CLAIMS

1. Use of a pharmaceutically acceptable co-suspension in the manufacture of a medicament for use in the treatment of a pulmonary disease or disorder by administration of the co-suspension to the patient twice daily as a respirable aerosol, wherein said pharmaceutically acceptable co-suspension comprises:

a suspension medium comprising a pharmaceutically acceptable propellant,

a first species of respirable active agent particles comprising glycopyrrolate or a pharmaceutically acceptable salt, ester, isomer or solvate thereof,

a second species of respirable active agent particles comprising formoterol or a pharmaceutically acceptable salt, ester, isomer or solvate thereof,

one or more species of respirable suspending particles, wherein the first and second species of respirable active agent particles and the respirable suspending particles co-locate to form a co-suspension within the suspension medium,

wherein a therapeutically effective amount of the glycopyrrolate or pharmaceutically acceptable salt, ester, isomer or solvate thereof and formoterol or pharmaceutically acceptable salt, ester, isomer or solvate thereof, comprising no more than 150 µg of the glycopyrrolate or pharmaceutically acceptable salt, ester, isomer or solvate thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, ester, isomer or solvate thereof, is delivered to the patient at each administration.

2. The use according to claim 1 wherein no more than 100 µg of the glycopyrrolate or pharmaceutically acceptable salt, ester, isomer or solvate thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, ester, isomer or solvate thereof are to be delivered to the patient at each administration.

3. The use according to claim 1 or 2 wherein no more than 80 µg of the glycopyrrolate or pharmaceutically acceptable salt, ester, isomer or solvate thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, ester, isomer or solvate thereof are to be delivered to the patient at each administration.

4. The use according to any preceding claim wherein no more than 50 µg of the glycopyrrolate or pharmaceutically acceptable salt, ester, isomer or solvate thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, ester, isomer or solvate thereof are to be delivered to the patient at each administration.

5. The use according to claim 1 wherein no more than 72 µg of glycopyrrolate is to be delivered to the patient at each administration.

6. The use according to claim 1 wherein no more than 36 µg of glycopyrrolate is to be delivered to the patient at each administration.

7. The use according to any preceding claim, wherein the co-suspension is suitable for delivery from a metered dose inhaler and wherein;

the suspension medium comprises a pharmaceutically acceptable HFA propellant substantially free of additional materials; and

the respirable suspending particles comprise a phospholipid material that is substantially insoluble in the propellant, wherein the total mass of the respirable suspending particles exceeds the total mass of the first and second species of respirable active agent particles.

8. The use according to any preceding claim, wherein the pulmonary disease or disorder is selected from at least one of the group consisting of asthma, COPD, allergic rhinitis, sinusitis, pulmonary vasoconstriction, inflammation, allergies, impeded respiration, respiratory distress syndrome, pulmonary hypertension, pulmonary inflammation experienced with cystic fibrosis, and pulmonary obstruction experienced with cystic fibrosis.

9. The use according to any preceding claim, wherein the pulmonary disease or disorder is COPD.

10. The use according to any preceding claim, wherein the glycopyrrolate is in any crystalline form.

11. The use according to any preceding claim, wherein the formoterol is in any crystalline form.

12. The use according to any preceding claim wherein the ratio of the total mass of the respirable suspending particles to the total mass of the first and second species of respirable active agent particles is from above 1 and up to 200.

13. The use according to claim 12, wherein the ratio of the total mass of the respirable suspending particles to the total mass of the first and second species of respirable active agent particles is selected from the ranges of between 10 and 200, between 60 and 200, between 15 and 60, and between 15 and 170.

14. The use according to any preceding claim, wherein the co-suspension comprises a pharmaceutically acceptable salt of glycopyrrolate selected from fluoride, chloride, bromide, iodide, nitrate, sulfate, phosphate, formate, acetate, trifluoroacetate, propionate, butyrate, lactate, citrate, tartrate, malate, maleate, succinate, benzoate, p-chlorobenzoate, diphenyl-acetate or triphenylacetate, o-hydroxybenzoate, p-hydroxybenzoate, 1 -hydroxynaphthalene-2-carboxylate, 3-hydroxynaphthalene-2-carboxylate, methanesulfonate, and benzenesulfonate salts.

