CLAIMS

1. A pharmaceutical composition deliverable from a metered dose inhaler, the pharmaceutical composition comprising:

a propellant of pharmaceutical grade (1*E*)-1,3,3,3-Tetrafluoro-1-propene (HFO-1234ze(E)) having a purity of at least 99.90%;

a plurality of glycopyrrolate particles;

a plurality of formoterol particles;

a plurality of budesonide particles; and

a plurality of phospholipid particles comprising perforated microstructures.

2. The pharmaceutical composition according to claim 1, further comprising a plurality of roflumilast particles.

3. The pharmaceutical composition according to claim 1 or 2, wherein (i) the glycopyrrolate is present at a concentration in the range of 0.04 mg/mL to 2.25 mg/mL, (ii) the formoterol is present at a concentration in the range of 0.01 mg/mL to 1 mg/mL and/or (iii) the budesonide is present at a concentration in the range of 0.1 mg/mL to 20 mg/mL.

4. The pharmaceutical composition according to any one of claims 1 to 3, wherein the perforated microstructures comprise 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) and calcium chloride.

5. The pharmaceutical composition according to any one of claims 1 to 4, wherein the phospholipid particles are present at a concentration in the range of 0.1 mg/mL to 10 mg/mL.

6. The pharmaceutical composition according to any one of the preceding claims, wherein the glycopyrrolate particles are in the propellant at a concentration sufficient to provide a delivered dose of glycopyrrolate per actuation of the metered dose inhaler

selected from between 5 µg and 50 µg per actuation, between 2 µg and 25 µg per actuation, and between 6 µg and 15 µg per actuation.

7. The pharmaceutical composition according to any one of the preceding claims, wherein the glycopyrrolate particles comprise micronized and crystalline glycopyrronium bromide.

8. The pharmaceutical composition according to any one of the preceding claims, wherein the formoterol particles are included in the composition at a concentration sufficient to provide a delivered dose of formoterol selected from between 1 µg and 30 µg, between 0.5 µg and 10 µg, between 2 µg and 5 µg, between 3 µg and 10 µg, between 5 µg and 10 µg, and between 3 µg and 30 µg per actuation of the metered dose inhaler.

9. The pharmaceutical composition according to any one of the preceding claims, wherein the formoterol particles comprise formoterol fumarate.

10. The pharmaceutical composition according to any one of the preceding claims, wherein the budesonide particles are included in the composition at a concentration sufficient to provide a delivered dose of budesonide selected from between 50 µg and 400 µg, between 20 µg and 600 µg, between 30 µg and 100 µg, between 50 µg and 200 µg, and between 150 µg and 350 µg per actuation of the metered dose inhaler.

11. The pharmaceutical composition according to any one of the preceding claims, wherein the budesonide particles comprise micronized budesonide.

12. The pharmaceutical composition according to any one of the preceding claims, wherein the phospholipid particles are included in the composition at a concentration sufficient to provide a delivered dose of the phospholipid particles selected from between 50 µg and 400 µg.

13. A metered dose inhaler comprising a canister with an outlet valve including an actuator for dispensing a metered amount of a pharmaceutical composition according to any one of the preceding claims, wherein the canister contains the pharmaceutical composition.

14. The metered dose inhaler according to claim 13, wherein the outlet valve comprises a neck gasket and at least one seat gasket; and the neck gasket or the at least one seat gasket is composed of bromobutyl material.

15. The metered dose inhaler according to claim 13 or 14, exhibiting less than 10%, 9%, 8%, 7%, 6%, or 5% reduced shot weight per actuation throughout emptying of the canister and/or exhibiting less than 1.0%, 0.5%, 0.4%, 0.3%, 0.2%, or 0.1% weight loss at 25°C/60% RH per year.

16. The metered dose inhaler according to any one of claims 13 to 15, which exhibits a delivered dose uniformity (DDU) for the pharmaceutical formulation selected from a DDU of ± 20%, or better, a DDU of ± 15%, or better, and a DDU of ± 10%, or better, throughout emptying of the canister.

17. A pharmaceutical composition according to any one of claims 1 to 12 for use in the treatment of a pulmonary disease or disorder.

18. The pharmaceutical composition for use according to claim 17, wherein the treatment comprises a method of treating a pulmonary disease or disorder in a patient, the method comprising administering the pharmaceutical composition to the patient by actuating a metered dose inhaler; wherein the metered dose inhaler contains the pharmaceutical composition.

19. The pharmaceutical composition for use according to claim 17 or 18, wherein the pulmonary disease or disorder is asthma or COPD.

20. The pharmaceutical composition for use according to any one of claims 17 to 19, wherein the metered dose inhaler is described according to any one of claims 13 to 16.

21. The pharmaceutical composition according to claim 9, wherein the formoterol particles comprise micronized and crystalline formoterol fumarate.