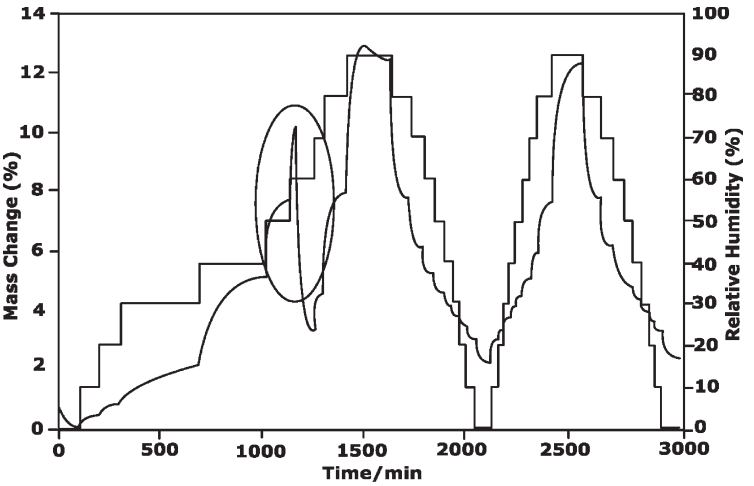

FIGURE 7.2 The dynamic vapor sorption chart for lactose. A humidity-induced recrystallization event of spray-dried lactose is marked. Steps refer to relative humidity changes. (Courtesy of Surface Measurement Systems; From http://www.smsuk.co.uk/index.php.)

studies to select the optimal drug and excipient combinations. The DVS-HT features the following:

- Rapid screens of salts, solvates, hydrates, polymorphs, and cocrystals
- Large-scale preformulation and *formulation* studies
- Characterization of polymers, food ingredients, and fine particles
- Process optimization monitoring of surface and bulk chemistry
- Quality control of incoming raw materials
- Investigation of batch-to-batch variations in material formulations
- At-line process analytical technology (PAT) support of production performance to specifications

Although microcalorimetery remains the workhorse of studies, the use of IGC is becoming more popular to determine the changes to drug substances on micronization. The IGC differs from traditional gas chromatography (GC) insofar as the stationary phase is the powder under investigation. The behavior of pharmaceutical solids, during either processing or use, can be noticeably affected by the surface energetics of the constituent particles. Several techniques exist to measure the surface energy, for example, sessile drop, and dynamic contact angle measurements. The IGC is an alternative technique where the powder surface is characterized by the retention behavior of minute quantities of well-characterized vapors that are injected into a column containing the material of interest. Recently published articles using IGC on pharmaceutical powders have ranged from linking surface energetic data with triboelectric charging to studying the effect of surface moisture on surface energetics. Molecular modeling has also recently been used to explore the links between IGC