Claims

1. A pharmaceutical aerosol solution formulation intended for use in a pressurised metered dose inhaler comprising:

(a) glycopyrronium bromide at a dosage in the range of from 5 to 26 μg per actuation;

(b) formoterol or a salt or a solvate thereof, at a dosage in the range of from 1 to 25 μg per actuation;

(c) a HFA propellant;

(d) a co-solvent;

(e) a mineral acid; and optionally

(f) an inhalation corticosteroid

said formulation being contained in an aerosol can made of stainless steel wherein the stainless steel grade is selected from 904L, 316, 316L, 305, 304, 304L, 6Mo and 2205.

2. The pharmaceutical aerosol solution formulation according to claim 1, wherein the stainless steel grade is selected from 904L and 316L.

3. The pharmaceutical aerosol solution formulation according to claim 1 or 2, wherein said glycopyrronium bromide is present in an amount from 6 to 25 μg per actuation.

4. The pharmaceutical aerosol solution formulation according to any one of claims 1 to 3, wherein said formoterol, or a salt or a solvate thereof is present in an amount from 6 to 12 μg per actuation.

5. The pharmaceutical aerosol solution formulation according to any one of claims 1 to 4, wherein the HFA propellant is HFA 134a, HFA 227, HFA 152a or a mixture

thereof.

6. The pharmaceutical aerosol solution formulation according to any one of claims 1 to 5, wherein the co-solvent is a (C_1-C_4) alkyl alcohol.

7. The pharmaceutical aerosol solution formulation according to claim 6, wherein the co-solvent is ethanol in a concentration suitable to completely dissolve the active ingredients in the formulation.

8. The pharmaceutical aerosol solution formulation according to claim 7, wherein ethanol is anhydrous ethanol at a concentration comprised from 5 to 30% w/w on the total weight of the formulation.

9. The pharmaceutical aerosol solution formulation according to any one of claims 1 to 8, wherein the mineral acid is a pharmaceutically acceptable monoprotic or polyprotic acid.

10. The pharmaceutical aerosol solution formulation according to claim 9, wherein the mineral acid is hydrochloric acid.

11. The pharmaceutical aerosol solution formulation according to claim 10, wherein the mineral acid is 1M hydrochloric acid in an amount in the range from 0.1 to 0.3 μg/μl of formulation.

12. The pharmaceutical aerosol solution formulation according to any one of claims 1 to 11, wherein the formoterol salt is formoterol fumarate.

13. The pharmaceutical aerosol solution formulation according to any one of claims 1 to 12, wherein the solvate form of the formoterol salt is formoterol fumarate dihydrate.

14. The pharmaceutical aerosol solution formulation according to any one of claims 1

to 13, wherein the inhalation corticosteroid is selected from the group of beclometasone dipropionate, budesonide or its 22R-epimer, ciclesonide, flunisolide, fluticasone propionate, fluticasone furoate, mometasone furoate, butixocort, triamcinolone acetonide, triamcinolone, methylprednisolone, prednisone, loteprednol and rofleponide.

15. The pharmaceutical aerosol solution formulation according to claim 14 wherein the inhalation corticosteroid is beclometasone dipropionate.

16. The pharmaceutical aerosol solution formulation according to claim 15, wherein the beclometasone dipropionate is present in an amount in the range from 50 to 250 μg per actuation.

17. The pharmaceutical aerosol solution formulation according to claim 16, wherein the beclometasone dipropionate is present in the amount of 100 or 200 μg per actuation.

18. An aerosol can made of stainless steel of a grade selected from 904L, 316, 316L, 305, 304, 304L, 6Mo and 2205, containing a pharmaceutical aerosol solution formulation according to any one of claims 1 to 17, intended for use in a pressurised metered dose inhaler.

19. A pressurised metered dose inhaler comprising a can according to claim 18.

20. A method to lower the amount of degradation product N-(3-bromo)-[2-hydroxy-5-[1-hydroxy-2-[1-(4-methoxyphenyl)propan-2-ylamino]ethyl]phenyl]formamide (DP3) during the shelf-life of a pharmaceutical aerosol solution formulation intended for use in a pressurised metered dose inhaler according to any one of claims 1 to 17, said method being characterised in containing said aerosol solution formulation in an aerosol can made of stainless steel.

21. Use of a stainless steel can to lower the amount of degradation product N-(3-bromo)-[2-hydroxy-5-[1-hydroxy-2-[1-(4-methoxyphenyl)propan-2-ylamino]ethyl]phenyl]formamide (DP3) during the shelf-life of a pharmaceutical aerosol solution formulation as defined in claims 1 to 17.