[005a] Disclosed herein is a transmucosal and/or transdermal delivery system comprising a micelle composition formulated as a fine mist spray, the micelle composition comprising: at least one surfactant, wherein the at least one surfactant is a non-ionic surfactant having a Hydrophile-Lipophile (HLB) value of from 12 to 16; at least one polyol; at least one active agent; at least one oil; and water, wherein the ratio of water to the at least one active agent, at least one non-ionic surfactant and at least one polyol is from 4:1 to 1:1 by weight; and wherein the micelle composition has a viscosity of from 5 cP to 35 cP when measured at 25°C on a Brookfield viscometer (spindle #1 at 20 rpm), and an average particle size of from 5 nm to 200 nm.

[006] In certain embodiments the delivery system further comprises at least one oil. The at least one oil may be ethyl oleate, ethyl linoleate, caproic acid, caprylic acid, capric acid, or lauric acid, or a combination thereof. In particular embodiments the at least one oil is a natural oil or is derived from a natural oil. Typically the natural oil is coconut oil, palm kernel oil, palm oil, lemon oil, or sunflower oil, or a combination thereof.

[007] Typically the at least one non-ionic surfactant is selected from the group consisting of a polyethoxylated castor oil, polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monoleate and tocopheryl polyethylene glycol succinate. In one embodiment the at least one non-ionic surfactant is a polyethoxylated castor oil. The at least one non-ionic surfactant may be obtained by reacting castor oil or hydrogenated castor oil with ethylene oxide. In one embodiment the at least one non-ionic surfactant is a polyethoxylated castor oil. In another embodiment the at least one non-ionic surfactant comprises glycerol polyethylene glycol ricinoleate, fatty acid esters of polyethylene glycol, free polyethylene glycols and ethoxylated glycerol. In another embodiment the at least one non-ionic surfactant comprises glycerol polyethylene glycol hydroxystearate, fatty acid glycerol polyglycol esters, polyethylene glycols and glycerol ethoxylate.

[008] Typically the at least one polyol is selected from the group consisting of glycerol and propylene glycol. In one embodiment the at least one polyol is glycerol. In another embodiment the at least one polyol is propylene glycol.

[009] Typically the active agent is a pharmaceutically active ingredient. In exemplary embodiments the at least one active agent is selected from the group consisting of 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.

[0010] In particular embodiments the active agent is a statin. The stain may be fat soluble or water soluble. In one embodiment the fat soluble statin is atorvastatin. In an exemplary embodiment the atorvastatin is atorvastatin calcium. In some embodiments the fat soluble statin is provided in oil or an oil mixture. In certain embodiments the at least one fat soluble statin is provided in ethanol or an ethanol and oil solution. In particular embodiments the statin is a water soluble statin. In one embodiment the water soluble statin is rosuvastatin. In an exemplary embodiment the atorvastatin is rosuvastatin calcium.

[0011] In some embodiments the at least one active agent is a vitamin. Typically, the

Claims

1. A transmucosal and/or transdermal delivery system comprising a micelle composition formulated as a fine mist spray, the micelle composition comprising:
at least one surfactant, wherein the at least one surfactant is a non-ionic surfactant having a Hydrophile-Lipophile (HLB) value of from 12 to 16;
at least one polyol;
at least one active agent;
at least one oil; and
water, wherein the ratio of water to the at least one active agent, at least one non-ionic surfactant and at least one polyol is from 4:1 to 1:1 by weight; and
wherein the micelle composition has a viscosity of from 5 cP to 35 cP when measured at 25°C on a Brookfield viscometer (spindle #1 at 20 rpm), and an average particle size of from 5 nm to 200 nm.

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

3. The delivery system of claim 1 or 2, wherein one or more of the at least one active agents is provided in one or more of the at least one oils as a carrier or solvent.

4. The delivery system of any one of claims 1 to 3, wherein the at least one oil is medium chain triglycerides, ethyl oleate, ethyl linoleate, caproic acid, caprylic acid, capric acid, or lauric acid, or a combination thereof.

5. The delivery system of any one of claims 1 to 4, wherein the at least one oil is a natural oil or is derived from a natural oil.

6. The delivery system of claim 5, wherein the natural oil is coconut oil, palm kernel oil, palm oil, seasame oil, vegetable oil, olive oil, lemon oil, or sunflower oil, or a combination thereof.

7. The delivery system of any one of claims 1 to 6, 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.

8. The delivery system of any one of claims 1 to 6, wherein the at least one non-ionic surfactant is obtained by reacting castor oil or hydrogenated castor oil with ethylene oxide.

9. The delivery system of any one of claims 1 to 6, 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 and ethoxylated glycerol.

10. The delivery system of any one of claims 1 to 9, wherein the at least one polyol is selected from the group consisting of glycerol and propylene glycol.

11. The delivery system of any one of claims 1 to 10, further comprising a non-aqueous solvent or a mixture of a non-aqueous solvent and water.

12. The delivery system of any one of claims 1 to 11, wherein the at least one active agent is provided in an alcohol and oil solution.

13. The delivery system of any one of claims 1 to 12, 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.

14. The delivery system of claim 13, wherein the statin is a fat soluble statin or a water soluble statin.

15. The delivery system of claim 14, wherein the fat soluble statin is atorvastatin calcium.

16. The delivery system of claim 14, wherein the water soluble statin is rosuvastatin calcium.

17. The delivery system of claim 13, wherein the at least one active agent is insulin.

18. The delivery system of claim 13, 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.

19. The delivery system of claim 13, 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.

20. The delivery system of claim 13, wherein the antioxidant is Coenzyme Q10.

21. The delivery system of claim 13, wherein the plant extract is a natural extract or a synthetic version thereof.

22. The delivery system of claim 21, wherein the plant extract comprises resveratrol, a cannabis extract or one or more cannabinoids.

23. The delivery system of claim 13, wherein the mineral is selected from the group consisting of zinc, calcium, chromium, copper, iron, magnesium, manganese, phosphorus, potassium.

24. The delivery system of claim 13, wherein the hormone is selected from the group consisting of melatonin, testosterone, insulin, progesterone and estrogen.

25. The delivery system of claim 24, wherein the testosterone is testosterone propionate.

26. The delivery system of any one of claims 1 to 25, further comprising at least one flavour, at least one acidulant, at least one preservative, and/or at least one sweetener.

27. The delivery system of claim 26, wherein the at least one flavour is a natural oil.

28. The delivery system of claim 26 or 27, wherein the at least one acidulant is citric acid.

29. The delivery system of any one of claims 26 to 28, wherein the at least one preservative is potassium sorbate or phenoxyethanol.

30. The delivery system of any one of claims 26 to 29, wherein the at least one sweetener is a natural sweetener.

31. The delivery system of any one of claims 1 to 30, wherein the ratio of the at least one

active agent to the at least one non-ionic surfactant is from 1:5 to 1:15 by weight.

32. The delivery system of any one of claims 1 to 31, wherein the ratio of the at least one non-ionic surfactant to the at least one polyol is from 2:1 to 1.5:1 by weight.

33. Use of a delivery system of any one of claims 1 to 32 in the manufacture of a medicament for reducing blood cholesterol in a subject in need thereof, wherein the active agent in the delivery system is a statin.

34. Use of a delivery system of any one of claims 1 to 32 in the manufacture of a medicament for treating dyslipidemia, wherein the active agent in the delivery system is a statin.

35. Use of a delivery system of any one of claims 1 to 32 in the manufacture of a medicament for preventing and/or treating cardiovascular disease, wherein the active agent in the delivery system is a statin.

36. Use of a delivery system of any one of claims 1 to 32 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.