

the mass of a 10-mg sample on exposure to the humidity-controlled gas flow is both easily discernable and reproducible. The DVS is a valued tool for studies related to polymorphism, compound stability, and bulk and surface adsorption effects of water and organic vapors. The DVS studies would typically show percent mass increases, but often, a hysteresis loop relationship is observed, where there is crystallization of compound that results in the expelling of excess moisture. This effect can be important in some formulations, such as dry powder inhaler devices, as it can cause agglomeration of the powders and variable flow properties. The DVS is a useful study when amorphous forms are involved on size reduction. In many cases, a low level of amorphous character cannot be detected by techniques such as XRPD; microcalorimetry can detect <10% amorphous content (the limit of detection is 1% or less). The amorphous content of a micronized drug can be determined by measuring the heat output caused by the water vapor inducing the crystallization of the amorphous regions.

Figure 7.1 shows a typical DVS chart for microcrystalline cellulose, and Figure 7.2 shows the chart for lactose. The reaction to moisture is dramatically represented in this study.

Excellent instrumentation support and advice are available through Surface Measurement Systems (SMS) (1), manufacturer of DVS-Advantage and DVS-1000 and 2000 series of equipment for dynamic vapor interaction studies. The DVS-HT represents the first new generation of gravimetric vapor sorption analyzers for more than a decade by Surface Measurement Systems (5 Wharfside, Rosemont Road, Alpertown, Middlesex, HA0 4PE, U.K.). The DVS-HT is recommended for stability

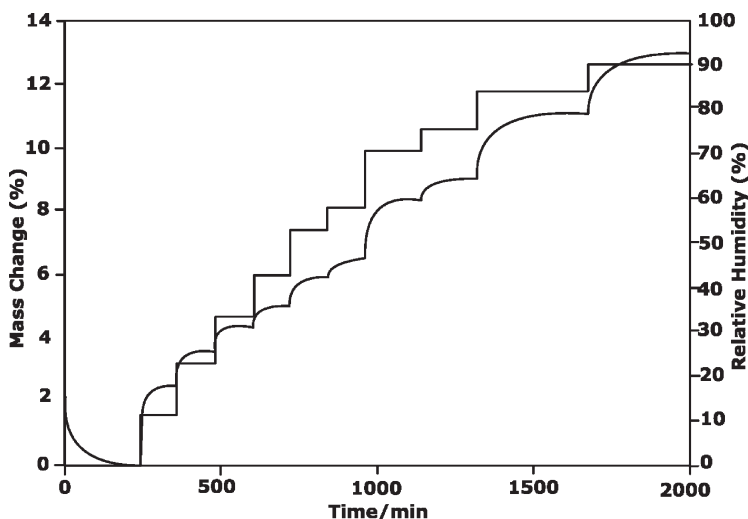


FIGURE 7.1 The dynamic vapor sorption chart for microcrystalline cellulose. The percentage mass change is based on a 10-mg sample of microcrystalline cellulose reference material. Steps refer to relative humidity changes. (Courtesy of Surface Measurement Systems; From <http://www.smsuk.co.uk/index.php>.)