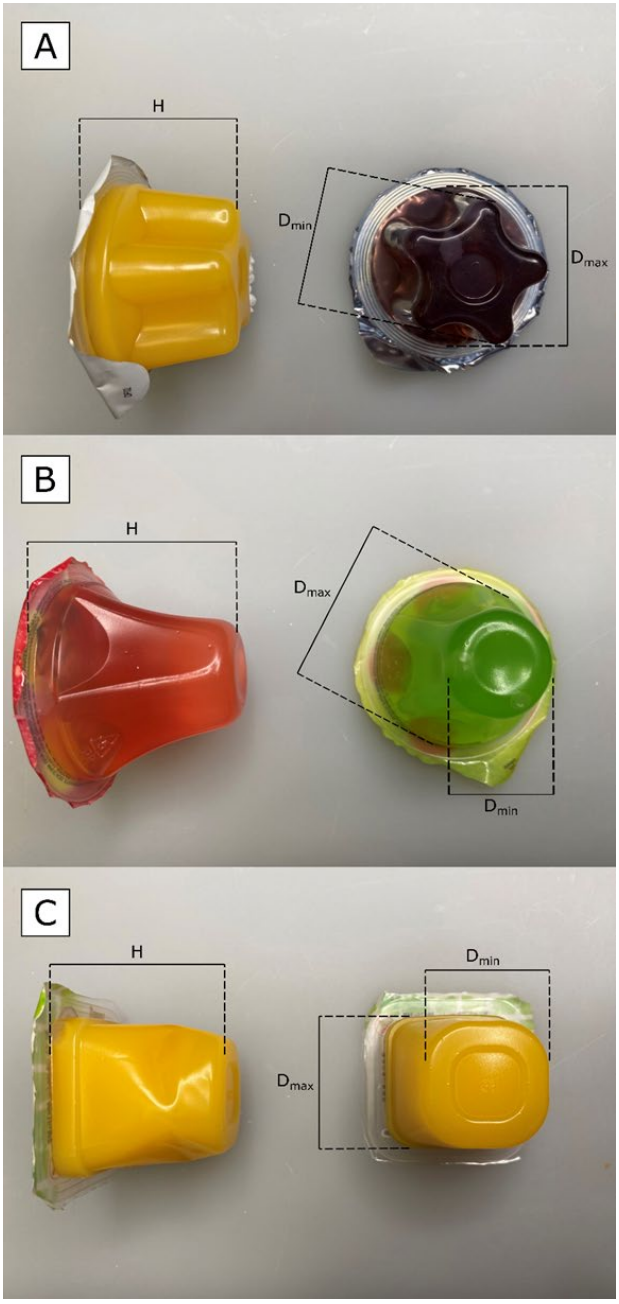
Quality Assurance:
Laboratory must follow the methodology specified in the private laboratory package submission. Any method modifications or deviations to the cited method must be explained and validation must be documented.

FDA does not endorse any private laboratory firms, nor requires specific methods to be used for Private Laboratory Analytical Packages (PLAPs). Information herein is provided as a courtesy, but private laboratories are not required to use them. The requirements state the method should be locally validated and should adequately identify and or quantitate the violative analyte(s). The information herein may also provide supplementary sampling, method information and/or sample preparation information to assist private laboratories who are analyzing products being held under Detention Without Physical Examination (DWPE) as part of an Import Alert to assist private laboratories with submitting scientifically sounds PLAPS as testimony pursuant to FD&C Act section 801 and 21 CFR 1.94 or FD&C Act section 422(b) and 21 CFR 1.1107.

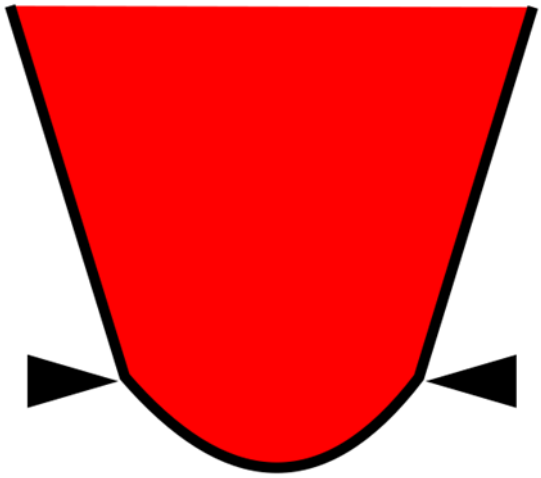
Additional information
For those using LIB 4686A for analyses, the following may be helpful in clarifying the procedures.



Measurement of cup lip thickness. Measure the cup lip at the thinnest portion to calculate estimate of overall cup thickness.



