ylamino]ethyl]phenyl]formamide, hereinafter shortly referred to as DP3, is lower than 0.10% w/w with respect to the theoretical formoterol fumarate content of 6 μg/actuation, which is the limit of quantification, when stored in accelerated conditions at 25°C and 60% relative humidity (RH) for at least 63 months.

Optionally, the composition further comprises an inhalation corticosteroid selected from the group consisting of beclometasone dipropionate, mometasone furoate, budesonide, flunisolide, fluticasone propionate, fluticasone furoate, ciclesonide, triamcinolone, triamcinolone acetonide, methylprednisolone and prednisone.

In another aspect, the invention provides an aerosol can provided with a metering valve having at least a butyl rubber gasket for use with 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.

In yet another aspect the invention provides 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;

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 63 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.

theoretical formoterol fumarate content of 6μg/actuation and the residual level of the formoterol fumarate is higher than 95% w/w with respect to its initial content.

18. A~~Use of 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.

19. Use of a pharmaceutical aerosol solution composition as defined in any one of claims 1 to 13 in the manufacture of a medicament for the prevention and/or treatment of an obstructive respiratory disorder selected from asthma and COPD.