CLAIMS

1. A pharmaceutical composition comprising aclidinium, or a pharmaceutically acceptable salt, in the form of a dry powder in admixture with a pharmaceutically acceptable dry powder carrier, the composition being adapted for use by inhalation in the treatment of asthma and/or chronic obstructive pulmonary disease, and wherein the composition is in a form for delivery at a metered nominal dose of aclidinium equivalent to about 400 µg aclidinium bromide.

2. The pharmaceutical composition according to claim 1, wherein the composition is in the form of a single-dose dry powder formulation comprising a single metered nominal dose of aclidinium equivalent to about 400 micrograms aclidinium bromide.

3. The pharmaceutical composition according to claim 1, wherein the composition is in the form of a multi-dose dry powder formulation for administration in a multi-dose dry powder inhaler device calibrated to provide metered nominal doses of aclidinium equivalent to about 400 micrograms aclidinium bromide.

4. The pharmaceutical composition according to any one of claims 1 to 3, wherein the pharmaceutically acceptable salt of aclidinium is aclidinium bromide.

5. The pharmaceutical composition according to any one of claims 1 to 4, wherein the pharmaceutically acceptable carrier is lactose particles.

6. The pharmaceutical composition according to any one of claims 1 to 5, wherein the ratio by weight of aclidinium to carrier is from 1:25 to 1:75.

7. The pharmaceutical composition according to claim 6 wherein the ratio by weight of aclidinium to carrier is from 1:50 to 1:75.

8. The pharmaceutical composition according to any one of claims 1 to 7, wherein the average particle diameter of the aclidinium is within 2-5 µm.

9. The pharmaceutical composition according to any one of claims 1 to 8, wherein the carrier particles have a d10 of 90 - 160 µm, a d50 of 170 – 270 µm, and d90 of 290 – 400 µm.

10. The pharmaceutical composition according to any one of claims 1 to 9, wherein the pharmaceutical composition further comprises one or more additional active agents, wherein said additional active agents are β2-agonists, PDE IV inhibitors, corticosteroids or a combination thereof.

11. The pharmaceutical composition according to claim 10, wherein the additional active agent is formoterol, salmeterol, budesonide, fluticasone propionate, or a combination thereof, in free or pharmaceutically acceptable salt form.

12. The pharmaceutical composition according to claim 11, wherein the additional active agent is formoterol fumarate in an amount of about 5-25 µg per dose.

13. The pharmaceutical composition according to claim 11, wherein the additional active agent is formoterol fumarate in an amount of about 6 µg per dose.

14. The pharmaceutical composition according to claim 11, wherein the additional active agent is formoterol fumarate in an amount of about 12 µg per dose.

15. Use of aclidinium in free or pharmaceutically acceptable salt form in the treatment of asthma and/or chronic obstructive pulmonary disease in a patient in need of such treatment, said aclidinium being in a form for administration by inhalation once or twice daily of a metered nominal dose of aclidinium equivalent to about 400 µg aclidinium bromide.

16. The use according to claim 15, wherein the aclidinium is in the form of a pharmaceutical composition according to any one of claims 1 to 14.

17. The use according to claim 15 or 16, further comprising the administration of one or more additional active agents, wherein said additional active agents are β2-agonists, PDE IV inhibitors, corticosteroids or a combination thereof.

18. The use according to claim 17, wherein the additional active agent is formoterol, salmeterol, budesonide, fluticasone propionate or a combination thereof, in free or pharmaceutically acceptable salt form.

19. The use according to claim 18, wherein the additional active agent is formoterol fumarate in an amount of about 5-25 µg per dose.

20. The use according to claim 18, wherein the additional active agent is formoterol fumarate in an amount of about 6 µg per dose.

21. The use according to claim 18, wherein the additional active agent is formoterol fumarate in an amount of about 12 µg per dose.

22. Use of aclidinium in free or pharmaceutically acceptable salt form in the manufacture of a medicament for treating asthma and/or chronic obstructive pulmonary disease in a patient in need of such treatment, said medicament being in a form for use by inhalation once or twice daily at a metered nominal dose of aclidinium equivalent to about 400 µg aclidinium bromide.

