A184 The Use of SEM/EDS and FT-IR Analyses in the Identification of Counterfeit Pharmaceutical Packaging

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After attending this presentation, attendees will have an understanding of a method to isolate and examine pharmaceutical packaging using scanning electron microscopy (SEM), energy dispersive x-ray spectrometry (EDS), and Fourier transform infrared (FT-IR) spectroscopy. The method allows for the detection of counterfeit pharmaceutical packaging and characterization of the counterfeit packaging itself.

This presentation will impact the forensic science community by providing knowledge of a method for the analytical identification and characterization of pharmaceutical packaging components.

The forensic analysis of counterfeit pharmaceuticals often focuses upon the analysis of the dosage forms with minimal analysis being performed on packaging components. The dosage form analysis is of primary importance due to the potential danger to public health. Counterfeit pharmaceuticals may be dangerous and possibly lethal if taken by a consumer as they may contain little or no active ingredient, undeclared drugs of uncertain potencies and possibly dangerous excipient materials. Counterfeit drugs without active ingredients could compromise an individual's health as they are not receiving the required medication for their health condition. In the area of counterfeit pharmaceutical analysis there has not been a great Drug Enforcement Administrationl of attention devoted to the analysis of the individual packaging components.

The packaging components used for a counterfeit pharmaceutical product can contain a wealth of forensic information which may help in a counterfeit pharmaceutical investigation. Packaging components may include, but are not limited to high density polyethylene (HDPE) bottles, bottle caps, safety induction seals, blister packages, cartons, paper intserts/outserts, and adhesives used on the carton closures and outserts. Each of these packaging components can be effectively analyzed using SEM/EDS and FT-IR spectroscopy. The chemical information derived from the materials can then be used to determine commonality and potentially be used to source counterfeit pharmaceutical products.

The examination of pharmaceutical packaging includes using alternative light sources and stereoscopic light microscopy (SLM). Both of these techniques allow for enhancing visual differences between the suspect packaging and the authentic. The use of SEM/EDS and FT-IR analysis provide unique chemical information about the suspect packaging, which enhances the forensic information provided by the visual examination techniques. The method the authors will present details the identification and sampling of regions of interest from pharmaceutical packaging for examination by SEM/EDS and FT-IR spectroscopy. Sample preparations are made from the same regions of interest on both suspected counterfeit packaging and authentic packaging. The study presented will detail printed regions of blister-style packaging from a variety of tablet and capsule products. The results of the elemental analyses of both top and bottom package surfaces will be covered in this study. SEM/EDX analyses will include backscattered electron imaging and elemental analyses of single features and full field analyses, as well as x-ray mapping of the region of interest, with the results reported as a comparison of suspected counterfeit and authentic pharmaceutical packaging. The FT-IR spectroscopic data will highlight the different polymer materials used in the blister packages. The SEM/EDX and FT- IR data are used to build data libraries of authentic and counterfeit products, which can be used in the analysis of future sample analyses.

Counterfeit, SEM/EDS, FT-IR

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