DEVELOPMENT AND EVALUATION OF PHARMACEUTICALLY EQUIVALENT LEVOSALBUTAMOL DRY POWDER INHALER WITH INCREASED *IN VITRO* DEPOSITION

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ABSTRACT

The advancement and assessment of an efficient and safe dry powder inhaler formulation for levosalbutamol are critical for optimizing its therapeutic potential in managing chronic obstructive pulmonary disease (COPD). This study aims to provide an overview of the development process and evaluation outcomes of a levosalbutamol dry powder inhaler, including formulation development, physicochemical characterization and *in vitro* performance assessment. It employed a stepwise approach to develop and evaluate the inhaler. Initially, different excipients (Respitose®SV010, Respitose®ML006, Respitose®SV003, Lactohale LH100, Lactohale LH300) and particle size distributions were evaluated to optimize the formulation. Physicochemical characterization, such as particle size, shape and density were conducted using appropriate techniques. *In vitro* performance assessments, together with fine particle fractions, emitted dose and aerodynamic particle size distribution was determined using validated methods. The formulation development process resulted in an optimized levosalbutamol dry powder inhaler with desirable physicochemical properties, including uniform particle size distribution and suitable density for effective inhalation. *In vitro* assessments demonstrated favourable aerodynamic characteristics, with a high emitted dose and significant fine particle fraction, indicating efficient lung deposition and therapeutic efficacy. These findings support the potential of the levosalbutamol dry powder inhaler as an effective treatment option for respiratory conditions such as asthma and COPD.