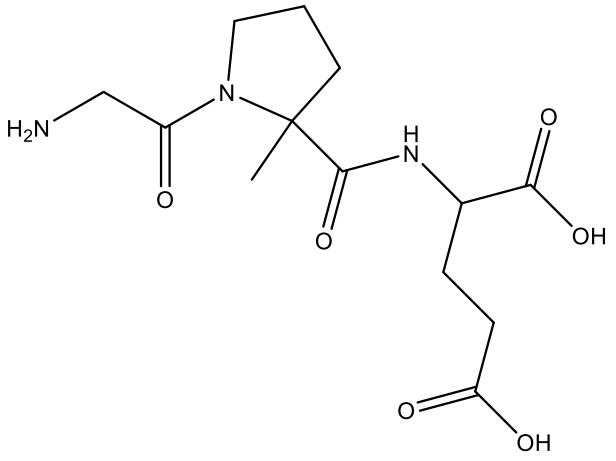
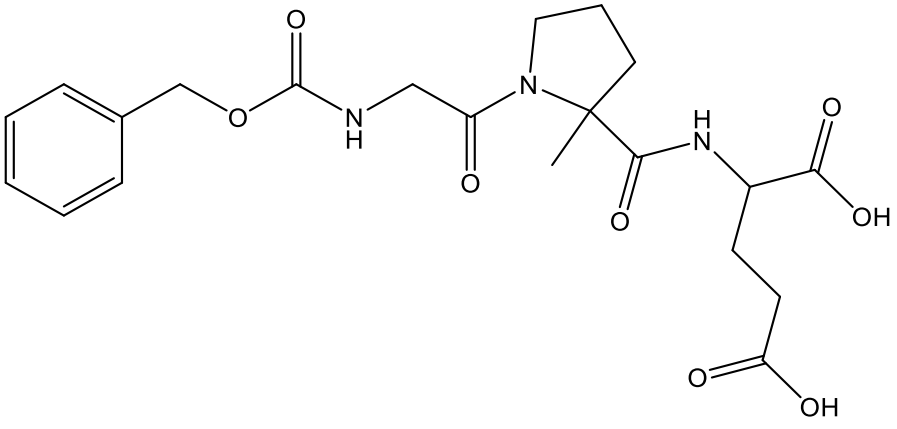
What is Claimed is:

1. A composition comprising a compound of Formula (I)



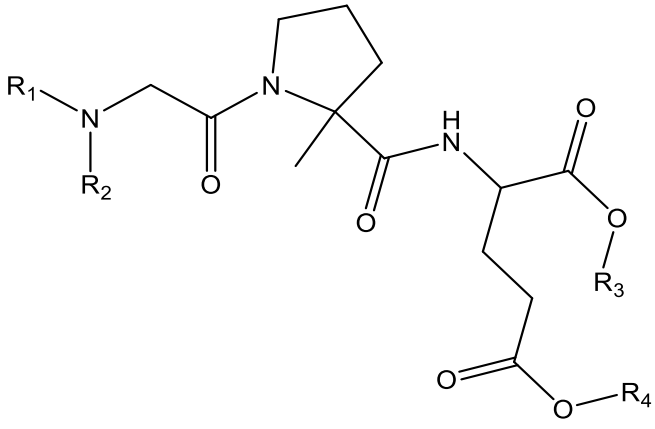
(I),

or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, and a compound of Formula (II):



(II),

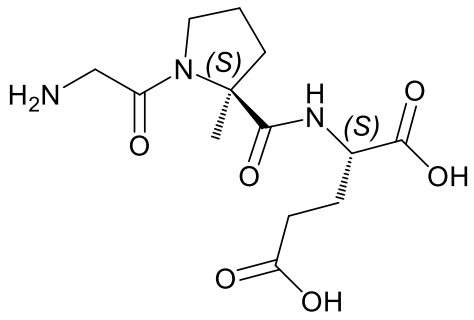
or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, and/or a compound of Formula (III):



(III),

or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, wherein R_1, R_2, R_3 and R_4 independently are selected from the group consisting of hydrogen and C_{1-4} alkyl, provided at least one of R_1, R_2, R_3 and R_4 is C_{1-4} alkyl.

2. The composition according to Claim 1, wherein the compound according to Formula (I) is a compound of Formula (Ia).



(Ia) (trofinetide),

or a hydrate, or pharmaceutically acceptable salt thereof.

