We Claim:

1. An ophthalmic emulsion, the emulsion comprising:
water forming an aqueous phase;
oil forming an oil phase;
a hydrophilic surfactant;
a hydrophobic surfactant;
a charged phospholipid;
borate; and
a mucoadhesive galactomannan polymer;
wherein:
   i. the oil phase is in droplets within the aqueous phase and the droplets have an average diameter that is no greater than about 1000 nm, but is at least 10 nm, wherein the average diameter is corresponding to 90% of the cumulative undersize distribution by volume measured using a Microtrac S3500 Particle Size Analyzer (Software Version 10.3.1); and
   ii. the borate and galactomannan polymer cooperatively act to form a gel upon instillation of the emulsion in an eye of an individual.

2. An emulsion as in claim 1 wherein the oil is a hydrocarbon selected from mineral oil, paraffin oil and petrolatum.

3. An emulsion as in claim 1 or 2 wherein the oil is at least 0.1 w/v% and no greater than 5 w/v%

4. An emulsion as in claim 3 wherein the oil is at least 0.8 w/v% of the emulsion and is also no greater than 1.5 w/v% of the emulsion

5. An emulsion as in claim 1, 2, 3 and 4 wherein the hydrophilic surfactant is present in the emulsion in an amount that is at least 0.08 w/v% and is present in the emulsion in an amount that is no greater than 0.8 w/v%.

6. An emulsion as in claim 5 wherein the hydrophilic surfactant is present in the emulsion in an amount that is at least 0.14 w/v% and is present in the emulsion in an amount that is no greater than 0.44 w/v%.

7. An emulsion as in any of the preceding claims wherein the hydrophilic surfactant is polyoxyethylene-40-stearate.

8. An emulsion as in any of the preceding claims wherein the hydrophobic surfactant is present in the emulsion in an amount that is at least 0.11 w/v% and is present in the emulsion in an amount that is no greater than 2.0 w/v%.

9. An emulsion as in any of the preceding claims wherein the hydrophobic surfactant is present in the emulsion in an amount that is at least 0.16 w/v% and is present in the emulsion in an amount that is no greater than 0.62 w/v%.

10. An emulsion as in any of the preceding claims wherein the hydrophobic surfactant is a sorbitan tristearate.

11. An emulsion as in any of the preceding claims wherein the mucoadhesive galactomannan polymer is selected from the group consisting of guar and hydroxypropyl guar.

12. An emulsion as in any of the preceding claims wherein the mucoadhesive galactomannan polymer is present in the emulsion at a concentration of at least 0.01 w/v %, but no greater than 1.0 w/v %.

13. An emulsion as in any of the preceding claims wherein the mucoadhesive galactomannan polymer is present in the emulsion at a concentration of at least 0.01 w/v %, but no greater than 0.08 w/v %.

14. An emulsion as in any of the preceding claims wherein the charged phospholipid is an anionic phospholipid named dimyristoyl phosphatidylglycerol.

15. An emulsion as in as in any of the preceding claims wherein the phospholipid is present in the emulsion in a concentration from 0.05 to 7.0 percent by weight

16. An emulsion as in any of the preceding claims further comprising a borate/polyol buffer system.

17. An emulsion as in any of the preceding claims further comprising a polymeric quaternary ammonium compound as an anti-microbial preservative.

18. An emulsion as in any of the preceding claims wherein the oil phase is in droplets within the aqueous phase and the droplets have an average diameter that is no greater than 500 nm but is at least 100 nm, wherein the average diameter is corresponding to 90% of the cumulative undersize distribution by volume measured using a Microtrac S3500 Particle Size Analyzer (Software Version 10.3.1).

19. Use of the emulsion of any of claims 1-18, for use in the manufacture of a medicament for instilling into an eye of a mammal.

20. The use as in claim 19 wherein the mammal is a human being and the medicament is to be instilled as drops from an eye dropper.

21. A method of forming an emulsion as in any of claims 1-18 comprising:

forming a first admixture by mixing the oil and the surfactants at an elevated temperature to form an oil phase admixture;

forming a second admixture by mixing the anionic phospholipid into purified water at an elevated temperature to form a water phase admixture;

mixing the oil phase admixture and the water phase admixture at an elevated temperature and subsequently homogenizing the oil phase mixture with the water phase mixture to form an initial emulsion; and

forming a third admixture by mixing the galactomannan polymer with water and adjusting pH as needed to form a galactomannan polymer slurry; and

mixing the galactomannan polymer slurry with the initial emulsion to form a polymer enhanced emulsion; and

forming a fourth admixture by mixing any combination of the following to form a salt solution: borate, polyol, preservative and any other ingredients; and

mixing the salt solution with the enhanced emulsion followed by the addition of a sufficient quantity (Q.S.) of water and pH adjustment.

