CLAIMS

[Claim 1]

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

a) 50 to 95% by weight of at least one compound selected from the group consisting of ω3 polyunsaturated fatty acids and their pharmaceutically acceptable salts and esters,

b) 0.5 to 6% by weight of water,

c) 1 to 29% by weight of a nonionic surfactant,

wherein the nonionic surfactant comprises a polyoxyethylene (POE) sorbitan fatty acid ester and POE castor oil, with a ratio of 120 parts by weight or less of POE castor oil to 100 parts by weight of POE sorbitan fatty acid ester, and

d) lecithin,

e) wherein a content of polyhydric alcohol is up to 4% by weight of the total amount of the self-emulsifying composition, and

a content of ethanol in the self-emulsifying composition is up to 4% by weight of the total amount of the self-emulsifying 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) the 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) an 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.

[Claim 2]

The self-emulsifying preparation according to claim 1, wherein the self-

emulsifying composition comprises, when the total amount of the self-emulsifying composition is 100% by weight, 70 to 90% by weight of at least one compound selected from the group consisting of ω3 polyunsaturated fatty acid, and their pharmaceutically acceptable salts and esters.

[Claim 3]

The self-emulsifying preparation according to claim 1 or 2, wherein the self-emulsifying composition comprises, when the total amount of the self-emulsifying composition is 100% by weight, 5 to 29% by weight of the nonionic surfactant.

[Claim 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 ω3 polyunsaturated fatty acids and their pharmaceutically acceptable salts and esters in the self-emulsifying composition to be administered to human is 1000 mg to 10000 mg.

[Claim 5]

The self-emulsifying preparation according to any one of claims 1 to 4, wherein the ω3 polyunsaturated fatty acids and their pharmaceutically acceptable salts and esters in theself-emulsifying composition to be administered to human are at least one member selected from the group consisting of EPA and their pharmaceutically acceptable salts and esters.

[Claim 6]

The self-emulsifying preparation according to claim 5 wherein the EPA and their pharmaceutically acceptable salts and esters are an ethyl ester of EPA.

[Claim 7]

The self-emulsifying preparation according to any one of claims 1 to 6, wherein when the self-emulsifying 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.

[Claim 8]

The self-emulsifying preparation according to any one of claims 1 to 7 wherein, when the self-emulsifying 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.

[Claim 9]

The self-emulsifying preparation according to any one of claims 1 to 8 wherein the self-emulsifying composition contains lecithin and a polyoxyethylene sorbitan fatty acid ester as the non-ionic surfactant.

[Claim 10]

The self-emulsifying preparation according to any one of claims 1 to 9, wherein the self-emulsifying composition comprising 3 to 40 parts by weight of lecithin in relation to 100 parts by weight of at least one compound selected from the group consisting of ω3 polyunsaturated fatty acid, and their pharmaceutically acceptable salts and esters.

[Claim 11]

The self-emulsifying preparation according to any one of claims 1 to 10 wherein the self-emulsifying composition containing 1000 mg to 10000 mg of the at least one compound selected from the group consisting of ω3 polyunsaturated fatty acids and their pharmaceutically acceptable salts and esters is to be administered once a day.

[Claim 12]

The self-emulsifying preparation according to any one of claims 1 to 11, wherein the polyhydric alcohol content in the self-emulsifying composition is up to 1% by weight of the total amount of the self-emulsifying composition.

[Claim 13]

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