WHAT IS CLAIMED IS:

1. A pharmaceutical composition according to claim 62, comprising between 0.03% (w/w) and 4.0% (w/w) vitamin A palmitate, a weight of a surfactant which is between 4.0 times and 5.0 times the weight of the vitamin A palmitate contained in the composition, wherein the remainder of the composition comprises water, and, optionally, wherein the pH has been adjusted to between pH 7.0 and pH 7.5 by addition of a pharmaceutically acceptable acid and/or a pharmaceutically acceptable base, and wherein the composition is composed of particles having outward faces, comprised of the hydrophilic portion of the surfactant molecules, that interact with water and inner portions that are hydrophobic, being comprised of the hydrophobic portion of the surfactant molecules and substantially all of the vitamin A palmitate introduced into the composition.

2. A pharmaceutical composition according to either of claims 1 or 62, wherein the surfactant is selected from polysorbate 20, polysorbate 60, polysorbate 80, stearyl alcohol, a polyethylene glycol derivative of hydrogenated castor oil, a polyethylene glycol derivative of hydrogenated castor oil, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, polyoxyethylene (20) oleyl ether, polyoxyethylene (20) cetyl ether, polyoxyethylene (10) cetyl ether, polyoxyethylene (10) oleyl ether, polyoxyethylene (100) stearyl ether, polyoxyethylene (10) stearyl ether, polyoxyethylene (20) stearyl ether, polyoxyethylene (4) lauryl ether, polyoxyethylene (20) cetyl ether, polyoxyethylene (2) cetyl ether , caprylocaproyl polyoxyl-8 glyceride, polyethylene glycol (20) stearate, polyethylene glycol (40) stearate, polyethylene glycol, polyethylene glycol (8) stearate, and polyoxyl 40 stearate, and mixtures thereof.

3. A pharmaceutical composition according to any one of claims 1, 2 or 62, wherein the surfactant is polysorbate 80.

4. A pharmaceutical composition according to any one of claims 1 to 3, or 62 , wherein the particles formed by vitamin A palmitate and the surfactant are in the configuration of micelles having a diameter of less than or equal to 500 nm.

5. A pharmaceutical composition according to claim 4, wherein the micelles have a diameter of less than or equal to 250 nm.

6. A pharmaceutical composition according to claim 4, wherein the micelles have a diameter of less than or equal to 100 nm.

7. A pharmaceutical composition according to any of claims 1 to 6, or 62, comprising between 0.3% and 3.0% vitamin A palmitate.

8. A pharmaceutical composition according to any of claims 1 to 7, or 62, comprising between 2.5% and 3.0% vitamin A palmitate.

9. A pharmaceutical composition according to any of claims 1 to 8, or 62, wherein the surfactant is polysorbate 80, and the fatty acid content of the polysorbate 80 is between 58% and 100% oleic acid.

10. A pharmaceutical composition according to any of claims 1 to 9, or 62, wherein the surfactant is polysorbate 80 and the fatty acid content of the polysorbate 80 is between 85% and 100% oleic acid.

11. A pharmaceutical composition according to any of claims 1 to 10, or 62, wherein the surfactant is polysorbate 80, and the fatty acid content of the polysorbate 80 is greater than or equal to 98% oleic acid.

12. A pharmaceutical composition according to any of claims 1 to 11, or 62, wherein the pharmaceutically acceptable acid is selected from hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid, phosphoric acid, acetic acid, oleic acid,

palmitic acid, stearic acid, glycolic acid, pyruvic acid, oxalic acid, maleic acid, malonic acid, succinic acid, fumaric acid, tartaric acid, citric acid, ascorbic acid, lactic acid, and tartaric acid.

13. A pharmaceutical composition according to any of claims 1 to12, or 62, wherein the pharmaceutically acceptable base is selected from sodium hydroxide, ammonium hydroxide, potassium hydroxide, histidine, arginine and lysine.

14. A pharmaceutical composition according to any one of claims 1 to 13, or 62, wherein the pharmaceutically acceptable acid is citric acid, and the pharmaceutically acceptable base is sodium hydroxide.

