CLAIMS

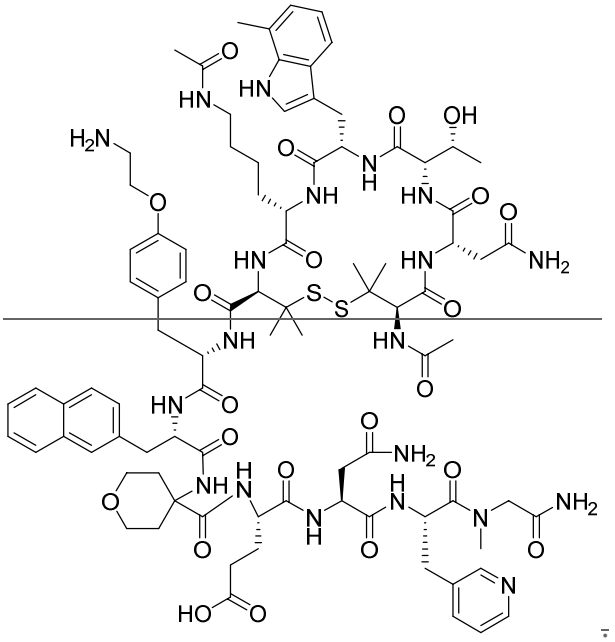
~~WHAT IS CLAIMED IS:~~

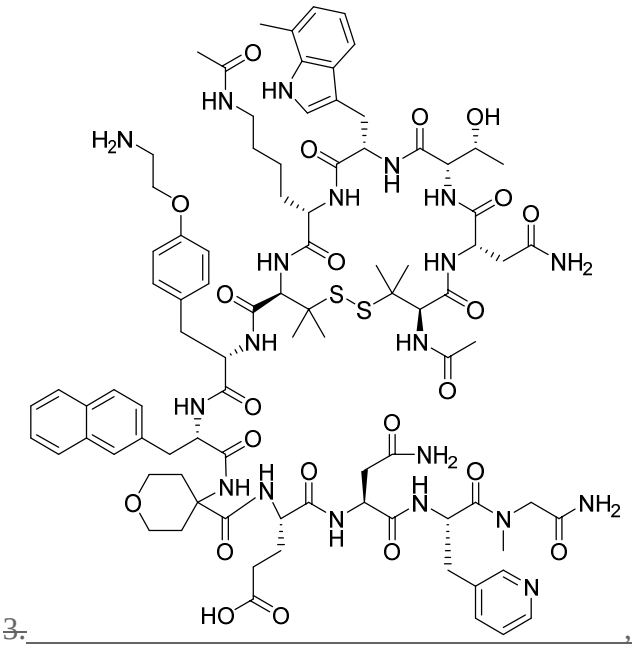
~~1.~~ ~~A~~1. A pharmaceutical composition comprising:

a peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof in an amount of from about 0.1% to about 15% (w/w) of the pharmaceutical composition; and

one or more pharmaceutically acceptable excipients.

~~2.~~2. The pharmaceutical composition of claim ~~1,~~1, wherein the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof, has the chemical structure:



~~3.~~ ,

and wherein the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is a pharmaceutically acceptable salt form.

3. The pharmaceutical composition of claim ~~1 or 2,~~1, wherein the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is an acetate form.

~~4.~~4. The pharmaceutical composition of claim ~~3,~~3, wherein the acetate form ~~of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof~~ is in an amorphous form.

~~5. The composition of any one of claims 1 to 4,~~5. The pharmaceutical composition of claim 1, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is from about 1 mg to about 1000 mg.

~~6. The composition of any one of claims 1 to 5,~~6. The pharmaceutical composition of claim 1, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is from about 10 mg to about 300 mg.

~~7. The composition of any one of claims 1 to 6,~~7. The pharmaceutical composition of claim 1, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is from about 25 mg to about 150 mg.

8.8. The composition of any one of claims 1 to 7, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is from about 25 mg to about 100 mg.

