

**Comparative *in vitro* performance evaluation of formoterol/budesonide combination delivered through a novel multi-dose dry powder inhaler versus a unit-dose dry powder inhaler (NAPCON Delhi 2023)**

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**Background & Objectives:**

Multidose dry powder inhalers (mDPI) are preferred over conventional unit-dose dry powder inhalers (DPIs) as they are easier to use, more portable and may help reduce errors due to lesser steps of use. Ciphaler<sup>®</sup> is a discrete mDPI with pre-loaded doses indigenously developed by Cipla Ltd with the objective of simplifying management of obstructive airway diseases.

Aim of this study was to evaluate *in vitro* performance of the formoterol/budesonide combination delivered through Ciphaler<sup>®</sup> in comparison to the same combination delivered through unit-dose DPIs.

**Methods:**

*In vitro* performance of formoterol/budesonide (200/6 mcg) combination delivered through Ciphaler<sup>®</sup> (Foracort Ciphaler<sup>®</sup>, Cipla Ltd.) was compared to the same combination delivered through unit-dose DPIs (Foracort Rotacaps<sup>®</sup> delivered via Revolizer<sup>®</sup> Cipla Ltd. and Budamate Transcaps<sup>®</sup> delivered via Lupihaler<sup>®</sup>, Lupin Ltd.) using random samples. The fine particle dose (FPD) and mass median aerodynamic diameter (MMAD) were evaluated. The FPD and MMAD were measured using Next Generation Impactor (NGI, Copley Scientific) at 30, 60, 90 L/min. The amount of drug deposited in the NGI was analyzed using high performance liquid chromatography.

**Results:**

The FPD and MMAD for formoterol/budesonide at 30, 60 and 90L/min were higher for Foracort Ciphaler<sup>®</sup> as compared to that delivered using the unit-dose DPIs (Table 1).

Table 1: FPD and MMAD for Formoterol/Budesonide delivered through Ciphaler<sup>®</sup> vs. Unit-dose DPIs at various flow rates.

Product	Flow rate	Formoterol Fumarate		Budesonide	
		FPD	MMAD	FPD	MMAD
Foracort 200 Ciphaler®	30 LPM	1.38	3.78	46.00	3.74
	60 LPM	2.05	2.96	70.74	2.79
	90 LPM	2.17	2.81	75.36	2.65
Foracort 200 Rotacaps via Revolizer®	30 LPM	1.32	3.35	42.50	3.65
	60 LPM	1.79	2.70	54.33	3.00
	90 LPM	1.91	2.65	57.60	2.90
Budamate 200 Transcaps via Lupihaler®	30 LPM	0.93	4.76	24.83	5.32
	60 LPM	1.61	3.39	38.08	4.13
	90 LPM	1.91	3.10	42.92	3.84

### Conclusion:

The *in vitro* deposition of formoterol/budesonide was higher when delivered through Ciphaler® as compared to that delivered through unit-dose DPIs.