15. A pharmaceutical composition according to any of claims 1 to 14, or 62 prepared by a process, according to claim 63, comprising the following steps:

(1) preparation of a mixture by combining vitamin A palmitate, and 4 to 5 times the weight of vitamin A palmitate of a surfactant;

(2) warming the mixture resulting from step (1) to a temperature of between 40°C and 70°C, and agitating until homogeneous;

(3) addition of water which has been warmed to a temperature of between 40°C and 70°C in an amount of between 20% and 80% of the weight of the mixture of step (1), with agitation, over a period of time of between 5 and 90 minutes to afford a homogeneous intermediate state;

(4) cooling of the mixture from step (3) to a temperature of between 15°C and 40°C;

(5) addition of water as a bolus in an amount, or about 95% or greater of this amount, to achieve the appropriate final concentration of vitamin A palmitate, followed by agitation for between 5 minutes and 6 hours to afford a stable mixture comprising the appropriate micelle size;

(6) adjustment of the pH of the mixture from step (5), if necessary, to between pH 7.0 and pH 7.5 by addition of a pharmaceutically acceptable acid and/or pharmaceutically acceptable base, or a solution or solutions of the acid and/or base,

and/or addition of water, resulting in the final appropriate concentration of vitamin A palmitate; and

(7) sterilization of the mixture from step (6) by filtration through a filter having a pore size of between 0.1 micron and 0.22 micron.

16. A pharmaceutical composition prepared by the process according to claim 15, wherein the surfactant is selected from polysorbate 20, polysorbate 60, polysorbate 80, stearyl alcohol, a polyethylene glycol derivative of hydrogenated castor oil, a polyethylene glycol derivative of hydrogenated castor oil, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, polyoxyethylene (20) oleyl ether, polyoxyethylene (20) cetyl ether, polyoxyethylene (10) cetyl ether, polyoxyethylene (10) oleyl ether, polyoxyethylene (100) stearyl ether, polyoxyethylene (10) stearyl ether, polyoxyethylene (20) stearyl ether, polyoxyethylene (4) lauryl ether, polyoxyethylene (20) cetyl ether, polyoxyethylene (2) cetyl ether , caprylocaproyl polyoxyl-8 glyceride, polyethylene glycol (20) stearate, polyethylene glycol (40) stearate, polyethylene glycol, polyethylene glycol (8) stearate, and polyoxyl 40 stearate, and mixtures thereof.

17. A pharmaceutical composition according to any of claims 1 to 14, or 62, prepared by a process comprising the following steps:

(1) preparation of a mixture by combining vitamin A palmitate, and 4 to 5 times the weight of vitamin A palmitate of polysorbate 80;

(2) warming the mixture resulting from step (1) to a temperature of between 40°C and 70°C, and agitating until homogeneous;

(3) addition of water which has been warmed to a temperature of between 40°C and 70°C in an amount of between 20% and 80% of the weight of the mixture of step (1), with agitation, over a period of time of between 5 and 90 minutes to afford a homogeneous intermediate state;

(4) cooling of the mixture from step (3) to a temperature of between 15°C and 40°C;

(5) addition of water as a bolus in an amount, or about 95% or greater of this amount, to achieve the appropriate final concentration of vitamin A palmitate, followed by agitation for between 5 minutes and 6 hours to afford a stable mixture comprising the appropriate micelle size;

(6) adjustment of the pH of the mixture from step (5), if necessary, to between pH 7.0 and pH 7.5 by addition of a pharmaceutically acceptable acid and/or pharmaceutically acceptable base, or a solution or solutions of the acid and/or base, and/or addition of water, resulting in the final appropriate concentration of vitamin A palmitate; and

(7) sterilization of the from step (6) by filtration through a filter having a pore size of between 0.1 micron and 0.22 micron.

18. A pharmaceutical composition prepared by the process according to any one of claims 15, 16 or 17, wherein the mixture resulting from step (1) is warmed to a temperature of between 45°C and 60°C.

19. A pharmaceutical composition prepared by the process according to any of claims 15, 16 or 17, wherein the mixture resulting from step (1) is warmed to a temperature of between 50°C and 60°C.

20. A pharmaceutical composition prepared by the process according to any of claims 15 to 19, wherein the amount of water added in step (3) is between 35% and 70% of the weight of the mixture from step (1).

21. A pharmaceutical composition prepared by the process according to any of claims 15 to 20, wherein the amount of water added in step (3) is between 50% and 60% of the weight of the mixture from step (1).

