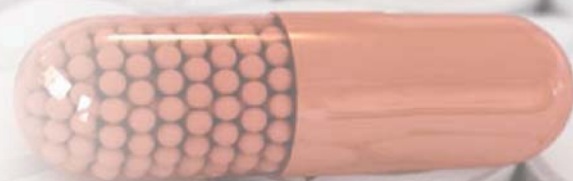




MICROMERITICS PHARMACEUTICAL SERVICES



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Characterizing Lyophilized Pharmaceutical Products

There is an expanding emphasis on the area of lyophilized products in the pharmaceutical and biotechnology industries. These companies are increasingly using lyophilization technologies and production processes to produce a final dosage form that has a longer shelf life, enhanced stability, and fewer restrictions on transportation and storage.

Typically, a lyophilized cake is the result of a freeze-drying process. The structure of the cake, including its density, total pore volume, pore size, and surface area, is tightly controlled by production. Any variability in the production process, such as the primary drying temperature, secondary drying temperature, and moisture content can impact the physical and chemical properties of the lyophilized cake.

Micromeritics Pharmaceutical Services offers a variety of analytical services to characterize lyophilized products. Mercury intrusion porosimetry can provide important information on the internal cake structure assisting in process development, batch variability, and integrity of the cake. Total pore volume and pore size distribution are directly related to the

integrity of the cake and reconstitution properties. BET surface area data provide insights into the morphology of the solid phase of the cake providing additional information on structure and reconstitution.

Selecting the optimal drying temperature for multi-component systems that may include water, buffers, fillers, and the active pharmaceutical ingredient is critical due to the fact that physical properties of these materials can change significantly with slight changes in temperature. Our analytical services for Modulated Differential Scanning Calorimetry (mDSC) identify the temperatures where these changes take place providing researchers with information that is critical in the determination of optimal drying temperatures. Unlike traditional Differential Scanning Calorimetry (DSC), mDSC provides the ability to accurately analyze complex transitions in frozen materials.

The amount of residual moisture in lyophilized products can impact long-term stability and shelf life. The type of water in the lyophilized product varies from physically bound, adsorbed, or chemically bound water. Water adsorption and desorption

kinetics of lyophilized materials provide data that is useful in the determination of drying conditions, product stability, and environmental considerations for storage and transportation. Thermo gravimetric analysis (TGA) and Karl Fischer titration can typically account for all water present in the cake. Dynamic Vapor Sorption (DVS) analysis can provide useful information on the behavior of the cake when exposed to varying levels of humidity.

To learn more about our analytical services for characterizing your lyophilized materials please visit our web site at www.micRx.com or call us at 770-624-3393.