23. The use according to claim 22, wherein the medicament comprises the pharmaceutical composition according to any one of claims 1 to 14.

24. An inhalable dosage form comprising a dry powder pharmaceutical composition of aclidinium in the form of a dry powder of a pharmaceutically acceptable salt in admixture with a pharmaceutically acceptable dry powder carrier, wherein the dosage form is adapted to deliver a dose of aclidinium equivalent to about 400 µg aclidinium bromide.

25. The dosage form according to claim 24, wherein the pharmaceutical composition of aclidinium is in a form for administration by a powder inhaler device.

26. The dosage form according to claim 25, wherein the inhaler device is adapted to deliver a single-dose of the dry powder pharmaceutical composition in a single metered nominal dose of aclidinium equivalent to about 400 micrograms aclidinium bromide.

27. The dosage form according to claim 25, wherein the inhaler device is adapted to deliver multiple doses of the dry powder pharmaceutical composition, and wherein the inhaler device is calibrated to provide metered nominal doses of aclidinium equivalent to about 400 micrograms aclidinium bromide.

28. The dosage form according to any one of claims 24 to 27, wherein the pharmaceutically acceptable salt of aclidinium is aclidinium bromide.

29. The dosage form according to any one of claims 24 to 28, wherein the pharmaceutically acceptable carrier is lactose particles.

30. The dosage form according to any one of claims 24 to 29, wherein the ratio by weight of aclidinium to carrier is from 1:25 to 1:75.

31. The dosage form according to claim 30, wherein the ratio by weight of aclidinium to carrier is from 1:50 to 1:75.

32. The dosage form according to any one of claims 24 to 31, wherein the average particle diameter of the aclidinium is within 2-5 μm.

33. The dosage form according to any one of claims 24 to 32, wherein the carrier particles have a d10 of 90 - 160 μm, a d50 of 170 – 270 μm, and d90 of 290 – 400 μm.

34. The dosage form according to any one of claims 24 to 33, wherein the pharmaceutical composition further comprises one or more additional active agents, wherein said additional active agents are β2-agonists, PDE IV inhibitors, corticosteroids or a combination thereof.

35. The dosage form according to claim 34, wherein the additional active agent is formoterol, salmeterol, budesonide, fluticasone propionate, or a combination thereof, in free or pharmaceutically acceptable salt form.

36. The dosage form according to claim 35, wherein the additional active agent is formoterol fumarate in an amount of about 5-25 μg per dose.

37. The dosage form according to claim 35, wherein the additional active agent is formoterol fumarate in an amount of about 6 µg per dose.

38. The dosage form according to claim 35, wherein the additional active agent is formoterol fumarate in an amount of about 12 µg per dose.

39. The pharmaceutical composition according to any one of claims 1 to 14, wherein the metered nominal dose of aclidinium is equivalent to 400 µg +/-10% aclidinium bromide.

40. The use according to any one of claims 15 to 23, wherein the metered nominal dose of aclidinium is equivalent to 400 µg +/-10% aclidinium bromide.

41. The dosage form according to any one of claims 24 to 38, wherein the metered nominal dose of aclidinium is equivalent to 400 µg +/-10% aclidinium bromide.

42. A pharmaceutical composition comprising aclidinium, or a pharmaceutically acceptable salt thereof, in the form of a dry powder in admixture with a pharmaceutically acceptable dry powder carrier, the composition being adapted for use by inhalation in the treatment of asthma and/or chronic obstructive pulmonary disease, and wherein the composition is in a form for delivery at an emitted dose of aclidinium equivalent to 360 µg +/- 35% aclidinium bromide.

43. The pharmaceutical composition according to claim 42, wherein the composition is in the form of a single-dose dry powder formulation comprising a single emitted dose of aclidinium equivalent to 360 µg +/- 35% aclidinium bromide.

44. The pharmaceutical composition according to claim 42, wherein the composition is in the form of a multi-dose dry powder formulation for administration in a multidose dry powder inhaler device calibrated to provide emitted doses of aclidinium equivalent to 360 µg +/- 35% aclidinium bromide.

45. The pharmaceutical composition according to any of claims 42 to 44, wherein the pharmaceutically acceptable salt of aclidinium is aclidinium bromide.

