formulations which include a co-solvent for the active ingredient. The co-solvent is generally present in order to solubilise the active ingredient and the precise nature of the co-solvent will therefore depend on the nature of the active ingredient. However, the co-solvent is preferably a C_{2-6} aliphatic alcohol, such as ethanol or propylene glycol, and preferably ethanol. When required, the co-solvent is present in an amount sufficient to dissolve substantially all of the medicament present in the formulation and to maintain the medicament dissolved over the time period and conditions experienced by commercial aerosol products. Preferably the solvent is present in an amount to prevent precipitation of the active ingredient even at temperatures down to -20°C. The solvent is preferably anhydrous, although trace amounts of water absorbed by the ingredients, for example during manufacture of the medicament, may be tolerated. Anhydrous ethanol is particularly preferred. The co-solvent, preferably ethanol, is typically present at 1-20% w/w, more preferably 6-15% w/w and most preferably about 8% w/w, based on the total weight of the formulation.

In various embodiments, the nasal spray device may additionally comprise a co-solvent which is present at 0.5 to 20% w/w, based on the total weight of the pharmaceutical formulation.

In a specific embodiment of the present invention, the pharmaceutical formulation comprises beclomethasone dipropionate, ethanol and a propellant selected from 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227) and a mixture thereof. This formulation is typically used for the prophylaxis and/or treatment of seasonal allergic rhinitis (including hay fever) and perennial rhinitis. The active ingredient beclomethasone dipropionate is generally present in a formulation of the present invention in a therapeutically effective amount, i.e. an amount such that metered volumes of the medicament administered to the patient contains an amount of drug effective to exert the intended therapeutic action. The aerosol formulation preferably contains 0.02% to 0.6% w/w, more preferably 0.05% to 0.5% w/w of beclomethasone dipropionate, based on the total weight of the formulation.

A preferred formulation according to the present invention comprises 0.02% to 0.6% w/w beclomethasone dipropionate, 1% to 20% w/w ethanol and 80 to 99% w/w of propellant, wherein the percentages by weight are based on the total weight of the aerosol. A particularly preferred formulation consists essentially of beclomethasone dipropionate, ethanol and a propellant selected from 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof; more preferably the formulation consists of these components.

The pharmaceutical formulation of the present invention is preferably substantially free of surfactant. Surfactants are often added to suspensions to stabilise the suspension. However, when the formulation of the present invention is a solution, a surfactant is not required. Nevertheless, small quantities can be tolerated without adversely affecting the formulation. Preferably the formulation contains no more than 0.0005% w/w of a surfactant

Claims

1. A nasal spray device for the delivery of a pharmaceutical formulation to the nasal cavity in metered doses, the device comprising:
a pressurised aerosol canister including a vial containing a pharmaceutical formulation comprising an active ingredient, and a propellant ~~and, optionally, a co-solvent~~, the aerosol canister further including a metering valve having a valve stem; and
an actuator for the aerosol canister, the actuator including a stem block having a receptacle into which the valve stem of metering valve of the aerosol canister is received and axially located and being displaceable relative to the vial of the aerosol canister to actuate the metering valve of the aerosol canister, a sump extending below the receptacle, the stem block further defining a discharge orifice for the pharmaceutical formulation and a transfer channel through which a dispensed dose of the pharmaceutical formulation is able to pass from the sump to the discharge orifice,
wherein the actuator further comprises a delivery outlet for the aerosol plume, the discharge orifice being arranged to direct the aerosol plume through the delivery outlet, and wherein the device is adapted to produce an aerosol plume for a dispensed dose having a spray force value no greater than 40 mN measured at a distance of 30 mm from the discharge orifice.

2. A nasal spray device as claimed in claim 1, wherein the discharge orifice has a diameter of 0.15 to 0.65 mm.

3. A nasal spray device as claimed in claim 1 or 2, wherein the maximum transverse dimension of the transfer channel is greater than the diameter of the discharge orifice.

4. A nasal spray device as claimed in any preceding claim, wherein the maximum transverse dimension of the transfer channel is from 1.0 to 3.0 mm.

5. A nasal spray device as claimed in any preceding claim, wherein the transfer channel has a circular cross-section.

6. A nasal spray device as claimed in any preceding claim, wherein the transfer channel has a transverse dimension which tapers down towards the discharge orifice end.

7. A nasal spray device as claimed in any preceding claim, wherein the transfer channel has a length of 3 to 20 mm.

8. A nasal spray device as claimed in any preceding claim, wherein the discharge orifice has a length of 0.5 to 1.0 mm.

9. A nasal spray device as claimed in any preceding claim, wherein the transfer channel has a first part in fluid communication with the sump of the stem block and a second part in fluid communication with the discharge orifice, the second part and the discharge orifice being defined by a separate insert received into an opening formed in the stem block of the actuator.

10. A nasal spray device as claimed in any preceding claim, wherein the discharge orifice has a diameter of 0.15 to 0.65 mm and a length of 0.5 to 1.0 mm, and wherein the transfer channel has a transverse dimension which tapers down towards the discharge orifice end.

11. A nasal spray device as claimed in any preceding claim, ~~wherein the~~additionally comprising a co-solvent which is present at 0.5 to 20% w/w, based on the total weight of the pharmaceutical formulation.

12. A nasal spray device as claimed in any preceding claim, wherein the active ingredient is beclomethasone dipropionate, the propellant is selected from P134a, P227 or mixtures thereof, or other suitable pressurised gases, and the co-solvent is present and is anhydrous ethanol.

~~13. Use of a nasal spray device according to any one of the preceding claims for the delivery of a pharmaceutical formulation to the nasal cavity in metered doses.~~

~~14~~13. A nasal spray device as claimed in claim 1, wherein the pharmaceutical formulation is a solution formulation.

~~15~~14. A nasal spray device as claimed in claim 1, wherein the pharmaceutical formulation is a suspension formulation.