3. The composition according to Claim 1 or 2, wherein the compound of Formula (II), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is absent or present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%; and the compound of Formula (III), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is absent or present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%, provided that at least one of the compounds of Formula (II) or (III), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present; and/or

wherein the compound of Formula (II), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount of between about 0.001±0.0002 wt% and about 0.3±0.06 wt%; and/or

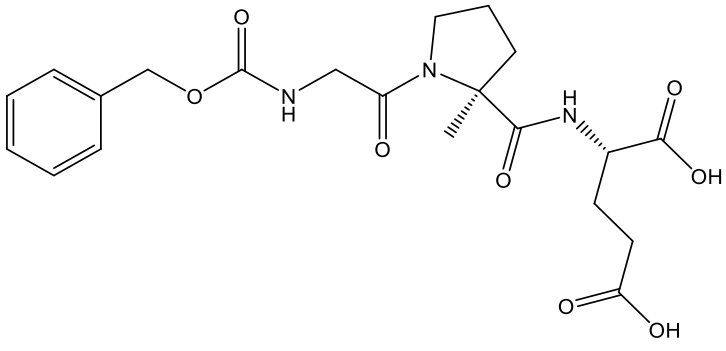
wherein the compound of Formula (II), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 0.1±0.02 wt%; and/or

wherein the compound of Formula (II), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%, or between about 0.001±0.0002 wt% and about 1.5±0.3 wt%, or between about 0.001±0.0002 wt% and about 1±0.2 wt%, or between about 0.001±0.0002 wt% and about 0.7±0.14 wt%, or between about 0.001±0.0002 wt% and about 0.5±0.1 wt%, or between about

0.001±0.0002 wt% and about 0.3±0.06 wt%, or between about 0.001±0.0002 wt% and about 0.2±0.04 wt%; and/or

wherein the compound of Formula (II), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is absent.

4. The composition according to any one of Claims 1 to 3, wherein the compound according to Formula (II) is a compound of Formula (IIa):

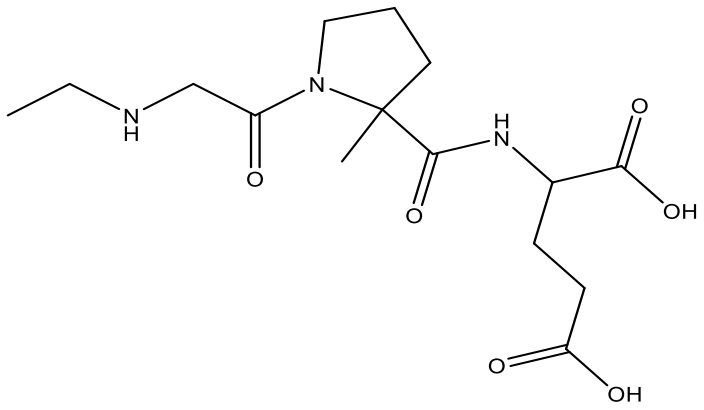


(IIa) (Z-Gly-MePro-Glu-OH),

or a hydrate, or pharmaceutically acceptable salt thereof.

5. The composition according to any one of Claims 1 to 4, wherein the compound of Formula (III), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 2.0±0.4 wt%.

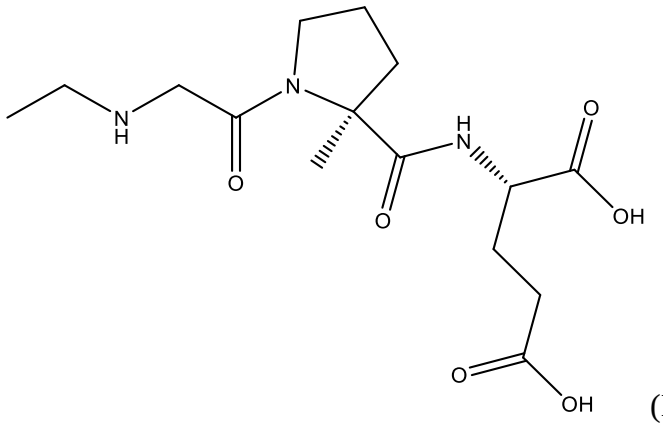
6. The composition according to any one of Claims 1 to 5, wherein said composition comprising the compound of Formula (III), wherein the compound of Formula (III) is a compound of Formula (IX),