9. The composition of any one of claims 1 to 7, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is about 25 mg.

10. The composition of any one of claims 1 to 7, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is about 100 mg.

11. The composition of any one of claims 1 to 7, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is about 150 mg.

12. The composition of any one of claims 1 to 11, wherein the composition further comprises microcrystalline cellulose.

13. Thepharmaceutical composition of claim 12, wherein the microcrystalline cellulose is in an amount of from about 1% to about 25% (w/w) of the composition.

14. The composition of any one of claims 1 to 13, wherein the composition further comprises a silicified microcrystalline cellulose.

15. The composition of claim 14, wherein the silicified microcrystalline cellulose is in an amount of from about 25% to about 60% (w/w) of the composition.

16. The composition of any one of claims 1 to 15, wherein the composition further comprises one or more of alpha cellulose, beta cellulose, gamma cellulose, starch, modified starch, sorbitol, mannitol, lactose, dextrose, sucrose, dibasic calcium phosphate, tribasic calcium phosphate, or calcium carbonate.

17. The composition of any one of claims 1 to 16, wherein the composition further comprises sorbitol.

18. The composition of claim 17, wherein the sorbitol is in an amount of from about 5% to about 15% (w/w) of the composition.

19. The composition of any one of claims 1 to 18, wherein the1, wherein the pharmaceutical composition further comprises an absorption enhancer.

~~20. A~~9. The pharmaceutical composition of claim 8 comprising:

a peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof in an amount of from about 0.1% to about 15% (w/w) of the pharmaceutical composition;

an absorption enhancer in an amount from about 10% to about 60% (w/w); and

one or more pharmaceutically acceptable excipients.

10. Use of a pharmaceutical composition of claim 1 for the manufacture of a medicament for the treatment of an inflammatory disease.

11. A pharmaceutical composition comprising:

a peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof in an amount of from about 0.1% to about ~~15~~20% (w/w) of the pharmaceutical composition; and

~~an absorption enhancer in an amount from about 10% to about 60% (w/w); and~~

~~one or more pharmaceutically acceptable excipients.~~

~~21.~~one or more pharmaceutically acceptable excipients.

12. The pharmaceutical composition of claim ~~19 or 20,~~11, wherein the ~~absorption enhancer is sodium caprate, sodium caprylate, sodium palmitate, sodium stearate, sodium citrate, sodium salicylate, sodium salcaprozate (SNAC), a polyethylene glycol (PEG) modified medium chain fatty acid triglyceride of capric and caprylic acid, sucrose laurate, or lauroyl-L-carnitine (LC).~~

~~22. The composition of claim 21, wherein the absorption enhancer is sodium caprate.~~

~~23. The composition of claim 21, wherein the absorption enhancer is sodium salcaprozate.~~

~~24. The composition of claim 21, wherein the absorption enhancer is a polyethylene glycol (PEG) modified medium chain fatty acid triglyceride of capric and caprylic acid.~~

~~25. The composition of any one of claims 19 to 22 comprising:~~

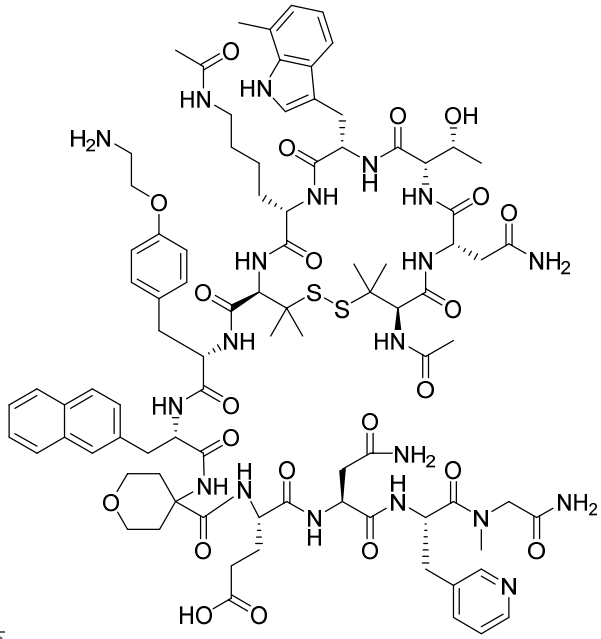
~~an internal phase comprising:~~

~~the~~ peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof ~~in an amount of from about 0.1% to about 15% (w/w) of the composition,~~ , has the chemical structure:

~~sodium caprate in an amount of from about 20% to about 45% (w/w) of the composition; and~~

~~an external phase disposed over the internal phase,~~

~~wherein the external phase comprises a microcrystalline cellulose.~~



~~26. The composition of claim 25,~~ _____ ,

and wherein the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is ~~present in an amount of from about 1% to about 5% (w/w).~~a pharmaceutically acceptable salt form.