Measurements for jelly-cup candies: height (*H*), maximum diameter (D_{max}) and minimum diameter (D_{min}). A) Star-shaped candy. B) Plug-shaped candy. C) Square-shaped candy.

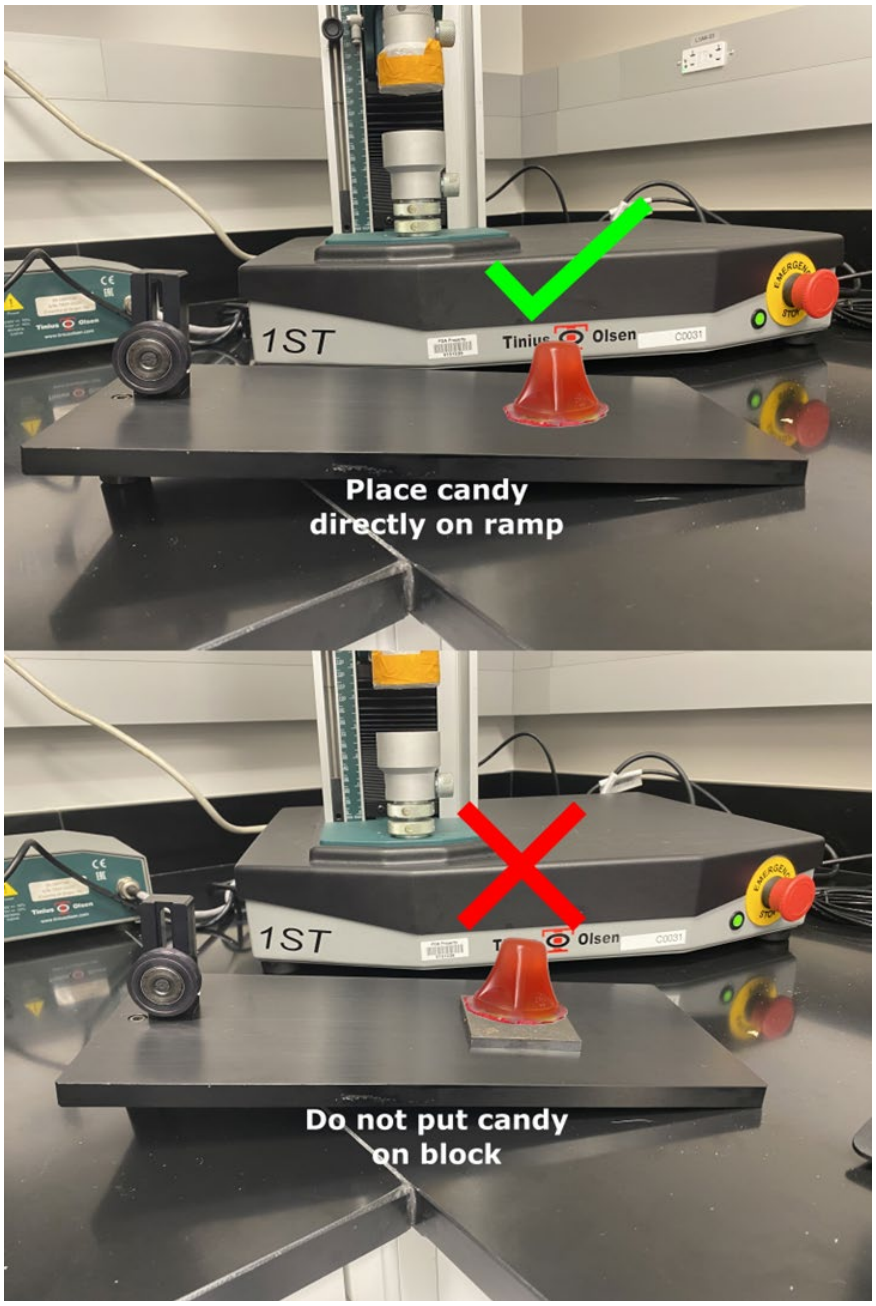


If candy has rounded end measure at arrows for D_{min}

Minimum diameter (D_{min}) measurement for candies with rounded, tapered shape at one end.



Three-inch (7.62 cm) US standard testing sieve pan. Place candy in pan and place pan on lower testing machine platen prior to measuring breaking strength.



Proper placement of candy on friction measurement device. Ensure that candy is in contact with the surface ramp of device and that no object sits between candy and ramp surface. Do not remove excess liquid from candy since the friction measurement is meant to reflect slipperiness as it enters a potential consumer's mouth as typically eaten. If there is no liquid in the container, put artificial saliva on the ramp prior to placing the candy on it.