9. The resulting solution was allowed to cool while stirring. The solution became clear as it approached room temperature.
10. The resulting pH was ~5.5.

Example 41 – 1% Vitamin A and Zinc Transdermal Spray Delivery System

[00133] 1.120 g vitamin A proprionate (0.9614% by weight) was added to 42.00 mg Kolliphor (EL) heated to 70°C. 32500 mg heated glycerol was added. An aqueous solution containing 0.43 mg zinc, 0.40 mg citric acid, 2.45 mg phenoxyethanol, and 1.75 mg allantoin dissolved in 74.691 g water was then added. The resulting clear micelle composition had a specific gravity of 1.165 g/mL and a pH of about 5.5.

Example 42 – Industrial Preparation of Vitamin A and Zinc Transdermal Spray Delivery system

[00134] The vitamin A and zinc transdermal spray of Example 41 was prepared as a large manufacturing scale batch as follows:

1. In a suitable jacketed vessel Kolliphor EL was heated to ~70°C.
2. Vitamin A proprionate oil was added and stirred until clear.
3. Glycerine heated to ~70°C was added and stirred until homogeneous.
4. In a separate heating vessel water was heated to ~70°C.
5. Zinc gluconate was added to the heated water and stirred until completely dissolved.
6. Phenoxyethanol was added to the heated water and stirred until completely dissolved.
7. Allantoin was added to the heated water and stirred until completely dissolved.
8. Citric acid was added to the heated water and stirred until completely dissolved.
9. The heated water solution was slowly added to the Kolliphor EL, vitamin A proprionate and glycerine mixture. The resulting solution was slightly cloudy.
10. The resulting solution was allowed to cool while stirring. The solution became clear as it approached room temperature.
11. Additional water was added if necessary to the required final concentration od 1.165 g/mL vitamin A.
12. The resulting pH was ~5.5.

Claims

1. A transmucosal and/or transdermal delivery system comprising:
   at least one non-ionic surfactant;
   at least one polyol; and
   at least one active agent,
   wherein the delivery system has a viscosity of from about 5 cP to about 35 cP.

2. A transmucosal and/or transdermal delivery system comprising:
   at least one non-ionic surfactant;
   at least one polyol; and
   at least one active agent,
   wherein the delivery system has an average particle size of from about 5 nm to about 200 nm.

3. The delivery system of claim 1 or claim 2, wherein the delivery system is delivered vial the oral or nasal mucosa.

4. The delivery system of any one of claims 1 to 3, further comprising at least one oil.

5. The delivery system of claim 4, wherein the at least one oil is ethyl oleate, ethyl linoleate, caproic acid, caprylic acid, capric acid, or lauric acid, or a combination thereof.

6. The delivery system of claim 5, wherein the at least one oil is a natural oil or is derived from a natural oil.

7. The delivery system of claim 6, wherein the natural oil is coconut oil, palm kernel oil, palm oil, lemon oil, or sunflower oil, or a combination thereof.

8. The delivery system of any one of claims 1 to 7, wherein the at least one non-ionic surfactant is selected from the group consisting of a polyethoxylated castor oil, polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monoleate, tocopheryl polyethylene glycol succinate and mixtures thereof.

9. The delivery system of any one of claims 1 to 7, wherein the at least one non-ionic surfactant is obtained by reacting castor oil or hydrogenated castor oil with ethylene oxide.

10. The delivery system of any one of claims 1 to 8, wherein the at least one non-ionic surfactant comprises one or more of glycerol polyethylene glycol ricinoleate, glycerol polyethylene glycol hydroxystearate, fatty acid esters of polyethylene glycol, fatty acid glycerol polyglycol esters, polyethylene glycols, free polyethylene glycols, glycerol ethoxylate and ethoxylated glycerol.

11. The delivery system of any one of claims 1 to 10, wherein the at least one polyol is selected from the group consisting of glycerol and propylene glycol.

12. The delivery system of any one of claims 1 to 11, further comprising a non-aqueous solvent or a mixture of a non-aqueous solvent and water.

