condition, ointments may be applied from every hour to just at bedtime. Ointments should not be used with contact lenses. Inflammation occurring in response to tears film hypertonicity can be suppressed by mild topical steroids or with topical immunosuppressants such as cyclosporine.

SUMMARY ~~OF THE INVENTION~~

The present ~~invention~~ disclosure is comprised of an artificial tear emulsion of the following formulation:

Table I

| | | | |
|---|---|---|---|
| [1] POLYSORBATE 80<br>Grade: NF Ph Eur | 0.5 | % w/w | Active |
| [2] CARBOXYMETHYLCELLULOSE SODIUM (LOW VISCOSITY 7LFPH)<br>Grade: Ph Eur USP | 0.5 | % w/w | Active |
| [3] GLYCERIN<br>Grade: Ph Eur USP | 1.0 | % w/w | Active |
| [4] PURITE<br>Grade: | 0.01 | % w/w | Preservative |
| BORIC ACID<br>Grade: NF Ph Eur | 0.6 | % w/w | Buffer |
| [5] PEMULEN TR-2<br>Grade: NF | 0.1 | % w/w | Stabilizer |
| [6] CASTOR OIL<br>Grade: Eur Ph USP | 0.25 | % w/w | Excipient |
| ERYTHRITOL<br>Grade: NF Ph Eur | 0.25 | % w/w | Excipient |
| LEVOCARNITINE<br>Grade: Ph Eur USP | 0.25 | % w/w | Excipient |
| [7] SODIUM HYDROXIDE<br>Grade: NF Ph Eur | 7.3 | pH | pH Adjust |
| [8] WATER FOR INJECTION / PURIFIED WATER<br>Grade: USP | 100 | % w/w | QS Adjust |

[1] PM# 12783. Super Refined Polysorbate 80 from CRODA. Primary emulsifer and demulcent.
[2] Demulcent
[3] Demulcent and tonicity agent
[4] Stabilized Oxychloro Complex (Purite). Add by assay value.
[5] Pemulen TR-2NF (Carbomer Copolymer Type A, Tested to Ph Eur). Secondary emulsifer.
[6] Lipophilic vehicle
[7] pH target 7.3
[8] Hydrophilic vehicle

The Table I formulation includes the concentrations of actives and/or excipients as disclosed above which can be in concentrations which vary from what is stated above. The variation may be such that the amounts are "about" what is stated above so long as that amount would be found bioequivalent by a regulatory agency such as the FDA or the EMEA.

The formulation may be preserved or non-preserved (not containing Purite®), such as a unit dose version. This version would be the same as that in Table 1 except it would contain no Purite®.

Some embodiments of the ~~invention~~ disclosure are included in the following paragraphs:

1) A composition useful as an artificial tear, which is a salt free emulsion comprising castor oil and specifically excludes olive oil and contains at least one active agent selected from the group consisting of polysorbate, carboxymethylcellulose and glycerine.

2) The composition of paragraph 1 wherein said mixture comprises from about 0.1% – 0.5% w/w, castor oil.

3) The composition of paragraphs 1 - 2 wherein castor oil is the only oil in the emulsion.

4) The composition of paragraphs 1 – 3 wherein the castor oil is emulsified in an aqueous phase.

5) The composition of paragraph 4 wherein the castor oil is present in about 0.25% w/w .

6) The composition of paragraphs 4 - 5 further including a primary and a secondary emulsifier.

7) The composition of paragraphs 1 - 6 wherein the composition contains a preservative.

8) The composition of paragraph 7 wherein the preservative is selected from the group consisting of PURITE and benzalkoniuim chloride.

11. The composition of paragraph 8 wherein the preservative is PURITE is present in a concentration of about 0.01% w/v.

12. An emulsion for use in treating dry eye wherein the emulsion is salt-free and comprises castor oil, polysorbate 80, carboxymethylcellulose and glycerine.

13. The composition of paragraph 12 wherein the emulsion also contains the emulsifier pemulin.

14. The emulsion of paragraphs 12 – 13 further comprising erythritol and levocarnitine.

15. An emulsion for treating dry eye as shown in Table 1.

16. A method of treating dry eye comprising administration of any one of the compositions or emulsions of paragraphs 1 – 15.

17. A composition for the treatment of dry eye or keratoconjunctivitis sicca wherein the composition comprises about 0.5% w/w Polysorbate 80, about 0.5% w/w carboxymethylcellulose, about 1.0% w/w glycerine, about 0.6% w/w boric acid, about 0.1% w/w pemulin, about 0.25% w/w castor oil, about 0.25% w/w erythritol, about 0.25% w/w levocarnitine, sodium hydroxide to adjust the pH to about 7.3 and water.

18. The composition of claim 17 further comprising 0.01% Purite®.

19. The composition of claim 17 wherein the composition is applied topically to an eye which is suffering from dry eye.

20. The composition of claim 17 wherein the composition is applied topically to an eye to alleviate the symptoms of dry eye.

21. The composition of claim 17 wherein the composition is applied topically to an eye to prevent dry eye syndrome.

There is also provided use of any one of the compositions as shown in Table 1 in the manufacture of a medicament for treating dry eye.

As used herein, the term "effective amount" or "effective dose" means an amount sufficient to achieve the desired result on the process or condition, and it accordingly will depend on the ingredient and the desired result. Nonetheless, once the desired effect is known, determining the effective amount is within the skill of a person skilled in the art.

CLAIMS:

1) A composition useful as an artificial tear, which is a salt free emulsion comprising castor oil and specifically excludes olive oil and contains at least one active agent selected from the group consisting of polysorbate, carboxymethylcellulose and glycerine.

2) The composition of claim 1 wherein said mixture comprises from 0.1% – 0.5% w/w, castor oil.

3) The composition of claim 2 wherein castor oil is the only oil in the emulsion.

4) The composition of claim 3 wherein the castor oil is emulsified in an aqueous phase.

5) The composition of claim 4 wherein the castor oil is present in about 0.25% w/w.

6) The composition of claim 5 further including a primary and a secondary emulsifier.

7) The composition of claims 5 wherein the composition contains a preservative.

8) The composition of claim 7 wherein the preservative is selected from the group consisting of PURITE and benzalkoniuim chloride.

~~11~~9. The composition of claim 8 wherein the preservative is Purite® is present in a concentration of about 0.01% w/v.

~~12~~10. An emulsion for use in treating dry eye wherein the emulsion is salt-free and comprises castor oil, polysorbate 80, carboxymethylcellulose and glycerine.

~~13~~11. The ~~composition~~ emulsion of claim ~~12~~ 10 wherein the emulsion also contains the emulsifier pemulin.

~~14~~12. The emulsion of claim ~~13~~ 11 further comprising erythritol and levocarnitine.

~~15~~13. An emulsion for treating dry eye as shown in Table 1.

~~16~~14. ~~A method of treating dry eye comprising administration~~ Use of any one of the compositions as shown in Table 1 in the manufacture of a medicament for treating dry eye.

~~17~~15. The ~~method of treating dry eye~~ use of claim ~~16~~ 14 wherein the ~~composition~~ medicament is preservative free.

~~18~~16. The ~~method of treating dry eye~~ use of claim ~~16~~ 14 wherein the ~~method~~ medicament is to be applied at least once a day.

~~19~~17. The ~~method~~ use of ~~treating dry eye~~ claim ~~17~~ 15 wherein the ~~composition~~ medicament alleviates the symptoms of dry eye syndrome.

~~20~~18. The ~~method~~ use of claim ~~17~~ 15 wherein the ~~composition~~ medicament treats and prevents dry eye syndrome.