

The Determination of Drug Composition and Manufacturer through FTIR Analysis

Introduction

FTIR has been used for many years to identify or confirm the presence of many drugs. Through the use of spectral databases, FTIR provides a relatively easy way to determine an unknown drug. On the other hand, it is much more difficult to identify the manufacturer of a particular drug based on infrared data. For example, the same IR spectrum of a commonly used analgesic such as aspirin would be obtained regardless of the manufacturer of the drug. Much of the time, the same fillers are used. So there is very little chance of making a determination of the manufacturer through analysis of drug composition alone.

In this communication, we report results of a study on enteric-coated aspirin tablets to determine if it would be possible to differentiate among manufacturers and to identify the manufacturer of a particular tablet.

Materials and Methods

The spectrometer used in this study was a Shimadzu FTIR-8400S Fourier Transform Infrared Spectrometer. An AMTIR MIRacle, single bounce ATR from Pike Technologies was used, as well as a Shimadzu AIM-8800 Automated Infrared Microscope. The AIM-8800 was equipped with an ATR Objective. The samples were used as is, with no type of sample preparation for analysis of coating materials. Four types of enteric-coated aspirin tablets were purchased from a local grocery store and were used for sample analysis.

Results and Discussion

The first step of this process was to determine whether it was possible to differentiate among the samples through a simple analysis of the aspirin material. Each tablet was broken in half before analysis. Background spectra were taken using the AMTIR MIRacle with no sample present before each sample spectrum was measured. The spectra of aspirin from four different manufacturers are shown overlaid in Figure 1.

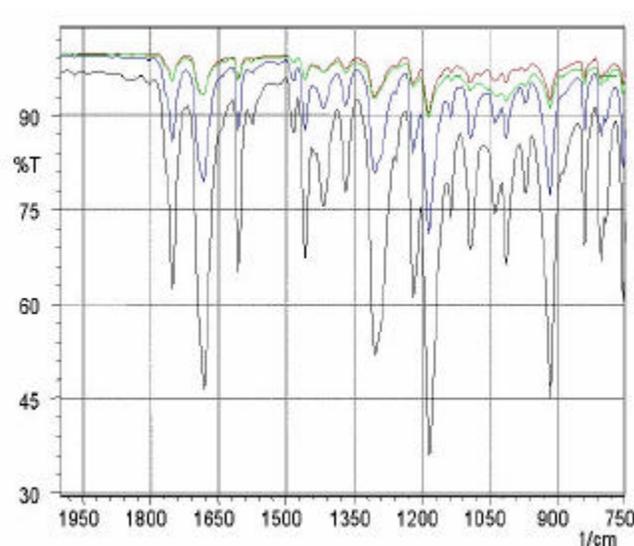


Figure 1: Spectra of Aspirin from 4 Manufacturers.

The data are qualitatively the same for each of the different tablets analyzed. Differences in the spectra are largely differences in the strength of the various bands indicative of differences in the amounts of active ingredient. Since fillers tend to be the same for all manufacturers in this case, the spectra are identical for the aspirin material. A spectral search was performed using Sadtler's Know-It-All database and

yielded the appropriate, expected spectrum for acetylsalicylic acid.

Since manufacturer differentiation was not possible using the inner drug composite material, another method was needed. Next, a spectrum from each of the coatings was obtained, once again using the AMTIR MIRacle. As shown in Figure 2, the coatings showed enough of a difference between manufacturers that a database was created using Shimadzu's IRsolution software, and unknown tablets were successfully identified using the database.

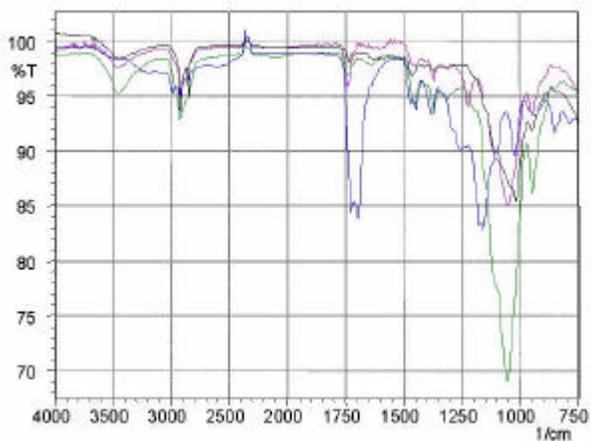


Figure 2: Spectra of Enteric Coatings

The next step was to determine if similar results could be obtained using microscopic techniques. Samples were analyzed using the AIM8800 Infrared Microscope. An ATR objective (Ge Crystal) was used for the analysis of the coating material. The data shown in Figure 3 indicate that it is also possible to distinguish among the various suppliers of Aspirin used in this study by micro-spectroscopic measurement of the tablet coatings.

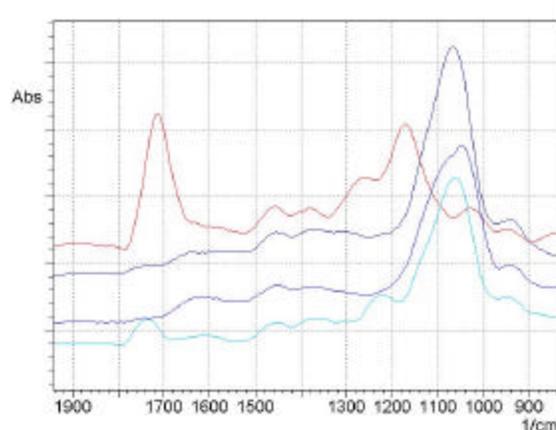


Figure 3: Microscopic Data of Coated Tablets Using Ge ATR

Conclusions:

Using the drug composite material was not enough to provide differentiation of the individual samples. Both the data obtained for the coating material from the microscope and SBATR proved to be reliable for creating a database and differentiating between manufacturers of the tablet. Searchable databases can be created that reference manufacturers, if the data shows enough differentiation between the individual samples.