# Evaluation of the delivered and the fine particle doses in different pharmaceutical formulations of dry powder inhaler containing formoterol

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Formoterol is known as a long-acting ß-agonist indicated in asthma and chronic obstructive pulmonary diseases treatments. Formoterol-based formulations are locally administrated in the lungs by oral inhalation.

A total of 8 capsule-based dry powder inhalers containing formoterol fumarate, marketed over the European and North African markets were involved in the present study, including the reference drug Foradil®. This work assessed and compared them in terms of aerodynamic performance, considering that only the fraction capable of reaching the lungs can provide therapeutic effects to patients. All studied medicinal products have a unit dose of 12 µg of formoterol fumarate and are all equipped with an Aerolizer®-like inhaler. However, they differ in the capsule composition and the packaging.

Three independent tests were performed for each evaluated drug. The assays were carried out using the standard procedures of the European Pharmacopoeia 0671 and 2.9.18 to determine respectively the delivered dose and the fine particle dose employing a multistage liquid impinger. After preparation, samples were further analyzed by a validated HPLC-UV method. Moreover, the current study also examined the impact of freezing-thawing cycles on the stability of samples concerning analytical purpose handling: investigation of the reanalysis capability in routine activities.

Among these studied pharmaceuticals, the aerodynamic profile varies from one product to another. Additionally, as expected, this work confirmed that the composition of hard capsules and the barrier properties of the primary packaging can affect the fine particle dose of capsule-based dry powder inhalers. A greater respirable fraction can be achieved using hydroxypropylmethylcellulose capsules and moisture-impermeable packaging as the primary barrier to water vapor.