CDS solutions

*APPLICATIONS INFORMATION USING ADVANCED SAMPLE HANDLING TECHNOLOGY*

# Coating Analysis on Pharmaceutical Tablet Forms

A large number of solid pharmaceutical dosage forms in the marketplace are coated. The reason for the coating varies from bioavailability control, stability considerations of the drug to a more aesthetically appealing dosage form. The components that make up any film coating consist of the polymer, plasticizer, colorant, and solvent. These components can be analyzed using pyrolysis which will volatilize the organic components, after which they will be chromatographically separated. This thermal treatment is clearly superior to a possible long solvent extraction in the process of product deformulation.

Figure 1 shows a chromatogram of methyl methacrylate obtained from the surface of a pharmaceutical dosage form. The tablet was lightly scraped collecting about 25 µg of sample. The sample was then pyrolyzed and analyzed by GC/MSD to produce the chromatogram. Figure 2 shows a chromatogram of the plasticizer ethyl citrate . This is used in a tablet coating to give it stability and make it less likely to chip or crack during shipping and handling. It is also believed to help in the adhesion process of the coating to the tablet.

Solvents are used in coating tablets to help ensure a uniform dispersal of the coating material on the tablet. Film coating solvents fall into the classes of alcohols, ketones, esters, chlorinated hydrocarbons, and water. Figure 3 is a chromatogram of a tablet coating that used isopropyl alcohol as the coating solvent. The peaks prior to that result from degradation of the active drug.

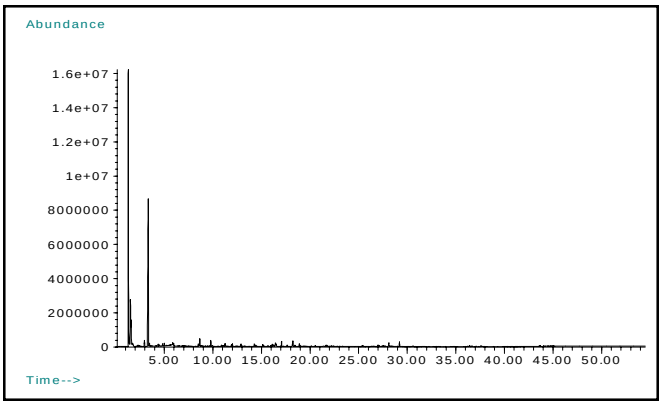


**Figure 1**. MMA from tablet

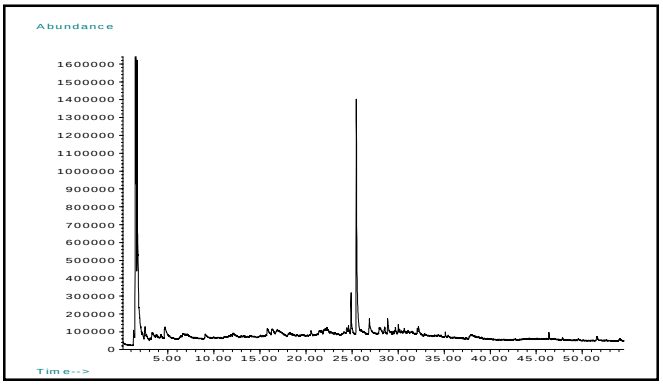


**Figure 2**. Plasticizer Ethyl Citrate from tablet

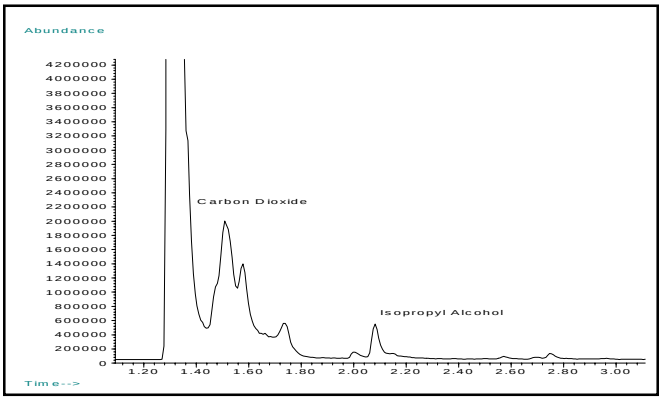


**Figure 3**. Coating Solvent Isopropyl Alcohol

## Equipment

The samples were analyzed using a CDS Analytical Pyroprobe Model 2500 Autosampler interfaced to a Hewlett-Packard 6890 gas chromatograph using the Hewlett-Packard 5972A MSD.

## Model 2500 Conditions

| | |
|---|---|
| Interface Temperature: | 300°C |
| Pyrolysis Temperature: | 750°C |
| Time: | 15 sec |
| Sample Amount: | 25 µg |

## Gas Chromatograph Conditions

| | |
|---|---|
| Carrier: | He, Inlet Pressure 5.9psi |
| Split: | 50:1 |
| Column: | HP-5 (30m x 250µm x .25µm) |
| Detector: | MSD |
| Oven Initial Temperature: | 40°C for 2 min. |
| Ramp: | 6°C/ min. |
| Final Temperature: | 295°C for 10 min |

**FOR MORE INFORMATION CONCERNING THIS APPLICATION, THE FOLLOWING READING IS RECOMMENDED:**

S. C. Porter, *Coating of Pharmaceutical Dosage Forms*, in Remington: The Science and Practice of Pharmacy, 19th edition, Alfonso R. Gennaro, Editor, Mack Publishing Co, 1995.

T. Wampler, Analytical Pyrolysis: An Overview, in Applied Pyrolysis Handbook, T. P. Wampler (Editor), Marcel Dekker,1995.

*Additional literature on this and related applications may be obtained by contacting your local CDS Analytical representative, or directly from CDS at the address below.*

CDS Analytical, Inc.

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**CDS Analytical, Inc. 465 Limestone Road, P.O. Box 277, Oxford, PA USA 19363-0277 PH: 610 932 3636 FX: 610 932 4158**