DRUG PRODUCT PERFORMANCE THROUGH INHALER

2016; Thorax was observed with the Breezhaler® (107.5 ± 2.4), followed by included in the analysis. The highest mean PIF rate (L/min ± SE) 96 completed the study and 93 patients (per-protocol set) were in total, 97 COPD patients were randomised, of whom Results The primary analysis was based on the per-protocol set compris- ing 93 patients who completed all three inhalations per device. A paired t-test was performed to compare PIF means between each combination of devices.

Results In total, 97 COPD patients were randomised, of whom 96 completed the study and 93 patients (per-protocol set) were included in the analysis. The highest mean PIF rate (L/min ± SE) was observed with the Breezhaler® (107.5 ± 2.4), followed by the Ellipta® (80.0 ± 2.2) and the HandiHaler® (53.6 ± 2.1), in all patients (patients with moderate-to-very severe airflow limitation). The mean PIF rate (L/min) achieved via the Breezhaler® was higher vs the Ellipta® (mean difference [Δ] = 27.7; p < 0.0001) and also vs the HandiHaler® (Δ = 53.9; p < 0.0001). Also, when assessed by severity of airflow limitation, the Breezhaler® device exhibited significantly higher PIF rate vs the Ellipta® and vs the HandiHaler® (Table).

Conclusions COPD patients with varying degree of airflow limitation (moderate-to-very severe COPD) achieved the highest PIF rates via the Breezhaler® compared with the Ellipta® or the HandiHaler® inhaler.

**P289 DRUG PRODUCT PERFORMANCE THROUGH INHALER LIFE USING A LAMA/LABA COMBINATION IN A DRY POWDER INHALER**

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Introduction Studies to test the delivered dose uniformity (DDU) and fine particle dose (FPD) delivery over inhaler life were performed with aclidinium bromide 400 µg/formoterol fumarate dihydrate 12 µg inhalation powder in the Genuair™ inhaler.

Methods Developmental batches representative for commercial production were used. Samples were tested before and after cleaning of the mouthpiece with a dry tissue, after dosing at various orientations (+45°/-45°) to the horizontal axis of the inhaler, or before and after dropping the inhaler in different orientations from a 1 m height. Test parameters included delivered dose uniformity (DDU) and fine particle dose (FPD).

Results All results for the LAMA (aclidinium bromide) and LABA (formoterol fumarate dihydrate) active ingredients were within the expected ranges and well inside the acceptance criteria applied during development (Figure 1). For aclidinium bromide, DDU mean values between 388 and 424 µg (specification range 320–480 µg), and single values between 343 and 464 µg (not specified) were observed. Mean FPD was tested within 136 and 175 µg (specification range 120–200 µg), and FPD single values between 136 and 198 µg (not specified). Results for the LABA active ingredient, formoterol fumarate dihydrate, were between 11.7 and 12.8 µg for DDU mean values (specification range 9.6–14.4 µg) and between 9.6 and 13.8 µg for DDU single values (not specified). Mean FPD was observed within 3.1 and 3.5 µg (specification range 2.2–4.5 µg), and FPD single values between 2.6 and 4.0 µg (not specified).

Conclusions The studies show that stable pharmaceutical quality can be guaranteed even if the device is used in different positions to the one explained in the patient information leaflet, after cleaning the mouthpiece, or after dropping the device in different orientations.

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