Testing Method Recommendations for
Filth in Papads and Farfar Wafers on IA 03-05

Date: 2/14/2025

**Please note, this recommendation is intended to provide supplemental general information to private laboratories on methods of analysis and test portion sizes of papads and farfar wafers. 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 6 subsamples, each with a minimum of 454 g, for official analysis.

Analytical Protocol:
There are a couple of options.
1) AOAC Official Method 970.70 Light Filth in White Breads and High-fat Products OR
2) AOAC Official Method 969.41 Light Filth in Alimentary Pastes
Regardless of method, 6 subsamples should be collected, each with a minimum of 454 g.

It may be helpful to review the product ingredient list when deciding which of the two methods is more applicable to the type of papad/wafer. Note that when using 970.70, autoclaving some papads may cause clumping, and use of steam bath may be more effective than autoclave.

Document all filth elements and report findings according to AOAC 970.66. Note that other extraneous materials (e.g., fibers, paint chips, etc.) need to be described and reported by type and appropriate quantitative figure.

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.