ABSTRACT

STABLE PRESSURISED AEROSOL SOLUTION COMPOSITION OF GLYCOPYRRONIUM BROMIDE AND FORMOTEROL COMBINATION

The invention concerns an aerosol solution composition intended for use with a pressurised metered dose inhaler, comprising glycopyrronium bromide and formoterol, or a salt thereof, optionally in combination with one or more additional active ingredient, stabilised by a selected amount of a mineral acid and wherein 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 the limit of quantification, when stored in accelerated conditions at 25°C and 60% relative humidity (RH) for at least 63 months in an aerosol can provided with a metering valve having at least a butyl rubber gasket. The optional one or more active ingredient may be an inhalation corticosteroid selected from beclometasone dipropionate, budesonide or its 22R-epimer, ciclesonide, flunisolide, fluticasone propionate, fluticasone furoate, mometasone furoate, etc.