

Dose emission following accidental double activation of a novel discrete multi-dose dry powder inhaler (mDPI): An in-vitro evaluation (NAPCON Jaipur 2025)

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Background: Ciphaler™ is a newly launched discrete mDPI by Cipla Ltd. in India, designed with individually sealed doses in a blister strip. The recommended step for activating the device is by sliding the thumb grip and lever to release a dose. However, accidental double activation (activating the device a second time without inhalation) is a known misuse of mDPIs observed in real-world settings, resulting in concerns of potential over-dosing. This study was done to evaluate effect of double activation on emitted doses of formoterol and budesonide delivered via Ciphaler™.

Methods: Formoterol/Budesonide (6/200 mcg) Ciphaler™ (Foracort Ciphaler™, Cipla Ltd.) was loaded twice (by sliding thumb grip and lever) in the correct upright position. The device was then connected to Dosage Unit Sampling Apparatus (DUSA), the dose was extracted and quantified using high performance liquid chromatography (HPLC). Dose delivered from 10 test devices (1 dose each) were evaluated and results were expressed as mean (% of drug delivered) ± standard deviation (SD).

Results: The results demonstrated that the drug delivered from Ciphaler™ after single and double activation was similar and did not show significant difference (Figure 1).

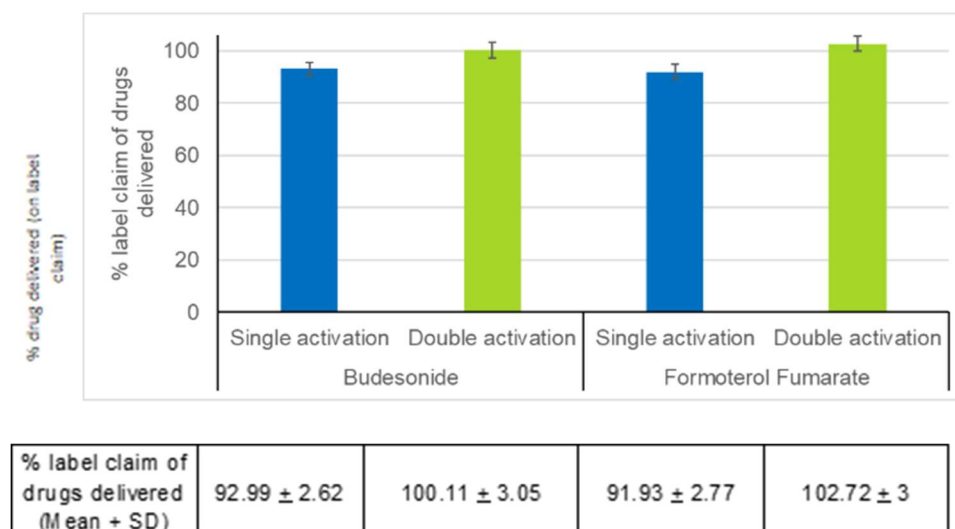


Fig.1: Drug delivery from formoterol/budesonide Ciphaler™ after single and double activation

Conclusion: While we recommend the use of Ciphaler™ as per labelled instructions-by activating the device only once before inhalation, the results of this *in vitro* evaluation, suggest that accidental double activation of the Ciphaler™ may not result in a risk of over-dosing.