Comparative Dispersion Study of Dry Powder Aerosols of Albuterol Sulfate/Lactose Monohydrate and Disodium Cromoglycate/Lactose Monohydrate Delivered by Standardized Entrainment Tubes

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RESULTS & DISCUSSION

MOTIVATION

The dispersion studies using standardized entrainment tubes (SETs) represent inhaler device independent screening tool of dry powder formulations (1). The well-defined and fully developed airflow conditions of SETs at given flow rate guarantee good reproducibility of drug deaggregation by overcoming the inter-particulate forces, thus good correlation of airflow conditions of SETs with the aerodynamic powder properties that are related to in vitro aerosolization performance prediction.

OBJECTIVE

To investigate in vitro aerosolization and particle deposition of albuterol sulfate and disodium cromoglycate with different lactose monohydrate carriers via SETs.

To gain insight into the influencing formulation elements including drug, carrier, and concentration to the dispersion efficiency, under defined airflow condition. To achieve aerodynamic performance prediction.

MATERIAL

Pulmonary Drugs

Micronised Albuterol Sulfate (AS) (C13H25NO3S)

Micronised Disodium cromoglycate (DSCG) (C23H14Na2O11)

Respitose® Carriers

Lactose monohydrate (C12H22O11)

Analysis led to selection of four batches:

Sieved batches: SV-1, SV-2;

Milled batches: ML-1, ML-2.

RESULTS & DISCUSSION

METHODS

Attrition milling of drug, followed by geometric dilution and Turbula mixing with the lactose carriers. Malvern laser diffraction for volume size distribution (PSD). Particle morphology was characterized by scanning electron microscopy. Thermodynamic phase behavior, molecular interaction, and long range/short range order were evaluated by differential scanning calorimetry (DSC) and X-ray powder diffraction (XRPD) before and after blending. The blends were prepared at 2% (w/w) concentration.

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