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Forensic Applications in Pharmaceutical Particulate Testing

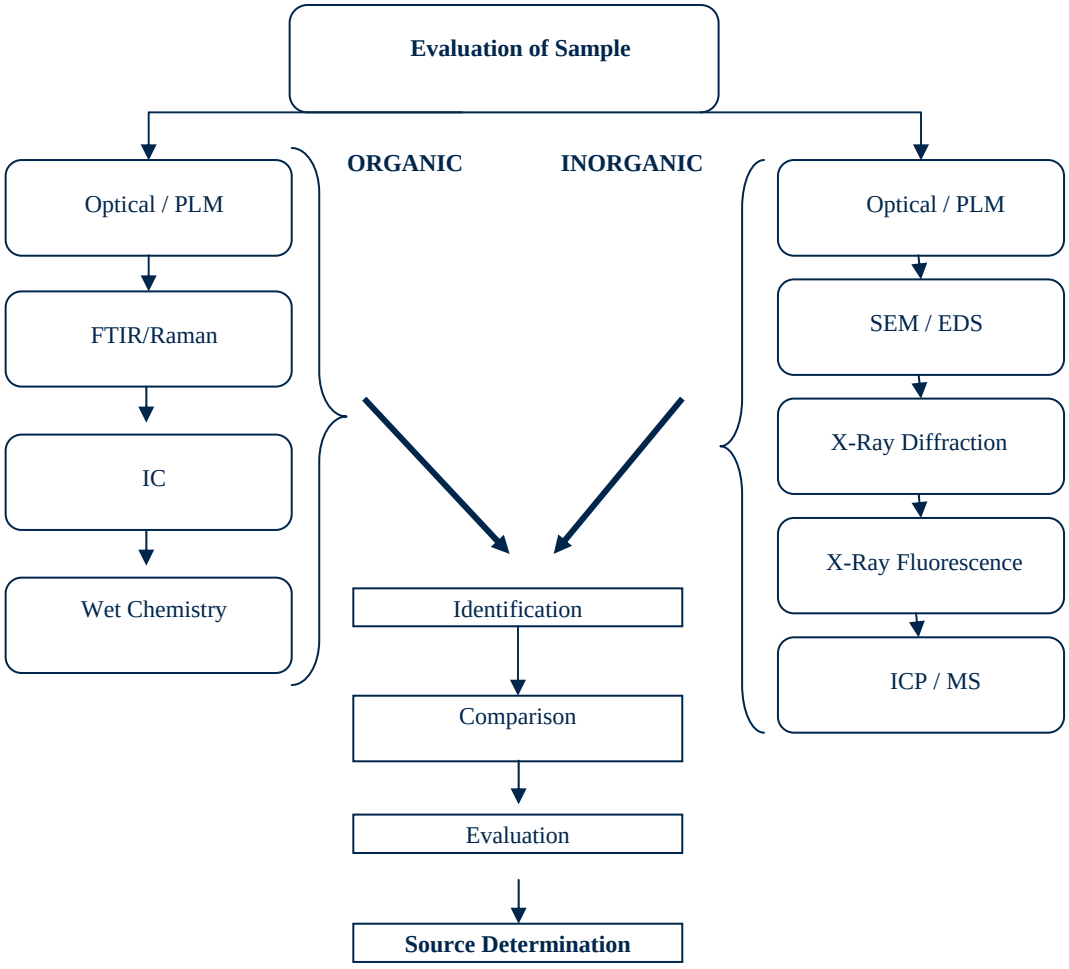
Author: Dave Exline

The main goals in forensic investigation are to first identify the questioned material of interest, and second, compare this particulate to known sample sources to determine possible origins of the unknown sample. In addition, the forensic scientist must understand the significance of various sample types and communicate that information in layman's terms so investigative teams can focus an investigation. This type of contamination identification and tracking is valuable to demonstrate efforts pharmaceutical companies make to identify contaminants and take corrective action as required by the FDA. This approach is also beneficial when validating new process methods and eliminating particulate contamination in manufacturing and packaging process.

Due to the minute size of typical particulate contamination (i.e., hair, fiber, paint, metal, glass, polymers), experience working with microscopic particulate is critical. Forensic trace evidence examiners specialize in the area of microscopic evidence analysis. They apply experience and training in identifying and comparing microscopic particulate in the following pharmaceutical areas: environmental particle contamination, particulate contamination from manufacturing process materials, particulate contamination from manufacturing product materials, and identification of customer returned contaminants. This presentation will discuss various analytical testing methods, sample preparation and isolation of particulate and the investigative approach to particulate identification. The flow of information and testing methods typically used in forensic particulate investigations are depicted in Figure 1. Focus will also be given to the importance of the initial investigation evaluation, laboratory communication, investigation of process methods, investigation of relevant product/process materials and indicators for choosing various analytical testing methods.

Lastly, several examples of forensic investigations in pharmaceutical particulate contamination and source apportionment will be discussed. The recent development of specialized searchable databases that consider analytical data, optical images and particle information in searchable formats for particle contamination archival, trending and source determination will also be discussed.

Figure 1


Evaluation of Sample
ORGANIC
INORGANIC
Optical / PLM
FTIR/Raman
IC
Wet Chemistry
Optical / PLM
SEM / EDS
X-Ray Diffraction
X-Ray Fluorescence
ICP / MS
Identification
Comparison
Evaluation
Source Determination