CLAIMS

What is claimed is:

1. A pharmaceutical composition comprising 95% to 99.9% ethyl-EPA enclosed in a capsule shell, wherein (a) the pharmaceutical composition has a baseline peroxide from 0 meq/kg to 5 meq/kg and upon storage of the pharmaceutical composition at 25°C and 60% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 8 meq/kg, (b) the capsule shell is free of succinated gelatin and comprises a film-forming material, a hygroscopic plasticizer selected from glycerin, sorbitol and alkylene glycols, and a non-hygroscopic plasticizer selected from maltitol, lactitol, xylitol, hydrogenated starch hydrolysate and glucose syrup, wherein the hygroscopic plasticizer and the non-hygroscopic plasticizer are present in a weight ratio of 2:1 to 6:1, and (c) if the capsule shell comprises glycerin and the film-forming material comprises gelatin, the capsule shell has a gelatin:glycerin weight ratio of 5:1 to 8:1.

2. The pharmaceutical composition of Claim 1 wherein the capsule shell comprises glycerin and the film-forming material comprises gelatin, and wherein the capsule shell has a gelatin:glycerin weight ratio of 5:1 to 8:1.

3. The pharmaceutical composition of Claim 1 wherein the pharmaceutical composition contains less than 1% of any individual fatty acid other than ethyl eicosapentaenoate.

4. The pharmaceutical composition of Claim 1 wherein the pharmaceutical composition contains less than 0.5% of any individual fatty acid other than ethyl eicosapentaenoate.

5. The pharmaceutical composition of Claim 1 wherein the pharmaceutical composition contains less than 0.3% DHA, if any.

6. The pharmaceutical composition of Claim 5 wherein the pharmaceutical composition contains no DHA.

7. The pharmaceutical composition of Claim 1 wherein the pharmaceutical composition comprises 0.1% to 1%, by weight, of an antioxidant.

8. The pharmaceutical composition of Claim 7 wherein the antioxidant is tocopherol.

9. The pharmaceutical composition of Claim 1 wherein upon storage of the composition at 25°C and 60% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 7 meq/kg.

10. The pharmaceutical composition of Claim 1 wherein upon storage of the composition at 25°C and 60% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 6 meq/kg.

11. The pharmaceutical composition of Claim 1 wherein the composition has a baseline peroxide value from 0 meq/kg to 5 meq/kg and wherein upon storage of the composition at 30°C and 65% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 12 meq/kg.

12. The pharmaceutical composition of Claim 11 wherein upon storage of the composition at 30°C and 65% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 10 meq/kg.

13. The pharmaceutical composition of Claim 1 wherein upon storage of the pharmaceutical composition at 30°C and 65% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 10 meq/kg.

14. The pharmaceutical composition of Claim 13 wherein upon storage of the pharmaceutical composition at 30°C and 65% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 6 meq/kg.

15. The pharmaceutical composition of Claim 1 wherein the film-forming material contains no chemically modified gelatin.

16. The pharmaceutical composition of Claim 15 wherein the film-forming material contains no succinated gelatin.

17. The pharmaceutical composition of Claim 1 wherein the capsule shell has a weight ratio of gelatin to glycerol of 2.5:1 to 10:1.

18. The pharmaceutical composition of Claim 1 wherein the capsule shell has a weight ratio of gelatin to glycerol of 4:1 to 8:1.

19. The pharmaceutical composition of Claim 1 wherein the non-hygroscopic plasticizer comprises maltitol.

20. The pharmaceutical composition of Claim 1 wherein the capsule shell has a hygroscopic plasticizer to non-hygroscopic plasticizer weight ratio of 3:1 to 5:1.

21. The pharmaceutical composition of claim 1 wherein the composition has a dissolution profile as measured by RDC including at least one of: (1) 20%-100% of the ethyl-EPA is dissolved by 10 minutes; (2) 45%-100% of the ethyl-EPA is dissolved by 30 minutes; (3)80%-100% of the ethyl-EPA is dissolved by 60 minutes; and (4)95%-100% of the ethyl-EPA is dissolved by 100 minutes.

22. The pharmaceutical composition of claim 21 wherein the composition has a dissolution profile as measured by RDC wherein: (1) 20%-100% of the ethyl-EPA is dissolved by 10 minutes; (2) 45%-100% of the ethyl-EPA is dissolved by 30 minutes; (3) )80%-100% of the ethyl-EPA is dissolved by 60 minutes; and (4) 95%-100% of the ethyl-EPA is dissolved by 100 minutes.