(IX),

or hydrate, or pharmaceutically acceptable salt thereof; and/or

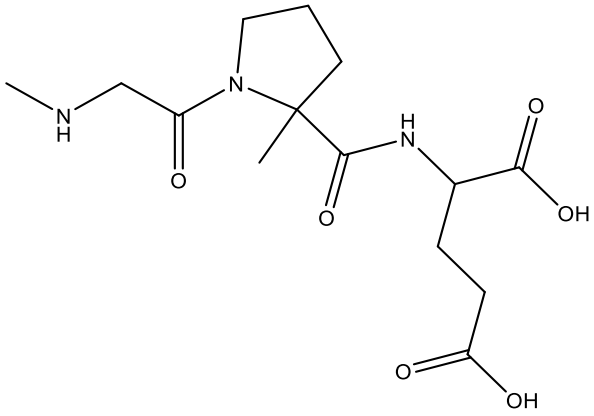
the compound according to Formula (III) is a compound of Formula (IIIa):



(IIIa) (Et-Gly-MePro-Glu-OH),

or hydrate, or pharmaceutically acceptable salt thereof; and/or

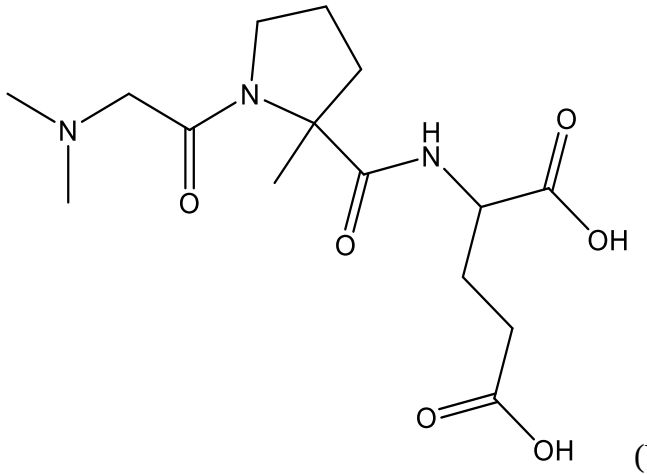
the compound according to Formula (III) is a compound of Formula (IV):



(IV) (Me-Gly-MePro-Glu),

or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof; and/or

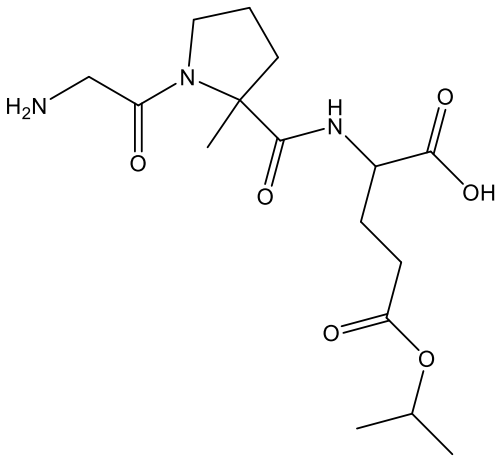
the compound of Formula (III) is a compound of Formula (V):



(V) (Me_2-Gly-MePro-Glu),

or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof; and/or

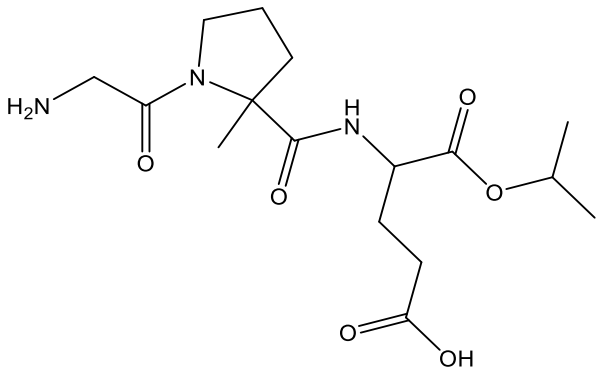
wherein the compound of Formula (III) is a compound of Formula (VI):



(VI) (Gly-MePro-Glu(OiPr)-OH),

or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof; and/or

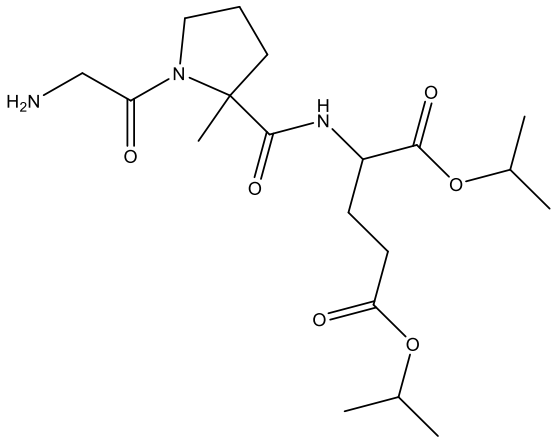
the compound of Formula (III) is a compound of Formula (VII):



(VII) (Gly-MePro-Glu-OiPr),

or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof; and/or

the compound of Formula (III) is a compound of Formula (VIII):



(VIII) (Gly-MePro-Glu-$(OiPr)_2$),

or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof.

