In-vitro Performance Evaluation of three Formoterol/Glycopyrronium/Budesonide Inhalers

Dr Sanjana Shastri¹, Kiran Rote², Anita Sawant², Dr Rushika Shah¹, Dr Meena Lopez¹, Dr Senthilnathan M¹, Dr Jaideep Gogtay¹

- 1- Medical Affairs, Cipla Ltd., Mumbai
- 2- Integrated Product Development, Cipla Ltd., Mumbai

Background: The GOLD 2025 Strategy Document recommends triple therapy (LABA/LAMA/ICS) in both, initial and follow-up therapy algorithms, particularly in patients with exacerbations and high eosinophil counts. Cipla's Formoterol/Glycopyrronium/Budesonide (FGB) (6/12.5/200 mcg) is a triple therapy with twice daily dosing and is available as a pressurized metered dose inhaler (pMDI) and breath-actuated inhaler (Synchrobreathe). The international innovator for this product is AstraZeneca's Breztri Aerosphere, which has been formulated using a phospholipid-based co-suspension MDI technology; it has been introduced recently in India (composition: formoterol 5 mcg/glycopyrronium 7.2 mcg/budesonide 160 mcg) as well. Considering the differences in formulation, a comparison of the available formulations is warranted to ensure comparable efficacy.

Aim: To compare the in-vitro performance of FGB MDI and Synchrobreathe (Cipla Ltd.) with Breztri Aerosphere (Innovator-AstraZeneca)

Materials and Methods: The in-vitro performances of Cipla FGB MDI and Synchrobreathe and Breztri Aerosphere were compared for Assay and Uniformity of Delivered Dose (UDD), using High performance liquid chromatography. The UDD measures the consistency of the dose delivered over the initial, middle and end doses of the inhalers. Percentage of Fine Particle Fraction (FPF%) of the three formulations was also assessed, using impactors at flow rates ranging from 28.3 to 30L/min. FPF% is the fraction or percentage of the drug mass which is <5 μm, which is an indicator of the respirable fraction of the drug.

Results:

Table: Comparison of in-vitro performance of the three triple therapy formulations

		Formoterol		Glycopyrronium			Budesonide			
		Assay	UDD	%	Assay	UDD	%	Assay	UDD	%
		% L.C	%	FPF	%L.C	%	FPF	%L.C	%	FPF
			TDD			TDD			TDD	
Brand and	Batch No.			•	•		•	•	•	
Device										

Cipla FGB Synchrobreathe	BA12360	100	98	53	99	99	47	97	95	53
Cipla FGB pMDI	BA12360	101	96	54	106	94	50	103	93	46
Innovator (Breztri Aerosphere)	6100878C 00	113	104	49	102	97	50	103	96	46

Conclusion: The in-vitro performance of Cipla's MDI and Synchrobreathe is within the accepted limits and comparable to the innovator i.e. Breztri Aerosphere.