22. A pharmaceutical composition prepared by the process according to any one of claims 15 to 21, wherein the agitation of step (5) is carried out for a time between 30 minutes and 2 hours.

23. A pharmaceutical composition prepared by the process according to any one of claim 15 to 22, wherein the cooling of step (4) is to a temperature of between 20°C and 30°C.

24. A pharmaceutical composition prepared by the process according to any one of claims 15 to 23, wherein the pharmaceutically acceptable acid is selected from hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid, phosphoric acid, acetic acid, oleic acid, palmitic acid, stearic acid, glycolic acid, pyruvic acid, oxalic acid, maleic acid, malonic acid, succinic acid, fumaric acid, tartaric acid, citric acid, ascorbic acid, lactic acid, and tartaric acid.

25. A pharmaceutical composition prepared by the process according to any one of claims 15 to 24, wherein the pharmaceutically acceptable base is selected from sodium hydroxide, ammonium hydroxide, potassium hydroxide, histidine, arginine and lysine.

26. A pharmaceutical composition prepared by the process according to any one of claims 15 to 25, wherein the pharmaceutically acceptable acid of step (6) is citric acid, and wherein the pharmaceutically acceptable base is sodium hydroxide.

27. A process for the preparation of the pharmaceutical composition according to any one of claims 1 to 14, or 62, comprising the following steps:

(1) preparation of a mixture by combining vitamin A palmitate, and 4 to 5 times the weight of vitamin A palmitate of a surfactant;

(2) warming the mixture resulting from step (1) to a temperature of between 40°C and 70°C, and agitating until homogeneous;

(3) addition of water which has been warmed to a temperature of between 40°C and 70°C in an amount of between 20% and 80% of the weight of the mixture of step (1), with agitation, over a period of time of between 5 and 90 minutes to afford a homogeneous intermediate state;

(4) cooling of the mixture from step (3) to a temperature of between 15°C and 40°C;

(5) addition of water as a bolus in an amount, or about 95% or greater of this amount, to achieve the appropriate final concentration of vitamin A palmitate, followed by agitation for between 5 minutes and 6 hours to afford a stable mixture comprising the appropriate micelle size;

(6) adjustment of the pH of the mixture from step (5), if necessary, to between pH 7.0 and pH 7.5 by addition of a pharmaceutically acceptable acid and/or pharmaceutically acceptable base, or a solution or solutions of the acid and/or base, and/or addition of water, resulting in the final appropriate concentration of vitamin A palmitate; and

(7) sterilization of the from step (6) by filtration through a filter having a pore size of between 0.1 micron and 0.22 micron.

28. A process according to claim 27, wherein the surfactant is selected from polysorbate 20, polysorbate 60, polysorbate 80, stearyl alcohol, a polyethylene glycol derivative of hydrogenated castor oil, a polyethylene glycol derivative of hydrogenated castor oil, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, polyoxyethylene (20) oleyl ether, polyoxyethylene (20) cetyl ether, polyoxyethylene (10) cetyl ether, polyoxyethylene (10) oleyl ether, polyoxyethylene (100) stearyl ether, polyoxyethylene (10) stearyl ether, polyoxyethylene (20) stearyl ether, polyoxyethylene (4) lauryl ether, polyoxyethylene (20) cetyl ether, polyoxyethylene (2) cetyl ether , caprylocaproyl polyoxyl-8 glyceride, polyethylene glycol (20) stearate, polyethylene glycol (40) stearate, polyethylene glycol, polyethylene glycol (8) stearate, and polyoxyl 40 stearate, and mixtures thereof.

29. A process according to either of claims 27 or 28 for the preparation of the pharmaceutical composition according to any one of claims 1 to 12 comprising the following steps:

(1) preparation of a mixture by combining vitamin A palmitate, and 4 to 5 times the weight of vitamin A palmitate of polysorbate 80;

(2) warming the mixture resulting from step (1) to a temperature of between 40°C and 70°C, and agitating until homogeneous;

(3) addition of water which has been warmed to a temperature of between 40°C and 70°C in an amount of between 20% and 80% of the weight of the mixture of step (1), with agitation, over a period of time of between 5 and 90 minutes to afford a homogeneous intermediate state;

