CLAIMS:

~~1) A pre-formulation comprising a low viscosity mixture of:~~

a) 20-80 wt.% of at least one diacyl glycerol and/or a tocopherol;
b) 20-80 wt.% of at least one phosphatidyl choline (PC);
c) 5-20 wt.% of at least one biocompatible, organic mono-alcoholic solvent;
d) up to 20 wt.% polar solvent
e) at least one peptide active agent;
f) optionally at least one antioxidant;

wherein the ratio of components a:b is in the range 40:60 to 54:46;
wherein the pre-formulation forms, or is capable of forming, at least one liquid crystalline phase structure upon contact with excess aqueous fluid.

2) A pre-formulation as claimed in claim 1 wherein component a) comprises glycerol dioleate (GDO).

3) A pre-formulation as claimed in any of claims 1 to 2 wherein component b) comprises soy PC.

4) A pre-formulation as claimed in any of claims 1 to 3 wherein component c) comprises ethanol, propanol, isopropanol or mixtures thereof, preferably ethanol.

5) A pre-formulation as claimed in any of claims 1 to 4 wherein component d) comprises water or propylene glycol or mixtures thereof and preferably comprises at least 2% water.

6) A pre-formulation as claimed in any of claims 1 to 5 wherein the peptide active agent comprises at least one somatostatin analogue selected from somatostatin 14, somatostatin 28, octreotide, lanreotide, pasireotide and vapreotide.

~~7) A pre-formulation as claimed in any of claims 1 to 6 wherein the antioxidant is ascorbic acid, EDTA or citric acid, preferably EDTA.~~

~~8) A pre-formulation as claimed in any of claims 1 to 7 wherein said pre~~ formulation excludes fragmentation agents, particularly polyethyleneoxides such as P80.

9) A pre-formulation as claimed in claims 1 to 8 wherein component a) is present at a level of 30-40% by weight.

10) A pre-formulation as claimed in claims 1 to 9 wherein component b) is present at a level of 30-40% by weight.

11) A pre-formulation as claimed in claims 1 to 10 wherein component c) is present at a level of 5-18 wt.%, preferably 8-15 wt.%.

12) A pre-formulation as claimed in claims 1 to 11 wherein component d) is present at a level of 1.2 to 20 % by weight, preferably 5 to 20 wt.%, more preferably 5-18 wt.%, most preferably 8-15 wt.%.

13) A pre-formulation as claimed in any of claims 1 to 12 wherein the ratio of components a:b is in the range 45:55 to 54:46.

14) A pre-formulation as claimed in any of claims 1 to 13 wherein the ratio of components c:d is preferably in the range 40:60 to 70:30.

15) A pre-formulation as claimed in any of claims 1 to 14 wherein the ratio of components d:f is in the range 1:50 to 1:1500.

16) A pre-formulation as claimed in any of claims 1 to 15 wherein said pre-formulation has an L_2 phase structure.

17) A pre-formulation as claimed in any of claims 1 to 16 comprising at least one formulation selected from those listed in Tables 1-3.

~~18) A pre-formulation as claimed in any of claims 1 to 17, excluding the following pre-formulations:~~

Formulation	GLP-1 / wt%	PC / wt%	GDO3 / wt%	EtOH / wt%	H_2O / wt%
Excl-K	0.5	35.775	43.725	10	10
Excl-L	1.0	35.55	43.45	10	10
Excl-M	2.0	37.35	45.65	5	10
Excl-N	2.0	32.85	40.15	10	15
Excl-O	2.0	30.4	45.6	10	12
Excl-P	3.0	30	45	10	12
Excl-Q	3.0	31.875	43.125	10	12
Excl-R	3.0	32.4	39.6	10	15
Excl-T	2.0*	32.85	40.15	10	15
Excl-U	2.0*	30.4	45.6	10	12

where EtOH is ethanol, PC is LIPOID S100 soybean phosphatidylcholine or LIPOID E 80 egg phosphatidylcholine (marked with *) and GDO is glycerol dioleate having quality (according to AC) as follows:

GDO quality (according to AC)	Monoglycerides	Diglycerides	Triglycerides
GDO3	0.5%	95.3%	4.0%

19) A process for the formation of a pre-formulation suitable for the administration of a peptide bioactive agent to a (preferably mammalian) subject, said process comprising forming a low viscosity mixture of:

a) 20-80 wt.% of at least one diacyl glycerol and/or a tocopherol;
b) 20-80 wt.% of at least one phosphatidyl choline (PC);
c) 5-20 wt.% of at least one biocompatible, organic mono-alcoholic solvent;
d) up to 20 wt.% polar solvent
e) at least one peptide active agent;
f) optionally at least one antioxidant;

wherein the ratio of components a:b is in the range 40:60 to 54:46;
and dissolving or dispersing at least one peptide active agent (preferably a somatostatin analogue) in the low viscosity mixture, or in at least one of components ~~a), b), c), d) and optionally f) prior to forming the low viscosity mixture.~~

~~20) The process as defined in claim 19 wherein the pre-formulation formed is a~~ pre-formulation as defined in any of claims 1 to 18.

