Verifying Product Integrity Using FTIR Spectroscopy

Due to its wide variety of data acquisition modes (transmission, reflectance, and attenuated total reflectance), FTIR spectroscopy understandably has become widespread in almost every industry. From competitor and failure analysis to identifying counterfeit materials, characterizing the integrity of a product is immeasurably important, not to mention heavily regulated for certain industries. This application note illustrates the ability of ATR-FTIR to analyze the components of pharmaceutical packaging.

FTIR traditionally has two imaging modes: transmission and reflectance. Reflectance modes can be further broken down into specular reflectance and attenuated total reflectance (ATR). Because the current communication focuses on packaging analysis, ATR-FTIR was chosen because industry standards have since recognized ATR-FTIR for use in polymer analysis according to USP 661.1. The FTIR used in this communication was an Agilent 670 FTIR with a MIRacle ATR accessory.

The pharmaceutical packaging chosen for analysis was pharmaceutical packaging. Pharmaceutical tablets are packaged in small arrays of wells, in which each tablet is placed inside of a well. The wells are composed of a clear plastic material, and the backing is composed of a reflective silver material. In this investigation, four unique areas of the package were analyzed: the inside and outside of the plastic well and the inside and outside of the backing. For reference, the part of the backing that is in contact with the tablet was denoted as the “inner foil”, and the other side of the backing was denoted the “outer foil”. The layers were cleaned prior to analysis to prevent contamination from the tablet. The four areas are shown in Figure 1.

The FTIR spectra of the four areas are shown in Figure 2. The inner and outer foils were both characterized using reflection FTIR microscopy because the surfaces are extremely reflective, and the signal to noise ratio was high (the microscope was chosen only to illustrate different imaging methods; as USP 661.1, all polymer characterization should be done in transmission or ATR modes). The inner and outer plastic layers were measured using ATR-FTIR. The BioRad KnowItAll® software suite was used to identify the unknown layers.

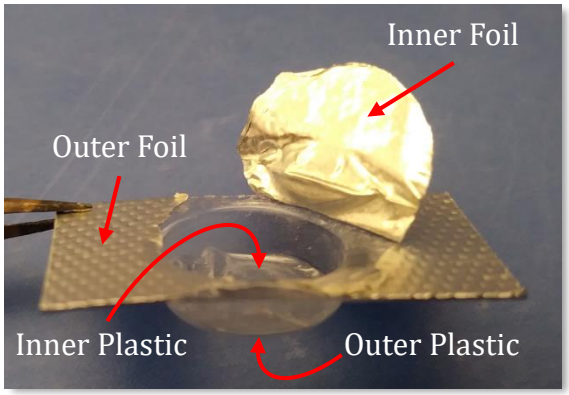

Figure 1. Photo of the tablet packaging style. The four areas analyzed by FTIR are indicated. Any part of the package in contact with the tablet is assigned as the “inner” part of the package.

While four unique areas were imaged in total, only three unique spectra were obtained (Figure 2). The inner foil was found to be primarily composed of a copolymer of butyl methacrylate

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and methyl methacrylate. The outer foil was found to be primarily composed of cellulose trinitrate. It is clear from the spectral analysis that there are minor amounts of additives present in both of these spectra as well. While the constituency of the inner and outer silver backing was different on the inside and outside, the plastic wells were found to be made out of only one material: a copolymer of polyvinyl chloride and poly(ethylene-vinyl acetate).

FTIR is a powerful and straightforward tool to use when analyzing packaging materials. As packaging materials are often composed of many layers of materials, FTIR allows samples to be measured extremely rapidly and according to USP 661.1 standards. FTIR spectroscopy is sensitive enough to detect additives below 4 %, making FTIR an extremely attractive option for identifying polymers, additives, contaminants, and fillers across almost any polymer-based industry.

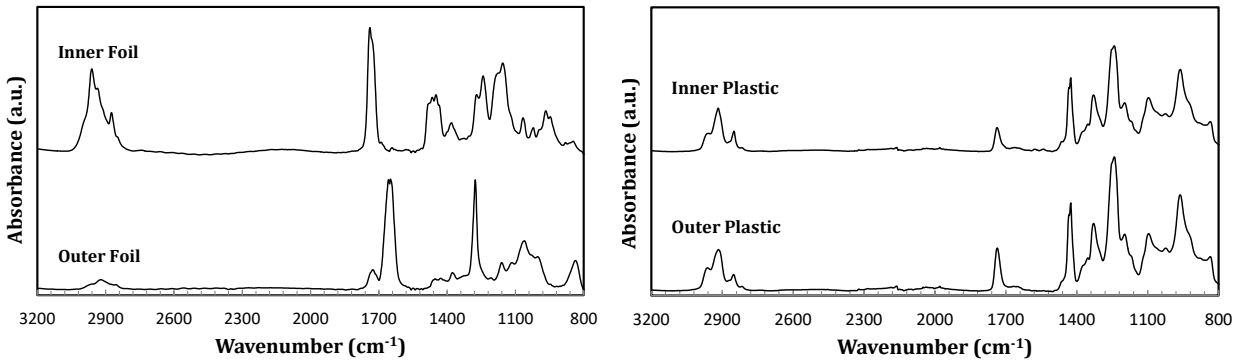

Figure 2. FTIR absorbance spectra of four elements in pharmaceutical packaging. The inner and outer foil (left) were identified as unique components, while inner and outer coatings of the plastic wells (right) were composed of a graft copolymer of polyvinyl chloride and acetate.