(4) cooling of the mixture from step (3) to a temperature of between 15°C and 40°C;

(5) addition of water as a bolus in an amount, or about 95% or greater of this amount, to achieve the appropriate final concentration of vitamin A palmitate, followed by agitation for between 5 minutes and 6 hours to afford a stable mixture comprising the appropriate micelle size;

(6) adjustment of the pH of the mixture from step (5), if necessary, to between pH 7.0 and pH 7.5 by addition of a pharmaceutically acceptable acid and/or pharmaceutically acceptable base, or a solution or solutions of the acid and/or base, and/or addition of water, resulting in the final appropriate concentration of vitamin A palmitate; and

(7) sterilization of the from step (6) by filtration through a filter having a pore size of between 0.1 micron and 0.22 micron.

30. The process according to any one of claims 27, 28 or 29, wherein the mixture resulting from step (1) is warmed to a temperature of between 45°C and 60°C.

31. The process according to any of claims 27 to 30, wherein the mixture resulting from step (1) is warmed to a temperature of between 50°C and 60°C.

32. The process according to any one of claims 27 to 31, wherein the amount of water added in step (3) is between 35% and 70% of the weight of the mixture from step (1).

33. The process according to any of claims 27 to 32, wherein the amount of water added in step (3) is between 50% and 60% of the weight of the mixture from step (1).

34. The process according to any one of claims 27 to 33, wherein the agitation of step (5) is carried out for a time between 30 minutes and 2 hours.

35. The process according to any one of claim 27 to 34, wherein the cooling of step (4) is to a temperature of between 20°C and 30°C.

36. The process according to any one of claims 27 to 35, wherein the pharmaceutically acceptable acid is selected from hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid, phosphoric acid, acetic acid, oleic acid, palmitic acid, stearic acid, glycolic acid, pyruvic acid, oxalic acid, maleic acid, malonic acid, succinic acid, fumaric acid, tartaric acid, citric acid, ascorbic acid, lactic acid, and tartaric acid.

37. The process according to any one of claims 27 to 36, wherein the pharmaceutically acceptable base is selected from sodium hydroxide, ammonium hydroxide, potassium hydroxide, histidine, arginine and lysine.

38. The process according to any one of claims 27 to 36, wherein the pharmaceutically acceptable acid of step (6) is citric acid and the pharmaceutically acceptable base is sodium hydroxide.

39. A pharmaceutical composition according to any one of claims 1 to 14, or 62, wherein the composition is suitable for parenteral administration.

40. A pharmaceutical composition according to any one of claims 1 to 14, or 62, wherein the composition is suitable for oral administration.

41. A pharmaceutical composition prepared by the process according to any one of claims 15 to 26, wherein the composition is suitable for parenteral administration.

42. A pharmaceutical composition prepared by the process according to any one of claims 15 to 26, wherein the composition is suitable for oral administration.

43. A method of treatment or prophylaxis of a vitamin A deficiency disorder, in a patient in need thereof, comprising administration of a pharmaceutically effective amount of a composition according to any one of claims 1 to 14, or 62.

44. A method of treatment or prophylaxis of a vitamin A deficiency disorder, in a patient in need thereof, comprising oral administration of a pharmaceutically effective amount of a composition according to claim 40.

45. A method of treatment or prophylaxis of a vitamin A deficiency disorder, in a patient in need thereof, comprising parenteral administration of a pharmaceutically effective amount of a composition according to claim 39.

46. A method of treatment or prophylaxis of a vitamin A deficiency disorder, in a patient in need thereof, comprising administration of a pharmaceutically effective amount of pharmaceutical composition prepared by the process according to any one of claims 15 to 26.

47. A method of treatment or prophylaxis of a vitamin A deficiency disorder, in a patient in need thereof, comprising parenteral administration of a pharmaceutically effective amount of a composition according to claim 41.

48. A method of treatment or prophylaxis of a vitamin A deficiency disorder, in a patient in need thereof, comprising oral administration of a pharmaceutically effective amount of a composition according to claim 40.

49. A method of treatment or prophylaxis according to any one of claims 43 to 48, wherein the vitamin A disorder is selected from neonatal sepsis, hospital-acquired sepsis, sepsis from premature rupture of membranes, bronchopulmonary dysplasia, retinopathy of prematurity, measles, meningitis, pneumonia, necrotizing enterocolitis, a viral infection and a bacterial infection, and a combination of such disorders.

