A COMPARATIVE EVALUATION OF THE AEROSOLIZATION PERFORMANCES OF MARKETED FLUTICASONE MULTI-UNIT AND SINGLE-UNIT DRY POWDER INHALERS: THE EFFECTS OF PRODUCT USE LIFE, SUBOPTIMAL AIRFLOW AND A HOT/HUMID ENVIRONMENT

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OBJECTIVES

Inhalation products based on the corticosteroid fluticasone propionate are frequently prescribed for the maintenance treatment of asthma and chronic obstructive pulmonary disease (COPD). Different inhalation products are marketed as multi-unit or single-unit dry powders for inhalation (DPIs).

The aim of this study was to evaluate the reproducibility and robustness of the aerosolization performance of a multi-unit DPI and a single-unit DPI reported in the Table, using a dosage unit sampling apparatus for the delivered dose determination (n=10) and a next generation impactor (10 doses/test, n=4) to determine the fine particle dose (FPD, ≤ 5 µm).

(i) throughout product use life using three marketed products of the same batch,
(ii) varied airflow conditions including suboptimal flows generated from asthmatic and COPD patients through Diskus and Aerolizer [1]. The latter presents a similar resistance and design as Axahaler,
(iii) exposure of preloaded doses (without mouth cap) in the device to hot and humid conditions.

CONCLUSIONS

Both DPIs showed reproducible and robust DDs and FPDs along the product use life. Flutaxa® delivered double the FPD with less variability compared to Flixotide®, whilst it delivered a slightly lower DD. Moreover, FPDs from Flutaxa®- unlike Flixotide®- were robust at suboptimal airflows – typical of those generated by asthmatic and COPD patients. Finally, Flutaxa® showed a slight decrease contrary to almost no powder emission when preloaded doses were exposed to a hot/humid environment.

REFERENCES


Respiratory Drug Delivery Europe; Palais des Congrès de Nantes, NICE, FRANCE, April 25-28, 2017