Impact of incorrect inclination angle during inhalation on in vitro performance of a new discrete multi-dose dry powder inhaler (mDPI) (ERS 2025)

Asthma - management, COPD – management

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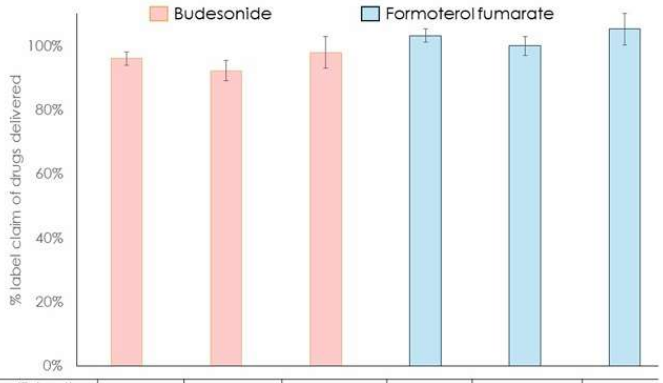
Background: Ciphaler™ is a discrete mDPI recently launched in India by Cipla Ltd. Correct technique of usage, including holding DPIs in right position during inhalation has been shown to be important to ensure optimum drug delivery into airways. Objective: To evaluate effect of inclination angle on drug delivery with Ciphaler™(formoterol/budesonide).

Methods: Formoterol/Budesonide (6/200 mcg) Ciphaler™ (Foracort Ciphaler™, Cipla Ltd.) was prepared for inhalation (by sliding thumb grip and lever) and positioned at different degrees of inclination: 0° (recommended), 45° and 90°, during dose extraction. Device was then connected to Dosage Unit Sampling Apparatus (DUSA, Copley Scientific, UK), rotated at the same angles, and dose was extracted & quantified by HPLC. Dose delivered from 3 devices (10 doses) at each inclination were evaluated.

Results: Emitted doses from Formoterol/Budesonide Ciphaler™ were found to be as per recommended label claim standards, when activated at recommended inclination angle (0°) as well as at angles of 45° & 90° (Fig.1)



Inclination/Extraction angle	0°	45°	90°	0°	45°	90°
% of label claim of drugs delivered (Mean ± SD)	96 ± 2	92 ± 3	98 ± 5	103 ± 2	100 ± 3	105 ± 5

Fig.1: Drug delivery from formoterol/budesonide Ciphaler™ at different inclination angles

Conclusion: It is recommended to always use Ciphaler™ as per labelled instructions. Nevertheless, based on this in vitro evaluation, we conclude that slight tilts during inhalation may not compromise dose delivery from Ciphaler™.