15. The use according to claim 14, wherein the pharmaceutically acceptable salt of glycopyrrolate is selected from fluoride, chloride, bromide, and iodide salts.

16. The use according to any preceding claim, wherein the pharmaceutically acceptable salt of glycopyrrolate is 3-[(cyclopentyl-hydroxyphenylacetyl)oxy]-1,1 -dimethylpyrrolidinium bromide.

17. The use according to any preceding claim, wherein the co-suspension comprises a pharmaceutically acceptable salt of formoterol selected from hydrochloric, hydrobromic, sulfuric, phosphoric, fumaric, maleic, acetic, lactic, citric, tartaric, ascorbic, succinic, glutaric, gluconic, tricarballylic, oleic, benzoic, p-methoxybenzoic, salicylic, o- and p-hydroxybenzoic, p-chlorobenzoic, methanesulfonic, p-toluenesulfonic and 3-hydroxy-2-naphthalene carboxylic acid salts.

18. The use according to claim 17, wherein the pharmaceutically acceptable salt of formoterol is formoterol fumarate.

CLAIMS

1. Use of a pharmaceutically acceptable co-suspension in the manufacture of a medicament for use in the treatment of asthma, COPD, allergic rhinitis, sinusitis, pulmonary vasoconstriction, inflammation, allergies, respiratory distress syndrome, pulmonary hypertension, pulmonary inflammation experienced with cystic fibrosis, or pulmonary obstruction experienced with cystic fibrosis, wherein said pharmaceutically acceptable co-suspension is to be delivered to the patient twice daily as a respirable aerosol, and comprises:

a suspension medium comprising a pharmaceutically acceptable propellant,

a first species of respirable active agent particles comprising glycopyrrolate or a pharmaceutically acceptable salt, or isomer thereof,

a second species of respirable active agent particles comprising formoterol or a pharmaceutically acceptable salt, or isomer thereof,

one or more species of respirable suspending particles, wherein the first and second species of respirable active agent particles and the respirable suspending particles co-locate to form a co-suspension within the suspension medium,

wherein a therapeutically effective amount of the glycopyrrolate or pharmaceutically acceptable salt, or isomer thereof and formoterol or pharmaceutically acceptable salt, or isomer thereof, comprising no more than 150 µg of the glycopyrrolate or pharmaceutically acceptable salt, or isomer thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, or isomer thereof, is to be delivered to the patient at each administration and

wherein administering the co-suspension to the patient results in an increase in FEV_1 of at least 200mL within a period of time selected from 0.5 hours or less, 1 hour or less and 1.5 hours or less.

2. The use according to claim 1 wherein no more than 100 µg of the glycopyrrolate or pharmaceutically acceptable salt, or isomer thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, or isomer thereof are to be delivered to the patient at each administration.

3. The use according to claim 1 or 2 wherein no more than 80 µg of the glycopyrrolate or pharmaceutically acceptable salt, or isomer thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, or isomer thereof are to be delivered to the patient at each administration.

4. The use according to any preceding claim wherein no more than 50 µg of the glycopyrrolate or pharmaceutically acceptable salt, or isomer thereof and no more than 12 µg of the formoterol or pharmaceutically acceptable salt, or isomer

thereof are to be delivered to the patient at each administration.

5. The use according to claim 1 wherein about 72 µg of glycopyrrolate or pharmaceutically acceptable salt or isomer thereof is to be delivered to the patient at each administration.

6. The use according to claim 1 wherein about 36 µg of glycopyrrolate or pharmaceutically acceptable salt or isomer thereof is to be delivered to the patient at each administration.

7. The use according to any preceding claim, wherein the co-suspension is suitable for delivery from a metered dose inhaler and wherein;

the suspension medium comprises a pharmaceutically acceptable HFA propellant substantially free of additional materials; and

the respirable suspending particles comprise a phospholipid material that is substantially insoluble in the propellant, wherein a ratio of the total mass of the respirable suspending particles to the total mass of at least one species of agent particles is selected from above about 1.5, up to about 5, up to about 10, up to about 15, up to about 17, up to about 20, up to about 30, up to about 40, up to about 50, up to about 60, up to about 75, up to about 100, up to about 150, and up to about 200, and

administration of the co-suspension to the patient comprises actuation of the metered dose inhaler.

