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 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, and 0.1 to 0.4 percent by weight, based on the total weight of said carrier, of magnesium stearate; and

(B) micronized particles of glycopyrronium bromide, formoterol fumarate dihydrate, and beclometasone dipropionate as active ingredients,

said process comprising:

(i) mixing all of said coarse particles of alpha-lactose monohydrate, all of said magnesium stearate, a first portion of said micronized particles of alpha-lactose monohydrate, all of said micronized particles of 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 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 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.

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%.