CLAIMS

1. An aqueous pharmaceutical formulation comprising dexamethasone and a concentration of equal to or less than 0.1 mg/ml of a preservative, wherein the formulation is packaged in a container with a headspace volume (ml) to dexamethasone content (mg) ratio of 0.0065 or less.

2. The aqueous pharmaceutical formulation of claim 1, wherein the concentration of dexamethasone is at least 24 mg/ml.

3. The aqueous pharmaceutical formulation of any preceding claim, wherein the preservative is an antioxidant and / or antimicrobial preservative.

4. The aqueous pharmaceutical formulation of any preceding claim, wherein:
(i) the headspace volume (ml) to dexamethasone content (mg) ratio is 0.0060 or less;
(ii) the headspace volume (ml) to dexamethasone content (mg) ratio is 0.00588 or less;
(iii) the headspace volume comprises less than 21 % oxygen; and / or
(iv) the headspace volume comprises less than 10 % oxygen.

5. The aqueous pharmaceutical formulation of any preceding claim, wherein the concentration of preservative is or is less than 0.035 mg/ml.

6. The aqueous pharmaceutical formulation of any preceding claim, wherein the preservative is a sulfite, a paraben, benzyl alcohol, benzethonium chloride, propylene glycol, and / or creatinine.

7. The aqueous pharmaceutical formulation of claim 6, wherein the sulfite is sodium sulfite (anhydrous), sodium bisulfite, and / or sodium metabisulfite.

8. The aqueous pharmaceutical formulation of any preceding claim, wherein the formulation does not comprise a preservative.

9. The aqueous pharmaceutical formulation of any preceding claim, wherein the formulation does not comprise a chelating agent.

10. The aqueous pharmaceutical formulation of any preceding claim, wherein:

(i) the dexamethasone is selected from the group consisting of dexamethasone base, dexamethasone sodium phosphate and dexamethasone acetate; and / or

(ii) the dexamethasone is dexamethasone sodium phosphate.

11. The aqueous pharmaceutical formulation of any preceding claim, wherein:

(i) the shelf-life of the formulation is at least 18, 24, 36, or 48 months when stored between 2°C to 40°C;

(ii) the formulation remains stable when stored between 2°C to 40°C for at least 18, 24, 36, or 48 months;

(iii) the amount of dexamethasone in the formulation is maintained between ± 5.0 % as compared to the date of manufacture when the formulation is stored between 2°C to 40°C for at least 18, 24, 36, or 48 months; and / or

(iv) the formulation exhibits less than ± 0.5 change in pH when stored between 2°C to 40°C for at least 18, 24, 36, or 48 months.

12. The aqueous pharmaceutical formulation of any preceding claim, wherein the dexamethasone is dexamethasone sodium phosphate and:

(i) the formulation exhibits less than 0.50 % accumulation of impurity A when stored between 2°C to 40°C for at least 18, 24, 36, or 48 months;

(ii) the formulation exhibits less than 0.50 % accumulation of impurity B when stored between 2°C to 40°C for at least 18, 24, 36, or 48 months;

(iii) the formulation exhibits less than 0.50 % accumulation of impurity G when stored between 2°C to 40°C for at least 18, 24, 36, or 48 months;

(iv) the formulation exhibits less than 0.20 % accumulation of unspecified impurities when stored between 2°C to 40°C for at least 18, 24, 36, or 48 months; and / or

(v) the formulation exhibits less than 3.0 % accumulation of total impurities when stored between 2°C to 40°C for at least 18, 24, 36, or 48 months.

13. An aqueous pharmaceutical formulation of any preceding claim for use in therapy.

14. A method for stabilising an aqueous pharmaceutical formulation comprising dexamethasone and a preservative, the method comprising packaging the aqueous pharmaceutical formulation of any preceding claim into a container with a headspace volume (ml) to dexamethasone content (mg) ratio of 0.0065 or less,

wherein the concentration of preservative is or is less than 0.1 mg/ml.

15. The method of claim 14, wherein the preservative is an antioxidant and / or antimicrobial preservative.