

Claims

1. A dry powder inhaler comprising:
a dry powder medicament comprising fluticasone propionate, salmeterol xinafoate and a lactose carrier;
- 5 wherein, the delivered dose of salmeterol per actuation is less than 50 µg; and
wherein the dose provides a baseline-adjusted Forced Expiratory Volume in the first second (FEV₁) in a patient of more than 150 mL within 30 minutes of receiving the dose.
2. The inhaler as claimed in claim 1, wherein the baseline-adjusted FEV₁ remains above 150 mL for at least 6 hours after receiving the dose.
- 10 3. The inhaler as claimed in claims 1 or 2, wherein the dose of salmeterol is less than 25 µg.
4. The inhaler as claimed in claim 3, wherein the doses of fluticasone/salmeterol in µg are 500/12.5, 400/12.5, 250/12.5, 200/12.5, 100/12.5, 50/12.5 or 25/12.5 per actuation.
5. The inhaler as claimed in any preceding claim, wherein the particle size of the
15 fluticasone propionate is d₁₀ = 0.4-1.1 µm, d₅₀ = 1.1-3.0 µm, d₉₀ = 2.6-7.5 µm and not less than (NLT)95% <10 µm, measured by laser diffraction as an aqueous dispersion.
6. The inhaler as claimed in any preceding claim, wherein the particle size of the salmeterol xinafoate is d₁₀ = 0.4-1.3 µm, d₅₀ = 1.4-3.0 µm, d₉₀ = 2.4-6.5 µm and NLT95% <10 µm, measured by laser diffraction as an aqueous dispersion.
- 20 7. The inhaler as claimed in any preceding claim, wherein the lactose carrier is composed of a coarse lactose and fine lactose, wherein the fine lactose is defined by a particle size of <10 µm, measured by laser diffraction as a dispersion in air.
8. The inhaler as claimed in claim 7, wherein the lactose contains 1-10 wt% of fine lactose.
- 25 9. The inhaler as claimed in any preceding claim, wherein the lactose particle size is d₁₀ = 15-50 µm, d₅₀ = 80-120 µm, d₉₀ = 120-200 µm.
10. The inhaler as claimed in any preceding claim, wherein the inhaler comprises a cyclone deagglomerator for breaking up agglomerates of the dry powder.
11. The inhaler as claimed in claim 10, wherein the deagglomerator comprises:
30 an inner wall defining a swirl chamber extending along an axis from a first end to a second end;
a dry powder supply port in the first end of the swirl chamber for providing fluid communication between a dry powder delivery passageway of the inhaler and the first end of the swirl chamber;

at least one inlet port in the inner wall of the swirl chamber adjacent to the first end of the swirl chamber providing fluid communication between a region exterior to the deagglomerator and the first end of the swirl chamber;

an outlet port providing fluid communication between the second end of the swirl chamber and a region exterior to the deagglomerator; and

vanes at the first end of the swirl chamber extending at least in part radially outwardly from the axis of the chamber, each of the vanes having an oblique surface facing at least in part in a direction transverse to the axis; whereby a breath induced low pressure at the outlet port causes air flows into the swirl chamber through the dry powder supply port and the inlet port.

12. The inhaler as claimed in any preceding claim, wherein the inhaler comprises a reservoir for containing the medicament and an arrangement for delivering a metered dose of the medicament from the reservoir.

13. The inhaler as claimed in any preceding claim, wherein the inhaler comprises a delivery passageway for directing an inhalation-induced air flow through a mouthpiece, a channel extending from the delivery passageway to the medicament.

14. The inhaler as claimed in any of the preceding claims, comprising:
a sealed reservoir including a dispensing port;

a channel communicating with the dispensing port and including a pressure relief port;

a conduit providing fluid communication between an interior of the sealed reservoir and the pressure relief port of the channel; and

a cup assembly movably received in the channel and including, a recess adapted to receive medicament when aligned with the dispensing port, a first sealing surface adapted to seal the dispensing port when the recess is unaligned with the dispensing port, and a second sealing surface adapted to sealing the pressure relief port when the recess is aligned with the dispensing port and unseal the pressure relief port when the recess is unaligned with the dispensing port.

15. The inhaler as claimed in any preceding claim for use the treatment of asthma or COPD.

16. Use of a dry powder medicament in the manufacture of a medicament for treatment of asthma or allergic rhinitis or COPD comprising fluticasone propionate, salmeterol xinafoate and a lactose carrier; wherein, the medicament is to be delivered at a dose of salmeterol per actuation is less than 50 µg; and wherein the dose provides a baseline-adjusted FEV₁ in a patient of more than 150 mL within 30 minutes of receiving the dose.

17. The use as claimed in claim 16, wherein the dose of salmeterol is less than 25 µg.

18. The use as claimed in claim 16, wherein the dose of fluticasone/salmeterol in μg is 500/12.5, 400/12.5, 250/12.5, 200/12.5, 100/12.5, 50/12.5 or 25/12.5 per actuation.