Vinod Musale, J Pulm Respir Med 2018, Volume 8
DOI: 10.4172/2161-105X-C1-027

In-Vitro evaluation to determine fine respirable fractions of Ipratropium and Salbutamol HFA Inhaler used for chronic obstructive and pulmonary diseases

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The purpose and interest of this research on the *In-Vitro* study of Pharmaceutical Inhalation/Aerosols, is to highlight the critical aspects of Fine Particle Dose (Respirable Fractions) to justify the efficacy of Pressurised Metered Dose Inhalers (pMDI). pMDI is the most common dosage form for inhalation by which the micronized drug is delivered from a pressurized container suspended in a liquefied gas (Propellant- HFA134a/HFA 227ea). Inhalation is the convenient way to deliver drugs to respiratory tract in treatment of respiratory disease like Asthma & Chronic Obstructive Pulmonary Diseases (COPD). Respirable Fraction is defined as the mass of active pharmaceutical ingredient per actuation of the inhaler contained in particles finer than 5.0 µm aerodynamic diameters. Pressurised Metered dose aerosols with particles in the aerodynamic particle size range of 1 to 5µm can penetrate deep into the lungs, permitting ready absorption of the drug into the blood. The suspension HFA MDI tested in this study contained Salbutamol sulphate and Ipratropium bromide are as active drug substances, and HFA-227ea and 134a are as propellants. The particle size distribution profiles of developed Ipratropium and salbutamol Inhaler MDI product were evaluated with an eight-stage Anderson Cascade Impactor Copley (ACI, Copley) at flow rate of 28.3 l/min to determine the fine respirable fraction.

The percentage respirable fractions and particle distribution profiles are determined by using Copley Data Analysis Software (CITIDAS).

Description	Salbutamol	Ipratropium
Respirable Fraction (%)	41.902	31.545
Fine Particle Dose (µg)	38.650	5.880
Mass Balance (µg)	92.24	18.64
MMAD (µm)	2.5	3.5
GSD	1.9	1.5

Table: Shows that the total mass of active ingredients is well within limit 75-125% of the average delivered dose and Fig. 01 Shows Drug Distribution per Discharge. Hence, the developed formulation was concluded that efficient with achieved respirable fractions by ACI, Copley.

Biography

Vinod Musale (Masters in Pharmacy), He has his expertise in development of pharmaceutical inhalation products. Vinod has good number of years of experience in the field of quality to ensure the delivery of quality Pressurized Metered Dose Inhalers (pMDI) and Dry Powder Inhalers (DPI) to the end users for improving the healthcare. He has taken the specialization in Quality Assurance Techniques at post-graduation level and pursuing PhD in specialization of Pharmaceutical Inhalations, from UTU, University - Gujarat (India). Currently heading the Position of Manager Quality Assurance at Vamsi Pharma Private Limited.

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