Testing Method Recommendations for IA 99-46 and 99-47

Filth/EMA in Saffron, *Crocus sativus* L.

Date: 5-20-2024

**Please note, this recommendation is intended to provide supplemental general information to private laboratories on methods of analysis and test portion sizes of saffron. 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

Analytical Protocol:
Samples should consist of at least 2 subsamples, each with a minimum of 3 - 4 grams, for official analysis.

Sample Methods:

- The recommended method for saffron in filaments is MPM V-8 supplemental method D for saffron.
- The recommended method for ground saffron is AOAC Official Method 975.49 A(a)B(a) Light Filth in Spices and Condiments. Analyze entire contents of each of the two subsamples. **Count 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.