7. The composition according to Claims 6, wherein

the compound of Formula (IIIa), or hydrate, or pharmaceutically acceptable salt thereof is present in an amount between about 0.001±0.0002 wt% and about 2.0±0.4 wt%, or between about 0.001±0.0002 wt% and about 1.5±0.3 wt%, or between about 0.001±0.0002 wt% and about 1±0.2 wt%, or between about 0.001±0.0002 wt% and about 0.7±0.14 wt%, or between about 0.001±0.0002 wt% and about 0.5±0.1 wt%, or between about 0.001±0.0002 wt% and about 0.3±0.06 wt%, or between about 0.001±0.0002 wt% and about 0.2±0.04 wt%; and/or

the compound of Formula (IV), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%, or between about 0.001±0.0002 wt% and about 1.5±0.3 wt%, or between about 0.001±0.0002 wt% and about 1±0.2 wt%, or between about 0.001±0.0002 wt% and about 0.7±0.14 wt%, or between about 0.001±0.0002 wt% and about 0.5±0.1 wt%, or between about 0.001±0.0002 wt% and about 0.3±0.06 wt%, or between about 0.001±0.0002 wt% and about 0.2±0.04 wt%; and/or

the compound of Formula (V), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%, or between about 0.001±0.0002 wt% and about 1.5±0.3 wt%, or between about 0.001±0.0002 wt% and about 1±0.2 wt%, or between about 0.001±0.0002 wt% and about 0.7±0.14 wt%, or between about 0.001±0.0002 wt% and about 0.5±0.1 wt%, or between about 0.001±0.0002 wt% and about 0.3±0.06 wt%, or between about 0.001±0.0002 wt% and about 0.2±0.04 wt%; and/or

the compound of Formula (VI), or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%, or between about 0.001±0.0002 wt% and about 1.5±0.3 wt%, or between about 0.001±0.0002 wt% and about 1±0.2 wt%, or between about 0.001±0.0002 wt% and about 0.7±0.14 wt%, or between about 0.001±0.0002 wt% and about 0.5±0.1 wt%, or between about 0.001±0.0002 wt% and about 0.3±0.06 wt%, or between about 0.001±0.0002 wt% and about 0.2±0.04 wt%; and /or

the compound of Formula (VII) or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%, or between about 0.001±0.0002 wt% and about 1.5±0.3 wt%, or between about 0.001±0.0002 wt% and about 1±0.2 wt%, or between about 0.001±0.0002 wt% and about 0.7±0.14 wt%, or between about 0.001±0.0002 wt% and about 0.5±0.1 wt%, or between about

0.001±0.0002 wt% and about 0.3±0.06 wt%, or between about 0.001±0.0002 wt% and about 0.2±0.04 wt%; and/or

the compound of Formula (VIII) or stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, is present in an amount between about 0.001±0.0002 wt% and about 2±0.4 wt%, or between about 0.001±0.0002 wt% and about 1.5±0.3 wt%, or between about 0.001±0.0002 wt% and about 1±0.2 wt%, or between about 0.001±0.0002 wt% and about 0.7±0.14 wt%, or between about 0.001±0.0002 wt% and about 0.5±0.1 wt%, or between about 0.001±0.0002 wt% and about 0.3±0.06 wt%, or between about 0.001±0.0002 wt% and about 0.2±0.04 wt%.

8. The composition according to any one of Claims 1 to 7 comprising between about 97 wt% and about 100 wt% of the compound of Formula (I) or Formula (Ia), alternatively between about 98 wt% and about 100 wt%, or between about 99 wt% and about 100 wt% on an anhydrous basis, or

comprising at least 90 wt%, such as at least 91 wt%, 92 wt%, 93 wt%, 94 wt%, 95 wt%, 96 wt%, and 97 wt%, of the compound of Formula (I) or a stereoisomer, hydrate, or pharmaceutically acceptable salt thereof, on an anhydrous basis, or comprising at least 90 wt%, such as at least 91 wt%, 92 wt%, 93 wt%, 94 wt%, 95 wt%, 96 wt%, and 97 wt%, of the compound of Formula (Ia) or a hydrate, or pharmaceutically acceptable salt thereof, on an anhydrous basis.

