CLAIMS

1. A self-emulsifying preparation containing a self-emulsifying composition encapsulated in a soft capsule, the self-emulsifying composition comprising, when total amount of the self-emulsifying composition is 100% by weight,

a) 70 to 90% by weight of ethyl ester of ω3 polyunsaturated fatty acids,

b) 0.5 to 6% by weight of water,

c) 1 to 29% by weight of an emulsifier which is a polyoxyethylene sorbitan fatty acid ester, and

d) 3 to 40 parts by weight of lecithin in relation to 100 parts by weight of ethyl ester of ω3 polyunsaturated fatty acids,

wherein

e) content of ethanol is up to 4% by weight of total amount of the composition,

f) content of polyhydric alcohol is up to 1% by weight of total amount of the composition,

which upon administration to human satisfies at least one selected from among following (f) to (j) calculated by conducting correction by subtracting plasma ω3 polyunsaturated fatty acid concentration before the administration:

(f) maximum plasma ω3 polyunsaturated fatty acid concentration is at least 50 μg/mL;

(g) plasma ω3 polyunsaturated fatty acid concentration 2 hours after the administration is at least 20 μg/mL;

(h) time required to reach the maximum plasma ω3 polyunsaturated fatty acid concentration (Tmax) is up to 6 hours;

(i) area under the curve of the plasma ω3 polyunsaturated fatty acid concentration at 0 to 72 hours after the administration is at least 500 μg.hr/mL; and

(j) blood ω3 polyunsaturated fatty acid concentration 24 hours after the administration is 5 to 100 μg/mL.

2. The self-emulsifying preparation according to claim 1 wherein the self-emulsifying composition is substantially free from the polyhydric alcohol.

3. The self-emulsifying preparation according to claim 1 or 2 wherein the polyhydric alcohol content in the self-emulsifying composition is 0% by weight of total amount of the composition.

4. The self-emulsifying preparation according to any one of claims 1 to 3 wherein the at least one compound selected from the group consisting of ethyl ester of ω3 polyunsaturated fatty

acids in the self-emulsifying composition to be administered to human is 1000 mg to 10000 mg.

5. The self-emulsifying preparation according to any one of claims 1 to 4 wherein the ethyl ester of ω3 polyunsaturated fatty acids contained in the self-emulsifying composition to be administered to human are ethyl ester of EPA.

6. The self-emulsifying preparation according to any one of claims 1 to 5 wherein when the composition is administered, the maximum plasma ω3 polyunsaturated fatty acid concentration calculated by conducting the correction by subtracting the plasma ω3 polyunsaturated fatty acid concentration before the administration is at least 50 μg/mL, and the area under the curve of the plasma ω3 polyunsaturated fatty acid concentration at 0 to 72 hours after the administration is at least 500 μg.hr/mL.

7. The self-emulsifying preparation according to any one of claims 1 to 6 wherein, when the composition is administered under fasting, the maximum plasma ω3 polyunsaturated fatty acid concentration calculated by conducting the correction by subtracting the plasma ω3 polyunsaturated fatty acid concentration before the administration is at least three times as high as the maximum plasma ω3 polyunsaturated fatty acid concentration immediately after the meal, or the area under the curve of the plasma ω3 polyunsaturated fatty acid concentration at 0 to 72 hours after the administration is at least twice as large as the area under the curve of the plasma ω3 polyunsaturated fatty acid concentration immediately after the meal.

8. The self-emulsifying preparation according to any one of claims 1 to 7 wherein the self-emulsifying composition further contains a polyoxyethylene castor oil as an emulsifier.

9. The self-emulsifying preparation according to claim 8 wherein when the total amount of the self-emulsifying composition is 100% by weight, the emulsifier being the polyoxyethylene sorbitan fatty acid ester and polyoxyethylene castor oil is 5 to 24% by weight, with the polyoxyethylene castor oil being up to 120 parts by weight in relation to 100 parts by weight of the polyoxyethylene sorbitan fatty acid ester

10. The self-emulsifying preparation according to any one of claims 1 to 9 wherein the self-emulsifying composition containing 1000 mg to 10000 mg of the ethyl ester of ω3 polyunsaturated fatty acids is administered once a day.

11. The self-emulsifying preparation according to any one of claims 1 to 10 wherein the self-emulsifying composition is substantially free from the ethanol.

12. The self-emulsifying preparation according to any one of claims 1 to 11 wherein the ethanol content in the self-emulsifying composition is 0% by weight of total amount of the composition.

13. The self-emulsifying preparation according to any one of claims 1 to 12 wherein a capsule film of the soft capsule contains gelatin.