CLAIMS

1. An aqueous pharmaceutical formulation comprising dexamethasone and apreservative, wherein the formulation is packaged in a container with a headspace volume (ml) to dexamethasone content (mg) ratio of 0.007 or less, and wherein the concentration of preservative is or is less than about 0.1 mg/ml.

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 0.00588 or less; and / or

(ii) the headspace volume comprises less than about 10 % oxygen, more preferably less than about 5 % oxygen.

5. The aqueous pharmaceutical formulation of any preceding claim, wherein the concentration of preservative is or is less than about 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 any preceding claim, wherein the sulfite is sodium sulfite (anhydrous), sodium bisulfite, and / or sodium metabisulfite.

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

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

(i) the formulation comprises one or more chelating agent, wherein the concentration of chelating agent is or is less than about 0.50 mg/ml;

(ii) the chelating agent is disodium edetate (disodium EDTA); and / or

(iii) 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 about 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 about 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 about 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 about 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 about 0.50 % accumulation of impurity A when stored between 2°C to 40°C for at least about 18, 24, 36, or 48 months;

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

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

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

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

13. An aqueous pharmaceutical formulation comprising dexamethasone and a preservative, wherein the formulation is packaged in a container, and wherein the concentration of dexamethasone is at least about 24 mg/ml, and the concentration of preservative is less than about 0.1 mg/ml.

14. The aqueous pharmaceutical formulation of claim 13, wherein the preservative is an antioxidant and / or antimicrobial preservative.

15. The aqueous pharmaceutical formulation of claim 13, wherein the concentration of preservative is or is less than about 0.035 mg/ml.

16. The aqueous pharmaceutical formulation of claim 13, wherein the formulation does not comprise a preservative.

17. The aqueous pharmaceutical formulation of any one of claims 13 to 16, wherein:

(i) the formulation comprises one or more chelating agent, wherein the concentration of chelating agent is or is less than about 0.50 mg/ml; or

(ii) the formulation does not comprise a chelating agent.

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

19. 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 0.007 or less,

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

20. The method of claim 19, wherein the preservative is an antioxidant and / or antimicrobial preservative.

Basis / Support

The proposed claims finrd basis / support in the application as filed, for example at the following locations:

New Claims	**Original Claims**
1	1
2	2
3	Paragraph [0015] of the application as filed
4	3-4
5	5
6	6
7	7
8	8
9	9-11
10	12-13
11	14-17
12	18-22
13	23, together with, for example, paragraphs [[0030], [0032], [0156]-[0158], and [0202] (which make clear that the formulations of the invention are packaged formulations in a container) of the application as filed
14	Paragraph [0015] of the application as filed
15	24
16	25
17	26
18	28
19	30
20	Paragraph [0015] of the application as filed