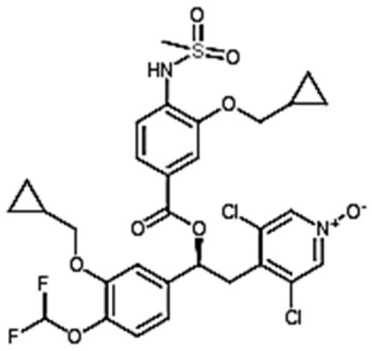
CLAIMS

1. A drug product comprising a single-dose dry powder inhalation device, comprising an inhaler body defining a recess for a capsule, wherein the capsule holds herein a pharmaceutical composition to be inhaled, a nosepiece or mouthpiece communicating with the recess, at least one rupturing element coupled to the inhaler body and configured for rupturing the capsule to allow an outside airflow to be mixed with the pharmaceutical composition of the capsule and inhaled through the nosepiece or the mouthpiece, and a pharmaceutical composition filled in a capsule, the pharmaceutical composition comprising micronized particles having a size comprised between 0.1 and 15 micron of the compound of formula (I)



(I)

and lactose carrier particles, wherein the inspiratory flow rate of said inhalation device is comprised between 30 l/min and 65 l/min and wherein the lactose carrier particles have an equivalent volume diameter lower than 110 micron, measured by means of laser diffraction or sieve analyzer.

2. The drug product according to claim 1, wherein carrier particles are made of alpha-lactose monohydrate.

3. The drug product according to claims 1 and 2, wherein the lactose carrier particles have an equivalent volumediameter comprised between 1 and 95 micron.

4. The drug product according to claim 3, wherein the lactose carrier particles have the dv(10) comprised between 1 and 5 micron, the dv(50) comprised between 18 and 30 micron and the dv(90) comprised between 65 and 95 micron.

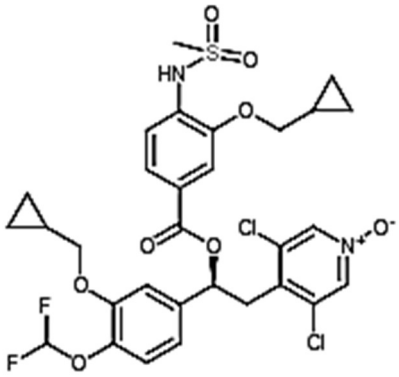
5. The drug product according to any one of the preceding claims, wherein the inspiratory flow rate of the inhalation device is comprised between 40 l/min and 65 l/min.

6. The drug product according to any one of the preceding claims, wherein the unitary nominal dose of the compound of formula (I) is comprised between 400 and 800 µg.

7. The drug product according to claim 6, wherein the unitary nominal dose of the compound of formula (I) is 800 µg.

8. The drug product according to claim 6, wherein the unitary nominal dose of the compound of formula (I) is 400 µg.

9. Use of a pharmaceutical composition comprising micronized particles having a size comprised between 0.1 and 15 micron of the compound of formula (I)



(I)

and lactose carrier particles, in the manufacture of a medicament for the treatment of a respiratory disease, wherein the medicament is to be administered using a single-dose dry powder inhalation device, wherein the inspiratory flow rate of said inhalation device is comprised between 30 l/min and 65 l/min, and wherein the lactose carrier particles have an equivalent volume diameter lower than 110 micron, measured by means of laser diffraction or sieve analyzer.

10. The use according to claim 9, wherein the respiratory disease is selected from asthma and chronic obstructive pulmonary disease (COPD).

11. The use according to claim 9 or 10, wherein the total daily dose of the compound of formula (I) is comprised between 800 and 4800 µg.

12. The use according to claim 11, wherein the total daily dose of the compound of formula (I) is comprised between 1600 and 3200 µg.

13. A process for the preparation of the drug product according to any one of claims 1 to 8, said process comprising the steps of: i) sieving the compound of formula (I) through a suitable mesh, ii) adding the lactose carrier particles to the compound of formula (I), iii) sieving the final blend and mixing to obtain the final pharmaceutical composition, iv) filling the obtained pharmaceutical compostion in a capsule, and v) loading the medicament chamber of the single dry powder inhalation device with the capsule.