9. A method of manufacturing a composition containing trofinetide comprising the steps:

a) coupling H-MePro-OH and Z-Gly-OH in the presence of an activating agent, silylating agent and a solvent; or

b) coupling Z-Gly-OH and Suc-OH and then coupling the obtained Z-Gly-OSu and H-MePro-OH in the absence or presence of an activating reagent, a solvent and in the absence or presence of a silylating agent;

c) coupling the obtained Z-Gly-MePro-OH and H-Glu-OH in the presence of an activating reagent, silylating agent and a solvent;

d) obtaining Z-Gly-MePro-Glu-OH; and

e) deprotecting Z-Gly-MePro-Glu-OH, thereby producing trofinetide, wherein trofinetide is dissolved or suspended in a solvent.

10. The method of Claim 9, where said silylating agent does not contain a cyano group and/or

said silylating agent is selected from the group consisting of N,O-bis(trimethylsilyl)acetamide, N,O-bis(trimethylsilyl)trifluoroacetamide, hexamethyldisilazane, N-methyl-N-(trimethylsilyl)acetamide (TMA), N.-methyl-N-(trimethylsilyl)trifluoroacetamide, N-(trimethylsilyl)acetamide, N-(trimethylsilyl)diethylamine, N-(trimethylsilyl)dimethylamine, 1-(trimethylsilyl)imidazole, and 3-(trimethylsilyl)2-oxazolidone.

11. The method of Claim 9 or Claim 10 wherein said solvent in step a) is a polar organic solvent, or a polar aprotic organic solvent, and/or said solvent in step b) is a polar organic solvent, or a polar aprotic organic solvent, and/or said solvent in step c) is a polar organic solvent, or a polar aprotic organic solvent, and/or the solvent is selected from the group consisting of alkyl acetates, chlorinated hydrocarbons, alkyl cyanides and amide type solvents, or mixture thereof.

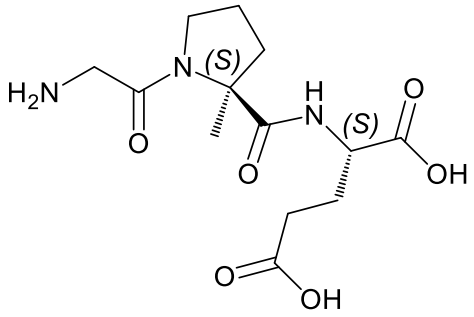
12. The method of any one of Claims 9 to 11, wherein said activating reagent is selected from the group consisting of carbodiimides, acyl halides, phosphonium salts, uronium salts and guanidinium salts.

13. The method of any one of Claims 9 to 12, wherein deprotecting is achieved by hydrogenation, and/or hydrogenation is performed in the presence of a Pd/C catalyst or a Pd/Si catalyst, and/or

hydrogenation is performed at a temperature from about 10-40 °C, or a temperature of about 20-30 °C, or a temperature of about 25 °C, and/or

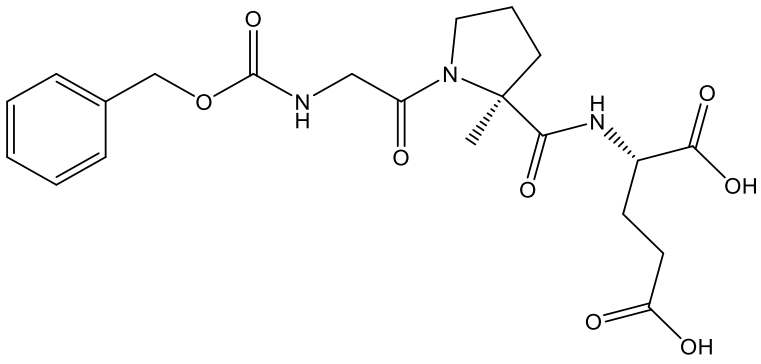
hydrogenation is performed at about 0 to about 6 bars of pressure, and/or hydrogenation is performed in at least one solvent selected from the group consisting of water, ethyl acetate, isopropyl acetate, methanol, ethanol, isopropanol, or mixtures thereof.

14. A kit containing a dosage form comprising a compound of Formula (Ia),



(Ia) (trofinetide),

a hydrate, or a pharmaceutically acceptable salt thereof, and a compound of Formula (IIa),



(IIa) (Z-Gly-MePro-Glu-OH),

or a hydrate, or pharmaceutically acceptable salt thereof, and instructions for administration to a subject in need thereof.

15. The kit of Claim 14, further comprising one or more compounds selected from the group consisting of Formula (III), Formula (IIIa), Formula (IV), Formula (V), Formula (VI), Formula (VII), Formula (VIII), and Formula (IX).