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.

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

3. The pharmaceutical aerosol solution formulation according to claim 1 or 2, wherein said formoterol, or a salt or a solvate thereof is present in an amount from 6 to 12 μg per actuation.

4. The pharmaceutical aerosol solution formulation according to any one of the preceding claims wherein the HFA propellant is HFA134a, HFA 227, HFA152a or a mixture thereof.

5. The pharmaceutical aerosol solution formulation according to any one of the preceding claims, wherein the co-solvent is a (C1-C4) alkyl alcohol.

6. The pharmaceutical aerosol solution formulation according to claim 5, wherein the co-solvent is ethanol in a concentration suitable to completely dissolve the active ingredients in the formulation.

7. The pharmaceutical aerosol solution formulation according to claim 6, wherein ethanol is anhydrous ethanol at a concentration comprised from 5 to 30% w/w on the total weight of the formulation.

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

9. The pharmaceutical aerosol solution formulation according to claim 8, wherein the mineral acid is hydrochloric acid.

10. The pharmaceutical aerosol solution formulation according to claim 9, wherein the mineral acid is 1M hydrochloric acid in an amount in the range from 0.1 to 0.3 μg/μl of formulation.

11. A pharmaceutical aerosol solution formulation according to any one of the preceding claims, characterised in that the amount of the degradation product N-(3-

bromo)-[2-hydroxy-5-[1-hydroxy-2-[1-(4-methoxyphenyl)propan-2-ylamino]ethyl]phenyl] formamide is lower than 0.10% w/w with respect to the theoretical formoterol fumarate content of 6 μg/actuation when stored in accelerated conditions at 25°C and 60% relative humidity (RH) for at least 3 months.

12. A pharmaceutical aerosol solution formulation according to any one of the preceding claims, wherein the formoterol salt is formoterol fumarate.

13. A pharmaceutical aerosol solution formulation according to any one of the preceding claims wherein the solvate form of the formoterol salt is formoterol fumarate dihydrate.

14. A pharmaceutical aerosol solution formulation according to any one of the preceding claims 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. A pharmaceutical aerosol solution formulation according to claim 14 wherein the inhalation corticosteroid is beclometasone dipropionate.

16. A 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. A 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. A pharmaceutical aerosol solution formulation according to any one of the preceding claims wherein the overall formoterol degradation products level is lower than 10% w/w with respect to the theoretical formoterol fumarate content of 6 µg/actuation and the residual level of formoterol fumarate is higher than 90% w/w with respect to its initial content.

19. A pharmaceutical aerosol solution formulation according to any one of the preceding claims wherein the overall formoterol degradation products level is lower than 2% w/w with respect to the theoretical formoterol fumarate content of 6 µg/actuation and the residual level of the formoterol fumarate is higher than 95% w/w with respect to its initial content.

20. An aerosol can made of stainless steel containing a pharmaceutical aerosol solution formulation according to any one of claims 1 to 19, intended for use in a pressurised metered dose inhaler.

21. A pressurised metered dose inhaler comprising a can according to claim 20.

22. 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 19, said method being characterised in containing said aerosol solution formulation in an aerosol can made of stainless steel.