46. The pharmaceutical composition according to any of claims 42 to 45, wherein the pharmaceutically acceptable carrier is lactose particles.

47. The pharmaceutical composition according to any one claims 42 to 46, wherein the ratio by weight of aclidinium to carrier is from 1:25 to 1:75.

48. The pharmaceutical composition according to claim 47, wherein the ratio by weight of aclidinium to carrier is from 1:50 to 1:75.

49. The pharmaceutical composition according to any of claims 42 to 48, wherein the average particle diameter of the aclidinium is within 2-5μm.

50. The pharmaceutical composition according to any of claims 42 to 49, wherein the carrier particles have a d10 of 90 - 160 μm, a d50 of 170 – 270 μm, and d90 of 290 – 400 μm.

51. The pharmaceutical composition according to any one of claims 42 to 50, wherein the pharmaceutical composition further comprises an effective amount of one or more additional active agents selected from β2-agonists, PDE IV inhibitors, and corticosteroids.

52. The pharmaceutical composition according to claim 51, wherein the additional active agent is selected from formoterol, salmeterol, budesonide, and fluticasone propionate, in free or pharmaceutically acceptable salt form.

53. The pharmaceutical composition according to claim 52, wherein the additional active agent is formoterol fumarate in an amount of 5-25 μg per nominal dose.

54. The pharmaceutical composition according to claim 52, wherein the additional active agent is formoterol fumarate in an amount of 6 μg per nominal dose.

55. The pharmaceutical composition according to claim 52, wherein (c) the additional active agent is formoterol fumarate in an amount of 12 μg per nominal dose.

56. Use of aclidinium in free or pharmaceutically acceptable salt form in the treatment of asthma and/or chronic obstructive pulmonary disease in a patient in need of such treatment, said aclidinium being in a form for administration by inhalation once or twice daily of an emitted dose of aclidinium equivalent to about 360 µg +/- 35% aclidinium bromide.

57. The use according to claim 56, wherein the aclidinium is in the form of a pharmaceutical composition according to any one of claims 42 to 55.

58. The use according to claim 56 or 57 further comprising the use of one or more additional active agents, wherein the additional active agents are β2-agonists, PDE IV inhibitors, corticosteroids or a combination thereof.

59. The use according to claim 58, wherein the additional active agent is formoterol, salmeterol, budesonide, fluticasone propionate or a combination thereof in free or pharmaceutically acceptable salt form.

60. The use according to claim 59, wherein the additional active agent is formoterol fumarate in an amount of 5-25 µg per nominal dose.

61. The use according to claim 59, wherein the additional active agent is formoterol fumarate in an amount of 6 µg per nominal dose.

62. The use according to claim 59, wherein the additional active agent is formoterol fumarate in an amount of 12 µg per nominal dose.

63. Use of aclidinium in free or pharmaceutically acceptable salt form in the manufacture of a medicament for treating asthma and/or chronic obstructive pulmonary disease in a patient in need of such treatment, said use medicament being in a form for use by inhalation once or twice daily at an emitted dose of aclidinium equivalent to 360 µg +/- 35% aclidinium bromide.

64. The use according to claim 63, wherein the aclidinium is in the form of a pharmaceutical composition according to any one of claims 42 to 55.

65. An inhalable dosage form comprising a dry powder pharmaceutical composition of aclidinium, or a pharmaceutically acceptable salt thereof, in the form of a dry powder of a pharmaceutically acceptable salt in admixture with a pharmaceutically acceptable dry powder carrier, wherein the dosage form is adapted to deliver an emitted dose of aclidinium equivalent to about 360 µg +/- 35% aclidinium bromide.

66. A pharmaceutical composition comprising aclidinium, or a pharmaceutically acceptable salt thereof, in the form of a dry powder in admixture with a pharmaceutically acceptable dry powder carrier, the composition being adapted for use by inhalation in the treatment of asthma and/or chronic obstructive pulmonary disease, and wherein the composition is in a form for delivery at a fine particle dose of aclidinium equivalent to 120 µg +/- 35% aclidinium bromide.