8. The use according to any preceding claim, wherein the medicament is for use in the treatment of COPD.

9. The use according to any preceding claim, wherein the glycopyrrolate or pharmaceutically acceptable salt or isomer thereof is in any crystalline form.

10. The use according to any preceding claim, wherein the formoterol salt or isomer thereof is in any crystalline form.

11. The use according to any preceding claim wherein the ratio of the total mass of the respirable suspending particles to the total mass of the first and second species of respirable active agent particles is from above 1 and up to 200.

12. The use according to claim 11, wherein the ratio of the total mass of the respirable suspending particles to the total mass of the first and second species of respirable active agent particles is selected from the ranges of between 10 and 200, between 60 and 200, between 15 and 60, and between 15 and 170.

13. The use according to any preceding claim, wherein the co-suspension comprises a pharmaceutically acceptable salt of glycopyrrolate selected from fluoride, chloride, bromide, iodide, nitrate, sulfate, phosphate, formate, acetate, trifluoroacetate, propionate, butyrate, lactate, citrate, tartrate, malate, maleate, succinate, benzoate, p-

chlorobenzoate, diphenyl-acetate or triphenylacetate, o-hydroxybenzoate, p-hydroxybenzoate, 1 -hydroxynaphthalene-2-carboxylate, 3-hydroxynaphthalene-2-carboxylate, methanesulfonate, and benzenesulfonate salts.

14. The use according to claim 13, wherein the pharmaceutically acceptable salt of glycopyrrolate is selected from fluoride, chloride, bromide, and iodide salts.

15. The use according to any preceding claim, wherein the pharmaceutically acceptable salt of glycopyrrolate is 3-[(cyclopentyl-hydroxyphenylacetyl)oxy]-1,1 -dimethylpyrrolidinium bromide.

16. The use according to any preceding claim, wherein the co-suspension comprises a pharmaceutically acceptable salt of formoterol selected from hydrochloric, hydrobromic, sulfuric, phosphoric, fumaric, maleic, acetic, lactic, citric, tartaric, ascorbic, succinic, glutaric, gluconic, tricarballylic, oleic, benzoic, p-methoxybenzoic, salicylic, o- and p-hydroxybenzoic, p-chlorobenzoic, methanesulfonic, p-toluenesulfonic and 3-hydroxy-2-naphthalene carboxylic acid salts.

17. The use according to claim 16, wherein the pharmaceutically acceptable salt of formoterol is formoterol fumarate.

18. The use according to any preceding claim, wherein administering the co-suspension to the patient results in an increase in FEV_1 of at least 250 mL within a period of time selected from 0.5 hours or less, 1 hour or less, and 1.5 hours or less.

19. The use according to any preceding claim, wherein administering the co-suspension to the patient results in an increase in FEV_1 of at least 300 mL within a period of time selected from 0.5 hours or less, 1 hour or less, and 1.5 hours or less.

20. The use according to any preceding claim wherein administering the co-suspension to the patient results in an increase in FEV_1 of at least 100 mL within 0.5 hours or less, and maintained for 12 hours or more.

21. The use according to any preceding claim wherein administering the co-suspension to the patient results in an increase in FEV_1 of at least 150 mL within 0.5 hours or less, and maintained for 12 hours or more.

22. The use according to any preceding claim wherein administering the co-suspension to the patient results in an increase in IC of 200 mL or greater.

23. The use according to any preceding claim wherein administering the co-suspension to the patient results in an increase in IC of 300 mL or greater.

24. The use according to claim 7 and any one of claims 18-23, wherein between about 1 µg and about 10 µg of formoterol is to be delivered to the patient per actuation of the metered dose inhaler.

25. A pharmaceutically acceptable co-suspension for use according to claim 24, wherein between about 2 µg and about 5 µg of formoterol is to be delivered to the patient per actuation of the metered dose inhaler.

26. The use according to claim 1 wherein about 9.6 µg of formoterol or pharmaceutically acceptable salt or isomer thereof is to be delivered to the patient at each administration.