50. A method of treatment or prophylaxis according to any one of claims 43 to 49, wherein the patient is a human born prematurely, or a neonate.

51. A method of treatment or prophylaxis according to claim 50, wherein the vitamin A deficiency disorder is bronchopulmonary dysplasia or retinopathy of prematurity.

52. A method of treatment or prophylaxis according to claim 51 wherein the vitamin A deficiency disorder is bronchopulmonary dysplasia.

53. A pharmaceutical composition according to any of claims 1 to 14, or 62, for use in the treatment or prophylaxis of a vitamin A deficiency disorder in a patient in need thereof.

54. A pharmaceutical composition according to claim 39 for use in the treatment or prophylaxis of a vitamin A deficiency disorder in a patient in need thereof.

55. A pharmaceutical composition according to claim 40 for use in the treatment or prophylaxis of a vitamin A deficiency disorder in a patient in need thereof.

56. A pharmaceutical composition prepared by the process according to any one of claims 15 to 26 for use in a method of treatment or prophylaxis of a vitamin A deficiency disorder in a patient in need thereof.

57. A pharmaceutical composition prepared according to either of claims 41 or 42 for use in a method of treatment or prophylaxis of a vitamin A deficiency disorder in a patient in need thereof.

58. A pharmaceutical composition according to any of claims 53 to 57, wherein the vitamin A deficiency disorder is selected from neonatal sepsis, hospital-acquired sepsis, sepsis from premature rupture of membranes, bronchopulmonary dysplasia, retinopathy of prematurity, measles, meningitis, pneumonia, necrotizing enterocolitis, a viral infection and a bacterial infection, and a combination of such disorders

59. A pharmaceutical composition for use according to claim 58, wherein the patient is a human born prematurely, or a neonate.

60. A pharmaceutical composition for the use according to claim 59, wherein the vitamin A deficiency disorder is bronchopulmonary dysplasia or retinopathy of prematurity.

61. A pharmaceutical composition for the use according to claim 60, wherein the vitamin A deficiency disorder is bronchopulmonary dysplasia.

62. A pharmaceutical composition comprising between 0.03% (w/w) and 4.0% (w/w) vitamin A palmitate, a weight of a surfactant which is 4.0 times or more of the weight of the vitamin A palmitate contained in the composition, wherein the remainder of the composition comprises water, and, optionally, wherein the pH has been adjusted to between pH 7.0 and pH 7.5 by addition of a pharmaceutically acceptable acid and/or a pharmaceutically acceptable base, and wherein the composition is composed of particles having outward faces, comprised of the hydrophilic portion of the surfactant molecules, that interact with water and inner portions that are hydrophobic, being comprised of the hydrophobic portion of the surfactant molecules and substantially all of the vitamin A palmitate introduced into the composition.

63. 15. A pharmaceutical composition according to any of claims 1 to 14, or 62, prepared by a process comprising the following steps:

(1) preparation of a mixture by combining vitamin A palmitate, and 4 to 5 times the weight of vitamin A palmitate of a surfactant;

(2) warming the mixture resulting from step (1) to a temperature of between 40°C and 70°C, and agitating until homogeneous;

(3) addition of water, optionally warmed to a temperature of between 40°C and 70°C, in an amount of between 20% and 80% of the weight of the mixture of step (1), with agitation, over a period of time of between 5 and 90 minutes to afford a homogeneous intermediate state;

(4) cooling of the mixture from step (3) to a temperature of between 15°C and 40°C;

(5) addition of water as a bolus in an amount, or about 95% or greater of this amount, to achieve the appropriate final concentration of vitamin A palmitate, followed by agitation for between 5 minutes and 6 hours to afford a stable mixture comprising the appropriate micelle size;

(6) adjustment of the pH of the mixture from step (5), if necessary, to between pH 7.0 and pH 7.5 by addition of a pharmaceutically acceptable acid and/or pharmaceutically acceptable base, or a solution or solutions of the acid and/or base, and/or addition of water, resulting in the final appropriate concentration of vitamin A palmitate; and

(7) sterilization of the mixture from step (6) by filtration through a filter having a pore size of between 0.1 micron and 0.22 micron.