Title- Comparative In-vitro Performance Evaluation of Two Salmeterol/Fluticasone

(50/250mcg) Multidose Discrete Dry Powder Inhalers

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Background:

Ease of use and portability make multidose dry powder inhalers (mDPI) preferrable over unit-dose

dry powder inhalers (DPI). Salmeterol/Fluticasone mDPI is available as Seretide

Accuhaler®/Diskus® globally. Seroflo Ciphaler® is an mDPI indigenously developed by Cipla

Ltd. and similar to the Seretide Accuhaler®/Diskus® device.

Aims and Objectives: To evaluate the *in-vitro* performance of Seroflo Ciphaler® (Cipla Ltd.)

with Seretide Accuhaler® (GSK Pharmaceticals Ltd.).

Materials/patients & methods: The performances of Seroflo Ciphaler® and Seretide Accuhaler®

were compared using random samples for various parameters, namely, fine particle dose (FPD),

mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD). The FPD,

GSD and MMAD were measured using Next Generation Impactor (NGI, Copley Scientific) at 30,

60, 90 L/min. High performance liquid chromatography was used to analyze the amount of drug

deposited in the NGI.

Results: The FPD, MMAD and GSD for salmeterol and fluticasone at 30, 60 and 90L/min were comparable between the two mDPIs.

| | Flow | Salmeterol | | |
|--------------------------|-----------|------------|------|-----|
| | rate | FPD | MMAD | GSD |
| | 30 LPM | 7.0 | 4.4 | 2.2 |
| Seroflo 250 Ciphaler® | 60 LPM | 9.8 | 3.7 | 2.1 |
| | 90 LPM | 11.1 | 3.4 | 2.0 |

| Fluticasone propionate | | | | |
|------------------------|------|-----|--|--|
| FPD | MMAD | GSD | | |
| 41.5 | 4.3 | 2.1 | | |
| 57.5 | 3.7 | 2.1 | | |
| 63.3 | 3.5 | 2.0 | | |

| | 30 LPM | 6.2 | 4.7 | 2.2 |
|-------------------------|-----------|-----|-----|-----|
| Seretide 250 Accuhaler® | 60 LPM | 9.1 | 3.5 | 2.2 |
| | 90 LPM | 9.7 | 3.2 | 2.0 |

| 38.3 | 4.4 | 2.1 |
|------|-----|-----|
| 55.9 | 3.4 | 2.1 |
| 59.8 | 3.1 | 2.1 |

Conclusion: The *in-vitro* drug deposition of Seroflo Ciphaler® was similar to that of Seretide Accuhaler®

Limitations: None

Conflict of Interest: Authors are employees of Cipla Ltd.