Claims:

1. An aqueous pharmaceutical composition comprising vitamin A palmitate and, a surfactant, wherein:
95% or more of the vitamin A palmitate of the aqueous pharmaceutical composition comprises particles formed by the vitamin A palmitate and the surfactant in the configuration of micelles;
the vitamin A palmitate is present in the aqueous pharmaceutical composition at a concentration of 0.03 to 4.0%w/w;
the weight of the surfactant present in the aqueous pharmaceutical composition is 4.0 or more times the weight of the vitamin A palmitate present in the aqueous pharmaceutical composition;
optionally, the pH of the aqueous pharmaceutical composition has been adjusted to pH 7.0 to 7.5 by addition of a pharmaceutically acceptable acid and/or a pharmaceutically acceptable base; and
each of the micelles has a diameter of less than or equal to 500 nm.

2. The aqueous pharmaceutical composition according to claim 1, wherein the weight of the surfactant present in the aqueous pharmaceutical composition is 4.0 to 5.0 times the weight of the vitamin A palmitate present in the aqueous pharmaceutical composition.

3. The aqueous pharmaceutical composition according to claim 1 or claim 2, wherein the surfactant comprises polysorbate 20, polysorbate 60, polysorbate 80, stearyl alcohol, 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 (1) stearyl ether, polyoxyethylene (20) stearyl ether, polyoxyethylene (4) lauryl ether, polyoxyethylene (2) cetyl ether , caprylocaproyl polyoxyl-8 glyceride, polyethylene glycol

(20) stearate, polyethylene glycol (40) stearate, polyethylene glycol, polyethylene glycol (8) stearate, polyoxyl 40 stearate, or a mixture thereof.

4. The aqueous pharmaceutical composition according to any one of claims 1 to 3, wherein the surfactant comprises polysorbate 80.

5. The aqueous pharmaceutical composition according to any one of claims 1 to 4, wherein each of the micelles has a diameter of less than or equal to 250 nm.

6. The aqueous pharmaceutical composition according to any one of claims 1 to 5, wherein each of the micelles has a diameter of less than or equal to 100 nm.

7. The aqueous pharmaceutical composition according to any one of claims 1 to 6, wherein the vitamin A palmitate is present in the aqueous pharmaceutical composition at a concentration of 0.3% to 3.0% w/w vitamin A palmitate.

8. The aqueous pharmaceutical composition according to any one of claims 1 to 7, wherein the vitamin A palmitate is present in the aqueous pharmaceutical composition at a concentration of 2.5% to 3.0% w/w vitamin A palmitate.

9. The aqueous pharmaceutical composition according to any one of claims 1 to 8, wherein the surfactant comprises polysorbate 80 and the fatty acid content of the polysorbate 80 is greater than or equal to 98% oleic acid.

10. The aqueous pharmaceutical composition according to any one of claims 1 to 9, wherein the pharmaceutically acceptable acid comprises citric acid and the pharmaceutically acceptable base comprises sodium hydroxide.

11. The aqueous pharmaceutical composition according to any one of claims 1 to 10, wherein the aqueous pharmaceutical composition is suitable for parenteral administration.

12. The aqueous pharmaceutical composition according to any one of claims 1 to 11, wherein the aqueous pharmaceutical composition is suitable for oral administration.

13. The aqueous pharmaceutical composition according to any one of claims 1 to 12, wherein the aqueous pharmaceutical composition has a clarity of that of water.

14. The aqueous pharmaceutical composition according to any one of claims 1 to 13, wherein the aqueous pharmaceutical composition has a clarity meeting or exceeding the standard set forth the European Pharmacopeia 7.0.

15. The aqueous pharmaceutical composition according to any one of claims 1 to 14, wherein the micelles are permanently miscible.

16. The aqueous pharmaceutical composition according to any one of claims 1 to 15, wherein the aqueous pharmaceutical composition is capable of being sterile filtered.

17. Use of the aqueous pharmaceutical composition according to any one of claims 1 to 16, in the manufacture of a medicament for the treatment or prophylaxis of a vitamin A deficiency disorder in a subject in need thereof.

18. The use according to claim 17, wherein the vitamin A deficiency disorder comprises neonatal sepsis, hospital-acquired sepsis, sepsis from premature rupture of membranes, bronchopulmonary dysplasia, retinopathy of prematurity, measles, meningitis, pneumonia, necrotizing enterocolitis, a viral infection, a bacterial infection, or a combination thereof.

19. A process for preparing an aqueous pharmaceutical composition comprising:

(1) providing a mixture of vitamin A palmitate and a surfactant, wherein the weight of the surfactant is 4 to 5 times the weight of the vitamin A palmitate;

(2) warming the mixture to a temperature of 40°C to 70°C and agitating the warmed mixture until homogeneous;

(3) adding water over 5 to 90 minutes with agitation to afford a homogeneous intermediate state, wherein the weight of the water is from 20% to 80% of the weight of the mixture of step (1), and wherein the water optionally has a temperature of 40°C to 70°C;

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

(5) adding water and agitating the resultant mixture for 5 minutes to 6 hours to afford a stable mixture comprising micelles; and

optionally adjusting the stable mixture to pH 7.0 to pH 7.5 by addition of a pharmaceutically acceptable acid and/or a pharmaceutically acceptable base; and

(6) passing the mixture of step (5) through a filter having a pore size of 0.1 to 0.22 microns.

20. The process according to claim 19, wherein the surfactant comprises polysorbate 80.