CLAIMS

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

(A) a carrier comprising:

(a) 80 to 95 percent by weight, based on the total weight of said carrier, of coarse particles of alpha-lactose monohydrate ~~a physiologically acceptable excipient~~ having a mean particle size of at least 175 μm and a mass diameter comprised between 100 and 600 micron; and

(b) 19.6 to 4.9 percent by weight, based on the total weight of said carrier, of micronized particles of alpha-lactose monohydrate~~a physiologically acceptable excipient~~, and 0.1 to 0.4 percent by weight, based on the total weight of said carrier, of magnesium stearate~~a salt of a fatty acid~~; and

(B) micronized particles of glycopyrronium bromide, formoterol fumarate dihydrate, and beclometasone dipropionate~~an anti-muscarinic drug, a long-acting β_2-agonist, and optionally, an inhaled corticosteroid,~~ as active ingredients,

said process comprising:

(i) mixing all of said coarse particles of alpha-lactose monohydrate~~a physiologically acceptable excipient~~, all of said magnesium stearate~~salt of a fatty acid~~, a first portion of said micronized particles of alpha-lactose monohydrate~~a physiologically acceptable excipient~~, all of said micronized particles of ~~said long-acting β_2-agonist, said anti-muscarinic drug, and, optionally, said inhaled corticosteroid~~the active ingredients 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 the remaining part of said micronized particles of alpha-lactose monohydrate ~~a physiologically acceptable excipient~~ to said first mixture, to obtain a second mixture, and mixing said second mixture at a speed of rotation not lower than 16 rpm for a time of at least 120 minutes; wherein said first portion of said micronized particles of alpha-lactose monohydrate is comprised between 40% and

60%, based on the total weight of all of said micronized particles of alpha-lactose monohydrate.

2. The 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 or 2, wherein said first portion of said micronized particles of a physiologically acceptable excipient is 40% to 60%, based on the total weight of all of said micronized particles of a physiologically acceptable excipient.~~

~~4. The process according to any of claims 1 to 3, wherein the LABA is selected from the group consisting of formoterol, salmeterol, indacaterol, olodaterol, and vilanterol.~~

~~5. The process according to any one of claims 1 or 4, wherein the anti-muscarinic drug is selected from the group consisting of glycopyrronium bromide or chloride, tiotropium bromide, umeclidinium bromide,and aclidinium bromide.~~

~~6. The process according to any one of claims 1 to 4, wherein the ICS is selected from the group consisting of beclomethasone dipropionate and its monohydrate form, budesonide, fluticasone propionate, fluticasone furoate, and mometasone furoate.~~

~~7. 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.~~

~~8. 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.~~

~~9. The process according to claim 8, wherein the salt of the fatty acid is magnesium stearate.~~

~~10~~3. The process according to claim 1 or 2~~any one of the preceding claims~~, wherein in step i) the mixing is performed at a speed of rotation comprised between 20 and 28 r.p.m for a time comprised between 60 and 120 minutes.

~~11~~4. The process according to any one of the preceding claims, wherein in step ii) the mixing is performed at a speed of rotation comprised between 16 and 32 r.p.m for a time comprised between 120 and 180 minutes.

5. The process according to any one of the preceding claims, wherein the mass diameter of the coarse particles is comprised between 200 and 400 micron.

6. The process according to claim 5, wherein the mass diameter of the coarse particles is comprised between 210 and 360 micron.

7. The process according to any one of the preceding claims, wherein the first portion of the micronized particles of alpha-lactose monohydrate is comprised between 45% and 55%.

8. The process according to claim 7, wherein the first portion of the micronized particles of alpha-lactose monohydrate is 50%.

9. The process according to any one of the preceding claims, wherein magnesium stearate coats the surface of both the coarse and micronized particles of alpha-lactose monohydrate in such a way as that the extent of the surface coating is at least of 5%.

10. The process according to claim 9, wherein the extent of the surface coating is higher than 10%.