23. A pharmaceutical composition comprising 95% to 99.9% ethyl-EPA enclosed in a capsule shell comprising a film-forming material free of chemically modified gelatin, a hygroscopic plasticizer selected from glycerin, sorbitol and alkylene glycols, and a non-hygroscopic plasticizer selected from maltitol, lactitol, xylitol, hydrogenated starch hydrolysate and glucose syrup, wherein the capsule shell has a weight ratio of hygroscopic plasticizer to non-hygroscopic plasticizer of 2:1 to 6:1, wherein if the capsule shell comprises glycerin and the film-forming material comprises gelatin, the capsule shell has a

gelatin:glycerin weight ratio of 5:1 to 10:1, and wherein the pharmaceutical composition has a baseline peroxide value from 0 meq/kg to 5 meq/kg and upon storage of the pharmaceutical composition at 30°C and 65% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value from 0 meq/kg to 5 meq/kg.

24. The pharmaceutical composition of claim 23 wherein the hygroscopic plasticizer comprises glycerol.

25. The pharmaceutical composition of Claim 23 wherein the capsule shell has a weight ratio of gelatin to glycerol of 5.2:1 to 10:1.

26. The pharmaceutical composition of claim 23 wherein the non-hygroscopic plasticizer comprises maltitol.

27. A pharmaceutical composition comprising 95% to 99.9% ethyl-EPA encapsulated in a capsule shell comprising non-chemically modified gelatin, a hygroscopic plasticizer selected from glycerin, sorbitol and alkylene glycols, and a non-hygroscopic plasticizer selected from maltitol, lactitol, xylitol, hydrogenated starch hydrolysate and glucose syrup, wherein the capsule shell has a weight ratio of gelatin to total plasticizer of 1.75:1 to 5:1 and a weight ratio of hygroscopic plasticizer to non-hygroscopic plasticizer of 3:1 to 5:1, wherein the pharmaceutical composition has a baseline peroxide value of 0 meq/kg to 5 meq/kg and upon storage of the pharmaceutical composition at 25°C and 60% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value of 0 meq/kg to 8 meq/kg, and wherein if the hygroscopic plasticizer comprises glycerin, the capsule shell has a gelatin:glycerin weight ratio of 5:1 to 10:1.

28. The composition of claim 27 wherein the hygroscopic plasticizer comprises glycerol and sorbitol and the non-hygroscopic plasticizer comprises maltitol.

29. The pharmaceutical composition of claim 27 wherein the pharmaceutical composition has a baseline peroxide value of 0 meq/kg to 5 meq/kg and upon storage of the pharmaceutical composition at 25°C and 60% RH for a period of 6 months, the pharmaceutical composition has a second peroxide value of 0 meq/kg to 5 meq/kg.

30. Use of a pharmaceutical composition of claim 1 in the manufacture of a medicament for treating or preventing a cardiovascular-related disease in a subject in need thereof, wherein 2 g per day to 4 g per day of said composition is to be administered to the subject.

31. The use of claim 30 wherein cardiovascular-related disease is selected from acute cardiac ischemic events, acute myocardial infarction, angina, angina pectoris, arrhythmia, atrial fibrulation, atherosclerosis, arterial fibrillation, cardiac insufficiency, cardiovascular disease, chronic heart failure, chronic stable angina, congestive heart failure, coronary artery disease, coronary heart disease, deep vein thrombosis, diabetes, diabetes mellitus, diabetic neuropathy, diastolic dysfunction in subjects with diabetes mellitus, edema, essential hypertension, eventual pulmonary embolism, fatty liver disease, heart disease, heart failure, homozygous familial hypercholesterolemia (HoFH), homozygous familial sitosterolemia, hypercholesterolemia, hyperlipidemia, hypertension, hypertriglyceridemia, ischemic complications in unstable angina and myocardial infarction, low blood pressure, metabolic syndrome, mixed dyslipidemia, moderate to mild heart failure, myocardial infarction, platelet aggregation, primary hypercholesterolemia, primary hyperlipidemia, pulmonary arterial hypertension, pulmonary hypertension, recurrent hemodynamically unstable ventricular tachycardia (VT), recurrent ventricular arrhythmias, recurrent ventricular fibrillation (VF), ruptured aneurysm, sitisterolemia, stroke, supraventricular tachycardia, symptomatic atrial fibrillation/flutter, tachycardia, type-II diabetes, vascular disease, venous thromboembolism, and ventricular arrhythmias.

32. The use of claim 31 wherein the cardiovascular-related disease is hypertriglyceridemia.