CLAIMS

1. A dry powder formulation for use in a dry powder inhaler, ~~(DPI)~~ comprising:

(a) a fraction of fine particles made of a mixture comprising~~composed 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, said mixture having a mass median diameter lower than 20 microns;

(b) a fraction of coarse particles comprising~~constituted of~~ a physiologically acceptable excipient having a mass median diameter equal to or higher than 100 microns, wherein the weight ratio between said~~the~~ fine particles and said~~the~~ coarse particles is~~being between~~ 1:99 to~~and~~ 30:70 percent by weight; and

(c1) formoterol fumarate dihydrate in the form of micronized particles;~~combination with~~

(c2) beclometasone dipropionate (BDP) ~~as active ingredient both~~ in the form of micronized particles;

wherein: (i) no more than 10% of said BDP particles (c2) have a volume diameter lower than 0.6 microns;~~,~~ (ii) no more than 50% of said BDP particles (c2) have a volume diameter of~~comprised between~~ 1.5 microns to~~and~~ 2.0 microns; and (iii) at least 90% of said BDP particles (c2) have a volume diameter lower than 4.7 microns,

wherein said BDP particles (c2) are further characterized by a specific surface area of 5.5 to 7.0 m^2/g.

2. A~~The~~ formulation~~,~~ according to claim 1, wherein said BDP particles (c2) have a~~the~~ d(v,0.1) of~~is comprised between~~ 0.8 to~~and~~ 1.0 microns, a~~the~~ d(v,0.5) of~~is comprised between~~ 1.5 to~~and~~ 2.0 microns, ~~the~~ a d(v,0.9) of~~is comprised between~~ 2.5 to~~and~~ 4.7 microns, and a~~the~~ particle size span, defined as [d(v,0.9) – d(v,0.1)]/d(v,0.5) of~~is comprised between~~ 1.2 to~~and~~ 2.2.

3. A~~The~~ formulation according to claim 2, wherein said~~the~~ BDP particles (c2) have a particle size span of~~comprised between~~ 1.3 to~~and~~ 2.1.

~~4. The formulation according to any one claims 1 to 3, wherein the BDP particles are further characterized by a specific surface area comprised between 5.5 and 7.0 m^2/g.~~

4~~5~~. A~~The~~ formulation according to claim 1~~4~~, wherein said BDP particles (c2) are further characterized by a~~the~~ specific surface area of~~is comprised between~~ 5.9 to~~and~~ 6.8 m^2/g.

5~~6~~. A~~The~~ formulation according to ~~any one of the preceding~~ claims 1, wherein the weight ratio of fine particles (a) to~~and~~ coarse particles (b) is ~~comprised between~~ 2:98 to~~and~~ 20:80 percent by weight.

6~~7~~. A~~The~~ formulation according to claim 5~~6~~, wherein said weight~~the~~ ratio is 10:90 percent by weight.

7~~8~~. A~~The~~ formulation according to ~~any of the preceding~~ claims 1, wherein said~~the~~ fraction of fine particles (a) has a mass median diameter equal to or lower than 10 microns.

8~~9~~. A~~The~~ formulation according to ~~any of the preceding~~ claims 1, wherein said~~the~~ coarse particles (b) comprise~~are made of~~ alpha-lactose monohydrate.

910. AThe formulation according to any of the preceding claims 1, wherein saidthe coarse particles (b) have a mass median diameter equal to or greater than 175 microns.

1011. AThe formulation according to claim 910, wherein saidthe mass median diameter is comprised between 212 toand 355 microns.

1112. AThe dry powder formulation for use in a dry powder inhaler, comprisingaccording to claim 1 constituted of:

(a) a fraction of fine particles consistingmade of a mixture consistingcomposed of 98 percent by weight of particles of alpha-lactose monohydrate and 2 percent by weight of magnesium stearate, said mixture having a mass median diameter equal to or lower than 6 microns;

(b) a fraction of coarse particles consistingconstituted of alpha-lactose monohydrate having a mass diameter ofcomprised between 212 toand 355 microns, whereinand the weight ratio between saidthe fine particles and saidthe coarse particles isbeing 10:90 percent by weight; and

(c1) formoterol fumarate dihydrate in the form of micronized particles;combination with

(c2) beclometasone dipropionate (BDP) as active ingredient both in the form of micronized particles;

wherein: (i) no more than 10% of said BDP particles (c2) have a volume diameter lower than 0.7 microns, (ii) no more than 50% of said BDP particles (c2) have a volume diameter ofcomprised between 1.6 microns toand 1.9 microns; and

(iii) at least 90% of said BDP particles (c2) have a volume diameter lower than 4.0 microns,

wherein said BDP particles (c2) are further characterized by a specific surface area of 5.5 to 7.0 m^2/g.

12~~13~~. A dry powder inhaler filled with a~~the~~ dry powder formulation according to~~of~~ claim 1.

~~14. The formulation according to claim 1 for use in the prevention and/or treatment of an inflammatory or obstructive airways disease.~~

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

~~16. Use of the formulation according to claim 1 in the manufacture of a medicament for the prevention and/or treatment of an inflammatory or obstructive airways disease.~~

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

13. A formulation according to claim 1, wherein said micronized particles of formoterol fumarate dehydrate (c1) have a diameter of less than 10 microns.

14. A formulation according to claim 1, wherein said micronized particles of formoterol fumarate dehydrate (c1) have a diameter of less than 6 microns.

15. A formulation according to claim 1, wherein at least 90% of said micronized particles of formoterol fumarate dehydrate (c1) have a volume diameter lower than 5.0 microns.

16. A formulation according to claim 1, wherein said micronized particles of formoterol fumarate dehydrate (c1) have a particle size distribution is such that:

(i) no more than 10% of said particles have a volume diameter lower than 0.8 microns;

(ii) no more than 50% of said particles have a volume diameter lower than 1.7 microns; and

(iii) at least 90% of said particles have a volume diameter lower than 5.0 microns.

17. A formulation according to claim 1, wherein said micronized particles of formoterol fumarate dehydrate (c1) are characterized by a specific surface area of 5 to 7.5 m^2/g.

18. A formulation according to claim 1, wherein said micronized particles of formoterol fumarate dihydrate (c1) are characterized by a specific surface area of 5.2 to 6.5 m^2/g.

19. A formulation according to claim 1, wherein said micronized particles of formoterol fumarate dehydrate (c1) are characterized by a specific surface area of preferably 5.5 to 5.8 m^2/g.