Claims

1. An ophthalmic emulsion, the emulsion comprising:

water forming an aqueous phase;

oil forming an oil phase;

a hydrophilic surfactant having an HLB value of at least 8;

a hydrophobic surfactant having an HLB value of below 8;

a charged phospholipid;

borate; and

a mucoadhesive galactomannan polymer;

wherein:

i. the oil phase is in droplets within the aqueous phase and the droplets have an average diameter that is no greater than 1000 nm, but is at least 10 nm, wherein the average diameter is corresponding to 90% of the cumulative undersize distribution by volume measured using a Microtrac S3500 Particle Size Analyzer (Software Version 10.3.1); and

ii. the borate and galactomannan polymer cooperatively act to form a gel upon instillation of the emulsion in an eye of an individual.

2. An emulsion as in claim 1 wherein the oil is a hydrocarbon selected from mineral oil, paraffin oil and petrolatum.

3. An emulsion as in claim 1 wherein the oil is at least 0.1 w/v% and no greater than 3 w/v% of the emulsion.

4. An emulsion as in claim 1 wherein the oil is at least 0.8 w/v% and no greater than 1.5 w/v% of the emulsion.

5. An emulsion as in claim 3 wherein the hydrophilic surfactant is present in the emulsion in an amount that is at least 0.08 w/v% and is present in the emulsion in an amount that is no greater than 0.8 w/v%.

6. An emulsion as in claim 3 wherein the hydrophilic surfactant is present in the emulsion in an amount that is at least 0.14 w/v% and is present in the emulsion in an amount that is no greater than 0.44 w/v%.

7. An emulsion as in claim 5 wherein the hydrophilic surfactant is polyoxyethylene-40-stearate.

8. An emulsion as in claim 5 wherein the hydrophobic surfactant is present in the emulsion in an amount that is at least 0.11 w/v% and is present in the emulsion in an amount that is no greater than 2.0 w/v%.

9. An emulsion as in claim 5 wherein the hydrophobic surfactant is present in the emulsion in an amount that is at least 0.16 w/v% and is present in the emulsion in an amount that is no greater than 0.62 w/v%.

10. An emulsion as in claim 8 wherein the hydrophobic surfactant is a sorbitan tristearate.

11. An emulsion as in claim 1 wherein the mucoadhesive galactomannan polymer is selected from the group consisting of guar and hydroxypropyl guar.

12. An emulsion as in claim 11 wherein the mucoadhesive galactomannan polymer is present in the emulsion at a concentration of at least 0.01 w/v %, but no greater than 1.0 w/v %.

13. An emulsion as in claim 11 wherein the mucoadhesive galactomannan polymer is present in the emulsion at a concentration of at least 0.01 w/v %, but no greater than 0.08 w/v %.

14. An emulsion as in claim 11 wherein the charged phospholipid is an anionic phospholipid named dimyristoyl phosphatidylglycerol.

15. An emulsion as in claim 14 wherein the phospholipid is present in the emulsion in a concentration from 0.05 to 7.0 percent by weight.

16. An emulsion as in claim 1 further comprising a borate/polyol buffer system.

17. An emulsion as in claim 16 further comprising a polymeric quaternary ammonium compound as an anti-microbial preservative.

18. An ophthalmic emulsion as in claim 1 wherein the oil phase is in droplets within the aqueous phase and the droplets have an average diameter that is no greater than 500 nm but is at least 100 nm, wherein the average diameter is corresponding to 90% of the cumulative undersize distribution by volume measured using a Microtrac S3500 Particle Size Analyzer (Software Version 10.3.1).

19. Use of the emulsion as in claim 1, for use in the manufacture of a medicament for instilling into an eye of a mammal.

20. The use as in claim 19 wherein the mammal is a human being and the medicament is to be instilled as drops from an eye dropper.

21. A method of forming an emulsion as in any of claims 1-20, comprising

forming a first admixture by mixing the oil and the surfactants at an elevated temperature to form an oil phase admixture;

forming a second admixture by mixing the anionic phospholipid into purified water at an elevated temperature to form a water phase admixture;

mixing the oil phase admixture and the water phase admixture at an elevated temperature and subsequently homogenizing the oil phase mixture with the water phase mixture to form an initial emulsion; and

forming a third admixture by mixing the galactomannan polymer with water and adjusting pH as needed to form a galactomannan polymer slurry; and

mixing the galactomannan polymer slurry with the initial emulsion to form a polymer enhanced emulsion; and

forming a fourth admixture by mixing any combination of the following to form a salt solution: borate, polyol, preservative and any other ingredients; and

mixing the salt solution with the enhanced emulsion followed by the addition of a sufficient quantity (Q.S.) of water and pH adjustment.