CLAIMS

1. A process for preparing a powder formulation for inhalation for use in a dry powder inhaler, said powder formulation comprising:

(A) a carrier, comprising:

(a) a fraction of coarse particles of a physiologically acceptable carrier having a mean particle size of at least 175 μm; and

(b) a fraction of fine particles, consisting of a mixture of 90 to 99.5 percent by weight of particles of a physiologically acceptable excipient and 0.5 to 10 percent by weight of a salt of a fatty acid, wherein at least 90% of all said fine particles have a volume diameter lower than 15 microns,

wherein the weight ratio of said fine particles to said coarse particles is 5:95 to 30:70; and

(B) micronized particles of an antimuscarinic drug, a long-acting β_2-agonist (LABA) and, optionally, an inhaled corticosteroid (ICS), as active ingredients, wherein said process comprises:

(i) mixing said carrier, said long-acting β_2-agonist, and, optionally, said inhaled corticosteroid in a vessel of a shaker mixer at a speed of rotation not lower than 16 r.p.m. for a time of not less than 60 minutes, to obtain a first mixture; and

(ii) adding said anti-muscarinic drug to said first mixture, to obtain a second mixture, and mixing said second mixture at a speed of rotation not higher than 16 r.p.m. for a time of not more than 40 minutes,

wherein

the long-acting β_2-agonist is selected from the group consisting of formoterol, salmeterol, indacaterol, olodaterol, and vilanterol;

the anti-muscarinic drug is selected from the group consisting of glycopyrronium bromide or chloride, tiotropium bromide, umeclidinium bromide, and aclidinium bromide;

the inhaled corticosteroid is selected from the group consisting of beclomethasone dipropionate and its monohydrate form, budesonide, fluticasone propionate, fluticasone furoate, and mometasone furoate.

2. A process according to claim 1, further comprising: (iii) further mixing the formulation obtained in (ii), to achieve a homogeneous distribution of said active ingredients.

3. The process according to claim 1, wherein the anti-muscarinic drug is glycopyrronium bromide, the ICS is beclometasone dipropionate, the LABA is formoterol fumarate dihydrate.

4. The process according to claim 1, wherein the salt of a fatty acid is selected from the group consisting of magnesium stearate; sodium stearyl fumarate; sodium stearyl lactylate; sodium lauryl sulphate, and magnesium lauryl sulphate.

5. The process according to claim 4, wherein the salt of the fatty acid is magnesium stearate.

6. The process according to any one of the preceding claims, wherein in step i) the mixing is performed at 16-32 r.p.m., for a time comprised between 60 and 120 minutes.

7. The process according to any one of the preceding claims, wherein in step ii) mixing is performed for a time comprised between 20 and 40 minutes.

8. A powder formulation for use in any dry powder inhaler comprising:

(A) a carrier, comprising:

(a) a fraction of coarse particles of a physiologically acceptable carrier having a mean particle size of at least 175 μm; and

(b) a fraction of fine particles consisting of a mixture of 90 to 99.5 percent by weight of particles of a physiologically acceptable excipient and 0.5 to 10 percent by weight of magnesium stearate, wherein at least

90% of all said fine particles have a volume diameter lower than 15 microns,

wherein the weight ratio of said fine particles to said coarse particles is 5:95 to 30:70; and

(B) micronized particles of glycopyrronium bromide, formoterol fumarate dihydrate, and, optionally, beclometasone dipropionate, as active ingredients, wherein said formulation is obtainable by a process comprising:

(i) mixing said carrier, said formoterol fumarate dihydrate, and, optionally, said beclometasone dipropionate in a vessel of a shaker mixer at a speed of rotation not lower than 16 r.p.m. for a time of not less than 60 minutes, to obtain a first mixture; and

(ii) adding said glycopyrronium bromide to said first mixture, to obtain a second mixture, and mixing said second mixture at a speed of rotation not higher than 16 r.p.m. for a time of not more than 40 minutes; and whereby the mid fine particle fraction of glycopyrronium bromide is higher than 25%.

9. The powder according to claim 8, wherein the process further comprises:
(iii) further mixing the formulation obtained in (ii), to achieve a homogeneous distribution of said active ingredients.

10. The powder formulation according to claim 8 or 9, wherein the mid fine particle fraction is comprised between 28 and 40%.

11. The powder formulation according to any one of claims 8 to 10, wherein the physiologically acceptable excipient is alpha-lactose monohydrate.

12. The powder formulation according to any one of claims 8 to 11, wherein the coarse particles have a mass diameter comprised between 210 and 360 µm.

13. A dry powder inhaler device filled with the dry powder formulation of any one of claims 8 to 12.

14. The dry powder formulation of any one of claims 8 to 12 for use for the prevention and/or treatment of an inflammatory and/or obstructive airways disease.

15. The dry powder formulation for use according to claim 14, wherein the disease is asthma or chronic obstructive pulmonary disease (COPD).

16. Use of the dry powder formulation of any one of claims 8 to 12 in the manufacture of a medicament for the prevention and/or treatment of an inflammatory and/or obstructive airways disease.

17. The use according to claim 16, wherein the disease is asthma or chronic obstructive pulmonary disease (COPD).