

Comparative in-vitro performance evaluation of two fluticasone furoate/vilanterol/umeclidinium (100/25/62.5 mcg) multi-dose dry powder inhalers

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Background:

Fluticasone Furoate/Vilanterol/Umeclidinium, a once-daily fixed-dose combination of ICS/LABA/LAMA, is available internationally as a multi-dose DPI (Trelegy Ellipta®). The same combination has also been developed by Cipla Ltd. as Voltido Trio Ciphaler® recently.

Aim: To compare the in-vitro performance of Voltido Trio Ciphaler® (Cipla Ltd.) with Trelegy Ellipta® (GSK Pharmaceuticals Ltd.).

Methods: Random samples were assessed for fine particle dose (FPD), mass median aerodynamic diameter (MMAD), and geometric standard deviation (GSD) using a Next Generation Impactor (Copley Scientific). Measurements were taken at 76 L/min for Ciphaler® and 75 L/min for Ellipta®, corresponding to a 4 kPa pressure drop. The mean of three readings was calculated for each parameter.

Results: Delivered dose, FPD, MMAD, and GSD for fluticasone furoate, vilanterol, and umeclidinium from both devices are summarized in the table below

Table: Delivered dose, FPD, MMAD and GSD for the individual components of the two multi-dose DPIs

	Flow rate	Fluticasone Furoate				Umeclidinium				Vilanterol			
		Delivered dose (mcg)	FPD (mcg)	MMAD (µm)	GSD	Delivered dose (mcg)	FPD (Mcg)	MMAD (µm)	GSD	Delivered dose (mcg)	FPD (mcg)	MMAD (µm)	GSD
Voltido Trio Ciphaler/ Batch No. 987-130	76 LPM	89.82	20.22	2.803	2.353	53.88	25.23	2.88	1.90	21.83	8.68	1.99	2.19
Trelegy Ellipta/ Batch no. UU4D	60 LPM	92	23.61	4.18	2.02	55	25.02	2.18	1.93	22	8.45	2.07	2.09

Discussion: The values of delivered dose, FPD, MMAD and GSD between the innovator product and Cipla's Ciphaler® were found to be similar for fluticasone furoate, umeclidinium

and vilanterol, indicating that the drug delivery with the two devices to the lungs would be similar.

Conclusion: Cipla's Ciphaler® and GSKs Trelegy Ellipta demonstrated similar delivered dose, FPD, MMAD and GSD of fluticasone furoate, vilanterol and umeclidinium delivered by at specified flow rates, suggesting similar drug delivery into the lungs under ideal conditions using correct inhaler technique.