67. The pharmaceutical composition according to claim 66, wherein the composition is in the form of a single-dose dry powder formulation comprising a fine particle dose of aclidinium equivalent to 120 µg +/- 35% aclidinium bromide.

68. The pharmaceutical composition according to claim 66, wherein the composition is in the form of a multi-dose dry powder formulation for administration in a multidose dry powder inhaler device calibrated to provide fine particle doses of aclidinium equivalent to 120 µg +/- 35% aclidinium bromide.

69. The pharmaceutical composition according to any of claims 66 to 68, wherein the pharmaceutically acceptable salt of aclidinium is aclidinium bromide.

70. The pharmaceutical composition according to any of claims 66 to 69, wherein the pharmaceutically acceptable carrier is lactose particles.

71. The pharmaceutical composition according to any one claims 66 to 70, wherein the ratio by weight of aclidinium to carrier is from 1:25 to 1:75.

72. The pharmaceutical composition according to claim 71, wherein the ratio by weight of aclidinium to carrier is from 1:50 to 1:75.

73. The pharmaceutical composition according to any of claims 66 to 71, wherein the average particle diameter of the aclidinium is within 2-5μm.

74. The pharmaceutical composition according to any of claims 66 to 71, wherein the carrier particles have a d10 of 90 - 160 μm, a d50 of 170 – 270 μm, and d90 of 290 – 400 μm.

75. The pharmaceutical composition according to any one of claims 66 to 74, wherein the pharmaceutical composition further comprises an effective amount of one or more additional active agents selected from β2-agonists, PDE IV inhibitors, and corticosteroids.

76. The pharmaceutical composition according to claim 75, wherein the additional active agent is selected from formoterol, salmeterol, budesonide, and fluticasone propionate, in free or pharmaceutically acceptable salt form.

77. The pharmaceutical composition according to claim 76, wherein the additional active agent is formoterol fumarate in an amount of 5-25 μg per nominal dose.

78. The pharmaceutical composition according to claim 76, wherein the additional active agent is formoterol fumarate in an amount of 6 μg per nominal dose.

79. The pharmaceutical composition according to claim 76, wherein (c) the additional active agent is formoterol fumarate in an amount of 12 μg per nominal dose.

80. Use of aclidinium in free or pharmaceutically acceptable salt form in the treatment of asthma and/or chronic obstructive pulmonary disease in a patient in need of such treatment, said aclidinium being in a form for administration by inhalation once or twice daily of a fine particle dose of aclidinium equivalent to 120 μg +/- 35% aclidinium bromide.

81. The use according to claim 80, wherein the aclidinium is in the form of a pharmaceutical composition according to any one of claims 66 to 79.

82. The use according to claim 80 or 81 further comprising the use of one or more additional active agents, wherein the additional active agents are β2-agonists, PDE IV inhibitors, corticosteroids or a combination thereof.

83. The use according to claim 82, wherein the additional active agent is formoterol, salmeterol, budesonide, fluticasone propionate or a combination thereof in free or pharmaceutically acceptable salt form.

84. The use according to claim 83, wherein the additional active agent is formoterol fumarate in an amount of 5-25 µg per nominal dose.

85. The use according to claim 83, wherein the additional active agent is formoterol fumarate in an amount of 6 µg per nominal dose.

86. The use according to claim 83, wherein the additional active agent is formoterol fumarate in an amount of 12 µg per nominal dose.

87. Use of aclidinium in free or pharmaceutically acceptable salt form in the manufacture of a medicament for treating asthma and/or chronic obstructive pulmonary disease in a patient in need of such treatment, said use medicament being in a form for use by inhalation once or twice daily at a fine particle dose of aclidinium equivalent to 120 µg +/- 35% aclidinium bromide.

88. The use according to claim 87, wherein the aclidinium is in the form of a pharmaceutical composition according to any one of claims 66 to 79.

89. An inhalable dosage form comprising a dry powder pharmaceutical composition of aclidinium or a pharmaceutically acceptable salt thereof, in the form of a dry powder in admixture with a pharmaceutically acceptable dry powder carrier, wherein the dosage form is adapted to deliver a fine particle dose of aclidinium equivalent to 120 µg +/- 35% aclidinium bromide.

