Testing method recommendations for gel candies/mini cup jelly products

Date: 11-8-2024

**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 jelly cup candies made with konjac. These recommendations also apply to jelly cup candies that do not contain konjac, but which may possess similar physical characteristics. This document does not outline all of 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

Analytical Protocol:
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.

Testing Method:
Test for the characteristics listed in IA 33-15 (i.e., size, shape, texture, and consistency). Due to safety concerns, it is not recommended that analysts conduct testing by placing the jelly cups into the mouth. Analysts should follow their laboratory's safety protocols with regard to this situation.

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.

Below is more information on how to perform the testing described in IA 33-15:

- Take 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.
- Record the size of the product, both inside the packaging and after removing from the packaging. (Record the size of the product inside the packaging after subtracting the packaging contributions to the size, e.g., thickness of the plastic cup).
    - Record all the following: the widest diameter, the narrowest diameter, and the height.
    - All measurements should be made with a certified set of calipers.
    - Measurements should be made out to one digit past the decimal place and should be made in millimeters (mm).
- For the data across all six subsamples, provide a range of sizes (min and max) and average.
- Describe the product shape. If the shape varies between subsamples, be sure to note and provide measurements for all product shapes.
- Describe the product texture; be detailed in your description. Slipperiness should be noted as part of the description.
- Describe the product consistency, specifically whether it is firm and dissolves readily. Note that Jell-O type texture is not as firm compared to konjac texture, which is relatively firm and does

not dissolve/disintegrate as easily; please describe the sample texture as compared to Jell-O and/or konjac. It is best to have a sample of Jell-O or konjac in the lab for direct comparison.

- When testing for dissolution, record both the temperature of water and the dissolution time. It is best to use a temperature that is relevant to physiological temperatures (i.e. 37 °C).
- Provide measurements and a description of consistency for any small pieces found within the product.

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.