21) Use of a low viscosity mixture of:

a) 20-80 wt.% of at least one diacyl glycerol and/or a tocopherol;
b) 20-80 wt.% of at least one phosphatidyl choline (PC);
c) 5-20 wt.% of at least one biocompatible, organic mono-alcoholic solvent;
d) up to 20 wt.% polar solvent;
e) at least one peptide active agent;
f) optionally at least one antioxidant;

wherein the ratio of components a:b is in the range 40:60 to 54:46;
in the manufacture of a pre-formulation for use in the sustained administration of said peptide active agent.

22) The use as claimed in claim 21 wherein the low viscosity mixture is as ~~defined in any of claims 1 to 18.~~

1.
~~23)~~ A method for the treatment of a human or non-human mammalian subject comprising administering to said subject a pre-formulation ~~as claimed in any of claims 1 to 18~~.

2. 1
~~24)~~ The method of claim ~~23~~ for the treatment of a human or non-human mammalian subject in need thereof to combat at least one condition selected from acromegaly, cancers, carcinomas, melanomas, tumours expressing at least one somatostatin receptor, sst(2)-positive tumours, sst(5)-positive tumours, prostate cancers, gastro-entero-pancreatic neuroendocrine (GEP NE) tumours, carcinoid tumours, insulinomas, gastrinomas, vasoactive intestinal peptide (VIP) tumours and glucagonomas, elevated growth hormone (GH), elevated insulin-like growth factor I (IGF-I), varicial bleeding (especially espohageal), chemotherapy induced gastro intestinal problems (such as diarrhea), lymphorrhea, diabetic retinopathy, thyroid eye disease, obesity, pancreatitis, and related conditions.

~~25)~~ A method of cosmetic treatment of a human or non-human mammalian subject comprising administering to said subject a pre-formulation ~~as claimed in any of claims 1 to 18.~~

~~26) Use of:~~

a) 20-80 wt.% of at least one diacyl glycerol and/or a tocopherol;
b) 20-80 wt.% of at least one phosphatidyl choline (PC);
c) 5-20 wt.% of at least one biocompatible, organic mono-alcoholic solvent;
d) up to 20 wt.% polar solvent
e) at least one peptide active agent;
f) optionally at least one antioxidant;

wherein the ratio of components a:b is in the range 40:60 to 54:46;
in the manufacture of a low viscosity pre-formulation medicament for use in the in vivo formation of a depot for treatment of at least one condition selected from acromegaly, cancers, carcinomas, melanomas, tumours expressing at least one somatostatin receptor, sst(2)-positive tumours, sst(5)-positive tumours, prostate cancers, gastro-entero-pancreatic neuroendocrine (GEP NE) tumours, carcinoid tumours, insulinomas, gastrinomas, vasoactive intestinal peptide (VIP) tumours and glucagonomas, elevated growth hormone (GH), elevated insulin-like growth factor I (IGF-I), varicial bleeding (especially espohageal), chemotherapy induced gastro intestinal problems (such as diarrhea), lymphorrhea, diabetic retinopathy, thyroid eye disease, obesity, pancreatitis, and related conditions.

27) The use according to claim 26 wherein the pre-formulation used is a pre-formulation as defined in any of claims 1 to 18.

28) A pre-filled administration device containing a pre-formulation as claimed in any of claims 1 to 18.

29) A device according to claim 28 wherein said pre-formulation delivers a ~~dosage in the range of 1 to 10 mg/week.~~

~~30) A kit comprising an administration device as claimed in any of claims 28 to 29.~~

4.

~~31)~~ A pre-formulation ~~as claimed in any of claims 1 to 18~~ for use in a method as claimed in claim ~~24.~~ 2.

~~32) Use of a polar solvent in a low viscosity mixture comprising:~~

a) 20-80 wt.% of at least one diacyl glycerol and/or a tocopherol;

b) 20-80 wt.% of at least one phosphatidyl choline (PC);

c) 5-20 wt.% of at least one biocompatible, organic mono-alcoholic solvent;

e) at least one peptide active agent;

f) optionally at least one antioxidant;

to reduce the discomfort on injection, decrease the viscosity and/or improve the release profile, without negatively affecting the release profile.