CLAIMS

1. A pharmaceutical composition for inhalation comprising aclidinium in the form of a dry powder of a pharmaceutically acceptable salt in admixture with a pharmaceutically acceptable dry powder carrier, providing a metered nominal dose of aclidinium equivalent to about 400 μg aclidinium bromide.
2. A pharmaceutical composition according to claim 1, in the form of a single-dose dry powder formulation comprising a single metered nominal dose of aclidinium equivalent to about 400 micrograms aclidinium bromide.
3. A pharmaceutical composition according to claim 1 in the form of a multi-dose dry powder formulation for administration in a mutlidose dry powder inhaler device calibrated to provide a metered nominal dose of aclidinium equivalent to about 400 micrograms aclidinium bromide.
4. The pharmaceutical composition according to any of the preceding claims wherein the pharmaceutically acceptable salt of aclidinium is aclidinium bromide.
5. The pharmaceutical composition according to any of the preceding claims wherein the pharmaceutically acceptable carrier is lactose particles.
6. The pharmaceutical composition according to any of the preceding claims wherein the ratio by weight of aclidinium to carrier is from 1:25 to 1:75.
7. The pharmaceutical composition according to claim 6 wherein the ratio by weight of aclidinium to carrier is from 1:50 to 1:75.
8. The pharmaceutical composition according to any of the preceding claims wherein the average particle diameter of the aclidinium is within 2-5μm.
9. The pharmaceutical composition according to any of the preceding claims wherein the carrier particles have a d10 of 90 - 160 μm, a d50 of 170 – 270 μm, and d90 of 290 – 400 μm.
10. The pharmaceutical composition according to any of the preceding claims further comprising an effective amount of one or more additional active agents selected from β2-agonists, PDE IV inhibitors, and corticosteroids.
11. The pharmaceutical composition according to claim 10 wherein the additional active agent is selected from formoterol, salmeterol, budesonide, and mometasone, in free or pharmaceutically acceptable salt form.

12. The pharmaceutical composition according to claim 11 wherein the additional active agent is formoterol fumarate in an amount of about 5-25 μg per dose.

13. The pharmaceutical composition according to claim 11 wherein the additional active agent is mometasone furoate in an amount of about 100-900 μg per metered nominal dose.

14. A method of treating a respiratory condition selected from asthma and chronic obstructive pulmonary disease in a patient in need of such treatment, comprising administering a single daily metered nominal dose of aclidinium equivalent to about 400 μg aclidinium bromide.

15. A method of treating a respiratory condition selected from asthma and chronic obstructive pulmonary disease in a patient in need of such treatment, comprising administering twice daily a metered nominal dose of aclidinium equivalent to about 400 μg aclidinium bromide.

16. The method of claim 14 or 15 comprising administering a pharmaceutical composition according to any of claims 1-13.

17. The method of any one of claims 14-16 further comprising administering an effective amount of one or more additional active agents selected from β2-agonists, PDE IV inhibitors, and corticosteroids.

18. The method of claim 17 wherein the additional active agent is selected from formoterol, salmeterol, budesonide, and mometasone in free or pharmaceutically acceptable salt form.

19. The method according to claim 18 wherein the additional active agent is formoterol fumarate in an amount of about 5-25 μg per metered nominal dose.

20. The method according to claim 18 wherein the additional active agent is mometasone furoate in an amount of about 100-900 μg per metered nominal dose.

21. The use of aclidinium in free or pharmaceutically acceptable salt form in the manufacture of a medicament for administration in accordance with the method of any of claims 14-20.

22. The use of aclidinium in free or pharmaceuticaly acceptable salt form in the manufacture of a pharmaceutical composition according to any of claims 1-13.

23. Aclidinium in free or pharmaceutically acceptable salt form for use in any of the methods of claims 14-20.

24. The formulation according to any of claims 1-13 for use in any of the methods of claims 14-20.

25. The formulation according to any of claims 1-13 for use in the treatment of a respiratory condition selected from asthma and chronic obstructive pulmonary disease.

26. A multidose dry powder inhaler device calibrated to deliver, upon actuation, a metered nominal dose of aclidinium equivalent to about 400 micrograms of aclidinium bromide.