13. The delivery system of any one of claims 1 to 11, further comprising ethanol or water.

14. The delivery system of any one of claims 1 to 13, wherein the at least one active agent is provided in an alcohol and oil solution.

15. The delivery system of any one of claims 1 to 14, wherein the at least one active agent is selected from a vitamin, a mineral, a hormone, an amino acid, a peptide, a fatty acid, an antioxidant, a plant extract, a nutraceutical, a statin, an immunosuppressive agent, an antibiotic, a sedative, a steroid, a proton pump inhibitor (PPI), a selective serotonin reuptake inhibitor (SSRI), an angiotensin converting enzyme (ACE) inhibitor and combinations thereof.

16. The delivery system of claim 15, wherein the statin is a fat soluble statin or a water soluble statin.

17. The delivery system of claim 16, wherein the fat soluble statin is atorvastatin calcium.

18. The delivery system of claim 16, wherein the water soluble statin is rosuvastatin calcium.

19. The delivery system of claim 15, wherein the at least one active agent is insulin.

20. The delivery system of claim 15, wherein the vitamin is selected from the group consisting of vitamin A, vitamin B, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B1, vitamin B2, vitamin B5, vitamin B6, vitamin B7, vitamin B9, vitamin B12 and combinations thereof.

21. The delivery system of claim 15, wherein the at least one active agent is a combination of vitamin D3 and vitamin K2 or a combination of vitamin B12 and vitamin E.

22. The delivery system of claim 15, wherein the antioxidant is Coenzyme Q10.

23. The delivery system of claim 15, wherein the plant extract is a natural extract or a synthetic version thereof.

24. The delivery system of claim 23, wherein the plant extract comprises resveratrol, a cannabis extract or one or more cannabinoids, or is hemp seed oil.

25. The delivery system of claim 15, wherein the mineral is selected from the group consisting of zinc, calcium, chromium, copper, iron, magnesium, manganese, phosphorus, potassium.

26. The delivery system of claim 15, wherein the hormone is selected from the group consisting of melatonin, testosterone, insulin, progesterone and estrogen.

27. The delivery system of claim 26, wherein the testosterone is testosterone propionate.

28. The delivery system of any one of claims 1 to 27, further comprising at least one flavour, at least one acidulant, at least one preservative, and/or at least one sweetener.

29. The delivery system of claim 28, wherein the at least one flavour is a natural oil.

30. The delivery system of claim 28, wherein the at least one acidulant is citric acid.

31. The delivery system of claim 28, wherein the at least one preservative is potassium sorbate or phenoxyethanol.

32. The delivery system of claim 28, wherein the at least one sweetener is a natural sweetener.

33. The delivery system of any one of claims 1 to 32, wherein the at least one non-ionic surfactant has an Hydrophile-Lipophile Balance (HLB) value of from about 8 to about 20 or from about 12 to about 18.

34. The delivery system of any one of claims 1 to 33, wherein the ratio of the at least one active agent to the at least one non-ionic surfactant is from about 1:5 to about 1:15 by weight.

35. The delivery system of any one of claims 1 to 33, wherein the ratio of the at least one non-ionic surfactant to the at least one polyol is from about 2:1 to about 1.5:1 by weight.

36. Use of a delivery system of any one of claims 1 to 35 in the manufacture of a medicament for reducing blood cholesterol in a subject, wherein the active agent in the delivery system is a statin.

37. Use of a delivery system of any one of claims 1 to 35 in the manufacture of a medicament for treating dyslipidemia, wherein the active agent in the delivery system is a statin.

38. Use of a delivery system of any one of claims 1 to 35 in the manufacture of a medicament for preventing and/or treating cardiovascular disease, wherein the active agent in the delivery system is a statin.

39. Use of a delivery system of any one of claims 1 to 35 in the manufacture of a medicament for treating diabetes, for regulating blood glucose levels and/or for preventing or treating hyperglycaemia, wherein the active agent in the delivery system is insulin.