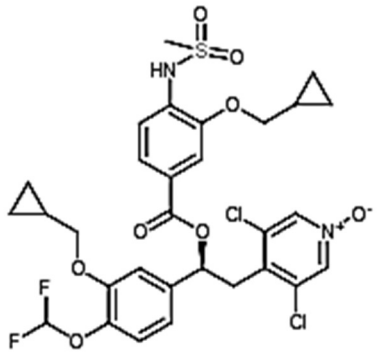
CLAIMS

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 a carrier consisting of a mixture of coarse and fine particles of pharmaceutically inert acceptable excipient, wherein the inspiratory flow rate of said inhalation device is comprised between 30 l/min and 65 l/min and wherein the carrier consists of a mixture of coarse and fine particles of a physiologically acceptable inert excipient in a ratio comprised between 70:30 and 95:5 by weight, the coarse particles having an equivalent volume diameter comprised between 200 and 500 micron, while the fine particles having the dv(0.1) comprised between 1 and 5 μm, the dv(0.5) comprised between 18 and 30 μm, and the dv(0.9) comprised between 65 and 95 μm, as measured by means of laser diffraction or a sieve analyzer.

2. The drug product according to claim 1, wherein the carrier is selected from the group consisting of polyols, crystalline sugars, inorganic salts, organic salts, organic compounds, polysaccharides and oligosaccharides.

3. The drug product according to claim 1 or 2, wherein the coarse particles have an

equivalent volume diameter comprised between 300 and 480 micrometers.

4. The drug product according to claim 3 , wherein the coarse particles have an equivalent volume diameter comprised between 350 and 450 micrometers.

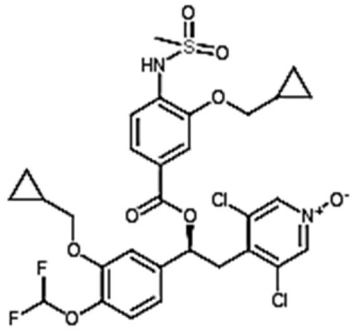
5. The drug product according to any one of claims 1 to 4, wherein the inspiratory flow rate is comprised between 40 l/min and 65 l/min.

6. The drug product 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 400 µg.

8. The drug product according to claim 6, wherein the unitary nominal dose of the compound of formula (I) is 800 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 a carrier, 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 carrier consists of a mixture of coarse and fine particles of a physiologically acceptable inert excipient in a ratio comprised between 70:30 and 95:5 by weight, the coarse particles having an equivalent volume diameter comprised between 200 and 500 micron, as measured by means of laser diffraction or a sieve analyzer, while the fine particles having the dv(0.1) comprised between 1 and 5 µm, the dv(0.5) comprised between 18 and 30 µm, and the dv(0.9) comprised between 65 and 95 µm, as measured by means of laser diffraction or a 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 claims 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 clams 1 to 8, said process comprising the steps of i) sieving the compound of formula (I) through a suitable mesh, ii) adding the carrier particles to the compound of formula (I), iii) sieving the final blend and mixing to obtain the phamraceutical composition, iv) filling the obtained pharmaceutical composition in a capsule, and v) loading the medicament chamber of the single dry powder inhalation device with the capsule.