Physical Characterization of Component Particles Included in Dry Powder Inhalers. I. Strategy Review and Static Characteristics


The motivation for this publication was the observation that studies of dry powder inhaler formulations are complex and correlations of performance with specific properties are rare. This paper describes the complex considerations of physicochemical, interfacial, and static bulk properties of lactose and their effects on the delivered dose uniformity and aerodynamic performance properties required to ensure product quality and therapeutic effect. The strategy outlined is the basis for work described in six subsequent papers in the *Journal of Pharmaceutical Science, Journal of Adhesion Science and Technology,* and *KONA Powder and Particle Journal.*

The majority of dry powder inhalers that deliver drugs to treat asthma and chronic obstructive pulmonary disease use lactose blends. Advair/Seretide, the most popular drug in this category, is a combination of two drugs: a long-acting β2-adrenergic agonist (salmeterol) to elicit bronchodilatation and a glucocorticosteroid (fluticasone) to treat inflammation, the underlying cause of disease. For preparation, the drugs are in respirable particle sizes (1-5µm) and are mixed with coarse, nonrespirable, lactose particles. These lactose particles aid in filling, metering, and dispersion of the drug as an aerosol from the inhaler. Historically, the formulations are prepared in batches only in the amount of material needed to evaluate its suitability for product development. Based on the outcome of initial studies, process variables can be adjusted based on scientific principles and experience to optimize the final product. This iterative approach can be costly and time-consuming.

Collating sufficient data on a range of important and relevant properties may lead to predictive correlations of powder properties to performance measures. This goal is worth striving for to advance knowledge, facilitate product development, and conform to regulatory requirements for quality by design.

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