CLAIMS

1. Method for stabilizing the pH of an aqueous composition comprising a drug, said method comprising the addition of an additive to prevent oxidation of the drug.

2. Method according to claim 1, wherein the aqueous composition comprises cyclodextrin, preferably gamma-cyclodextrin.

3. Method according to claim 1 or 2, wherein the drug is a corticosteroid.

4. Method according to claim any of the preceding claims, wherein the drug is dexamethasone.

5. Method according to any of the preceding claims, wherein the additive to prevent oxidation of the drug is selected from antioxidants, oxygen scavengers and mixtures thereof.

6. Method according to any of the preceding claims, wherein the additive to prevent oxidation of the drug is selected from phenolic antioxidants, water-soluble natural antioxidants or food antioxidants.

7. Method according to any of the preceding claims, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine, 3,4-dihydroxybenzoic acid, sodium citrate, malic acid, sodium ascorbate, tartaric acid, α-monothioglycerol, butylated hyroxyanisole, lauryl gallate, lactic acid, tert-butylhydroquinone, and their salts or derivatives.

8. Method according to any of the preceding claims, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine (typically L-methionine), 3,4-dihydroxybenzoic acid, sodium citrate (e.g. sodium citrate tribasic dehydrate), malic acid (typically DL-malic acid, sodium ascorbate (e.g. (+)-sodium L-ascorbate), tartaric acid (typically DL-tartaric acid), α-monothioglycerol, and butylated hyroxyanisole.

9. Method according to any of the preceding claims, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine, and, 3,4-dihydroxybenzoic acid,

10. Method according to any of the preceding claims, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine, and, 3,4-dihydroxybenzoic acid,

11. Method according to any of the preceding claims, wherein the additive to prevent oxidation is sodium thiosulfate.

12. Method according to any of the preceding claims, wherein the additive to prevent oxidation of the drug is added to the aqueous composition at a concentration of at least 0.05 % (w/v), preferably at a concentration between 0.05% (w/v) and 1% (w/v), more preferably between 0.1 to 0.5%, and still more preferably between 0.2% (w/v) and 0.4% (w/v).

13. Method according to any of the preceding claims, wherein the pH of the aqueous composition comprising a drug is between 4 and 8, preferably between 4.5 and 6.

14. Aqueous composition comprising a corticosteroid, cyclodextrin, preferably gamma-cyclodextrin, and an additive to prevent oxidation of the corticosteroid, wherein said additive is present in the composition at a concentration between 0.15% (w/v) and 0.6% (w/v), and preferably at a concentration between 0.2% (w/v) and 0.5% (w/v).

15. The composition according to claim 14, wherein the corticosteroid is dexamethasone, typically 1.5% (w.v) dexamethasone.

16. The composition according to claim 14 or 15, wherein the additive to prevent oxidation of the corticosteroid is selected from antioxidants, oxygen scavengers and mixtures thereof.

17. The composition according to any of claims 14 to 16, wherein the additive to prevent oxidation of the corticosteroid is selected from phenolic antioxidants, water-soluble natural antioxidants or food antioxidants.

18. The composition according to any of claims 14 to 17, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine, 3,4-dihydroxybenzoic acid, sodium citrate, malic acid, sodium ascorbate, tartaric acid, α-monothioglycerol, butylated hyroxyanisole, lauryl gallate, lactic acid, tert-butylhydroquinone, and their salts or derivatives.

19. The composition according to any of claims 14 to 18, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine (typically L-methionine), 3,4-dihydroxybenzoic acid, sodium citrate (e.g. sodium citrate tribasic dehydrate), malic acid (typically DL-malic acid, sodium ascorbate (e.g. (+)-sodium L-ascorbate), tartaric acid (typically DL-tartaric acid), α-monothioglycerol, and butylated hyroxyanisole.

20. The composition according to any of claims 14 to 19, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine, and, 3,4-dihydroxybenzoic acid,

21. The composition according to any of claims 14 to 20, wherein the additive to prevent oxidation is selected from the group consisting of sodium thiosulfate, methionine, and, 3,4-dihydroxybenzoic acid,

22. The composition according to any of claims 14 to 21, wherein the additive to prevent oxidation is sodium thiosulfate.

23. The composition according to any of claims 14 to 22, wherein the pH of the composition is between 4 and 8, preferably between 4.5 and 6.

24. The composition according to any of Claims 14 to 23, which is a microsuspension, preferably comprising 80% to 95% of the corticosteroid in microparticles having a diameter of 1 μm to 10 μm.

25. The composition according to any of claims 14 to 24 for use in the treatment of an ocular condition, in particular an anterior ocular condition or a posterior ocular condition.

26. The composition according to any of claims 14 to 25, wherein said corticosteroid is dexamethasone, for use in treating central retinal vein occlusion or eye inflammations.

27. The composition according to any of claims 14 to 25, wherein said corticosteroid is dexamethasone, for use in treating

- diabetic macular edema ; or
- inflammation following ocular surgery, typically following cataract surgery.

28. Use of an additive to prevent oxidation of a corticosteroid for stabilizing the pH of an aqueous composition comprising a corticosteroid, in particular an aqueous composition comprising dexamethasone/gamma-cyclodextrin complexes.