CLAIMS

1. A pharmaceutical aerosol solution composition 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 thereof or a solvate of said salt, at a dosage in the range of from 1 to 25 μg per actuation;

(c) a HFA propellant;

(d) a co-solvent;

(e) a stabilising amount of a mineral acid;

said composition being contained in an aerosol can provided with a metering valve having at least a butyl rubber gasket.

2. A pharmaceutical aerosol solution composition according to claim 1 **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 6 months.

3. A pharmaceutical aerosol solution composition according to claim 1 or 2 wherein the stabilising amount of a mineral acid is an amount of acid equivalent to 1M hydrochloric acid in the range from 0.15 to 0.28 μg/μl.

4. A pharmaceutical aerosol solution composition according to claim 3 wherein a mineral acid is an amount of acid equivalent to 0.22 μg/μl of 1M hydrochloric acid.

5. A pharmaceutical aerosol solution composition according to any one of claims 1 to 4 wherein the co-solvent is ethanol.

6. A pharmaceutical aerosol solution composition according to claim 1 wherein the formoterol salt is formoterol fumarate.

7. A pharmaceutical aerosol solution composition according to claim 1 wherein the solvate form of the formoterol salt is formoterol fumarate dihydrate.

8. A pharmaceutical aerosol solution composition according to claim 1 further comprising one or more pharmaceutically active ingredient selected from the group consisting of beta-2 agonists, inhalation corticosteroids, antimuscarinic agents, and phosphodiesterase-4 inhibitors.

9. A pharmaceutical aerosol solution composition according to claim 8 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, methyl-prednisolone, prednisone, loteprednol and rofleponide.

10. A pharmaceutical aerosol solution composition according to claim 9 wherein the inhalation corticosteroid beclometasone dipropionate is present in an amount in the range from 50 to 250 μg per actuation.

11. A pharmaceutical aerosol solution composition according to claim 9 wherein the inhalation corticosteroid budesonide is present in an amount in the range from 50 to 250 μg per actuation.

12. A pharmaceutical aerosol solution composition according to claim 1 wherein the 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.

13. A pharmaceutical aerosol solution composition according to claim 12 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.

14. A pressurised metered dose inhaler including an aerosol can provided with a metering valve having at least a butyl rubber gasket, said can containing a pharmaceutical aerosol solution composition comprising:

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

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

(c) a HFA propellant;

(d) a co-solvent;

(e) a stabilising amount of a mineral acid; and, optionally,

(f) an inhalation corticosteroid.

15. 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 composition 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 thereof or a solvate of said salt, at a dosage in the range of from 1 to 25 μg per actuation;

(c) a HFA propellant;

(d) a co-solvent;

(e) a stabilising amount of a mineral acid; and, optionally,

(f) an inhalation corticosteroid

said method comprises containing the above composition in an aerosol can provided with a metering valve having at least a butyl rubber gasket.

16. A method according to claim 15 further **characterised by** the fact that the overall formoterol degradation products level 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.

17. A method according to claim 15 or 16 further **characterised by** the fact that 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.

18. A pharmaceutical aerosol solution composition as defined in any one of claims 1 to 13 for use in the prevention and/or treatment of an obstructive respiratory disorder selected from asthma and COPD.