

CDSolutions

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.

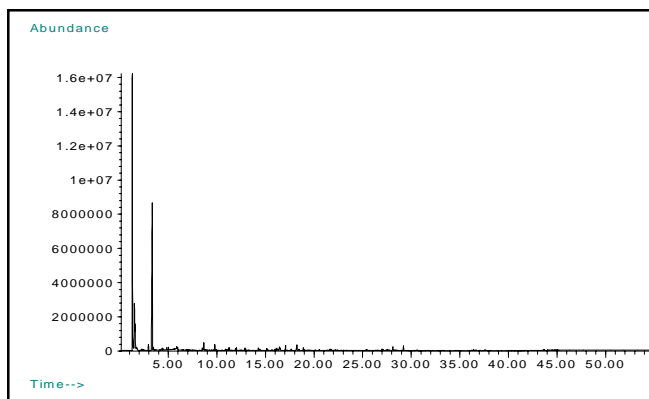


Figure 1. MMA from tablet

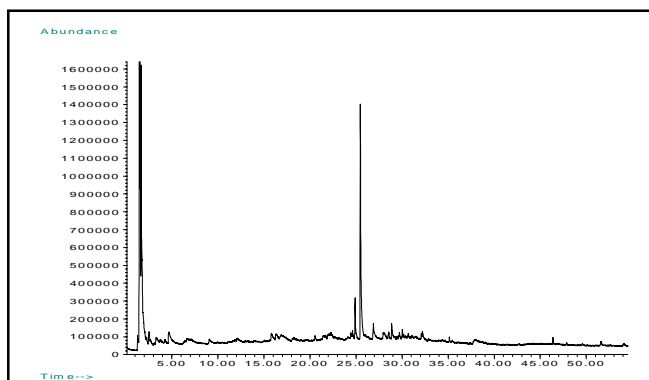


Figure 2. Plasticizer Ethyl Citrate from tablet

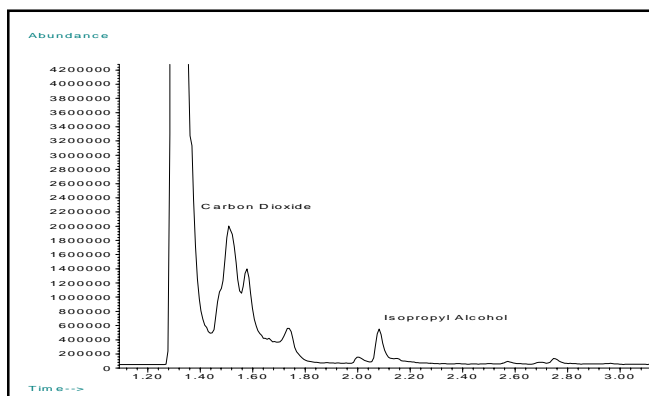


Figure 3. Coating Solvent Isopropyl Alcohol

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. has been a leader in the design and manufacture of laboratory instruments for sample preparation and analysis since 1969. We are dedicated to providing the best possible instruments for both research and routine analysis. Well known in the field of pyrolysis, CDS manufactures the Pyroprobe® 1000, 2000 and 2500 autosampler for the introduction and analysis of solid materials by GC, MS and FT-IR. CDS offers a complete line of dynamic headspace instruments for the analysis of volatile organic compounds in environmental, pharmaceutical and food applications, including the model 6500 16 position autosampler for complex, multicomponent materials investigation. Our customers, their requirements and applications are important to us. To help meet your needs, we offer a wide range of analytical information and the services of our applications laboratory. If you would like additional information, please contact us at the address below, call us at 1 800 541 6593, or log onto www.cdsanalytical.com.