~~27.~~13. The pharmaceutical composition of claim ~~25 or 26,~~12, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is ~~present in an amount of~~from about 1~~.8% (w/w).~~ mg to about 1000 mg.

~~28.~~14. The pharmaceutical composition of ~~any one of claims 25 to 27,~~claim 13, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is ~~present in an amount of~~ from about 10 mg to about 500 mg.

15. The pharmaceutical composition of claim 14, wherein the amount of the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof is from about 10 mg to about ~~50~~300 mg.

~~29. The composition of any one of claims 25 to 28, wherein the sodium caprate is present in an amount of from about 30% to about 40% (w/w).~~

~~30. The composition of any one of claims 25 to 29, wherein the sodium caprate is present in an amount of about 35.7% (w/w).~~

~~31. The composition of any one of claims 25 to 30, wherein the sodium caprate has a purity of at least 98%.~~

~~32. The composition of any one of claims 25 to 31, wherein the peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof and the sodium caprate form a granulated mixture.~~

~~33. The composition of any one of claims 25 to 32, wherein the composition further comprises a disintegrant.~~

~~34. The composition of claim 33, wherein the disintegrant is in an amount of from about 1% to about 10% (w/w) of the composition.~~

~~35. The composition of any one of claims 25 to 34, wherein the composition further comprises a hydrophilic silica.~~

~~36. The composition of claim 35, wherein the hydrophilic silica is in an amount of from about 0.1% to about 1.5% (w/w) of the composition.~~

~~37. The composition of any one of claim 25 to 36, wherein the internal phase further comprises at least one of:~~

~~a disintegrant in an amount from about 1% to about 10% (w/w) of the composition,~~

~~a microcrystalline cellulose in an amount from about 1% to about 10% (w/w) of the composition,~~

~~a hydrophilic silica in an amount from about 0.1% to about 1.5% (w/w) of the composition, or~~

sorbitol in an amount from about 5% to about 15% (w/w) of the composition.

38. The composition of any one of claims 25 to 37, wherein the microcrystalline cellulose of the external phase comprises a silicified microcrystalline cellulose (SMCC).

39. The composition of claim 38, wherein the microcrystalline cellulose of the external phase is a silicified microcrystalline cellulose (SMCC).

40. The composition of claim 38 or 39, wherein the silicified microcrystalline cellulose is SMCC 50, SMCC 50LD, SMCC 90, SMCC HD90 or SMCC 90LM.

41. The composition of any one of claims 38 to 40, wherein the silicified microcrystalline cellulose is present in an amount of from about 25% to about 45% (w/w) of the composition.

42. The composition of any one of claims 25 to 41, wherein the external phase further comprises at least one of:

a glidant in an amount from about 0.1% to about 0.5% (w/w) of the composition,

a disintegrant in an amount from about 1% to about 10% (w/w) of the composition, or

a hydrophilic silica in an amount from about 0.1% to about 1.5% (w/w) of the composition.

43. The composition of any one of claims 1 to 42, wherein the composition is a tablet or capsule composition.

44. The composition of any one of claims 1 to 43, wherein the composition is a tablet composition.

45. The composition of claim 43 or 44, wherein the tablet composition comprises a unit dose size of from about 500 mg to about 2000 mg.

46. The composition of claim 44 or 45, wherein the tablet composition comprises a unit dose size of about 1400 mg.

47. The composition of claim 25, wherein:

the internal phase comprises:

the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 1.8%

~~(w/w), and~~

~~sodium caprate in an amount of about 35.7% (w/w); and~~

~~the external phase comprises:~~

~~silicified microcrystalline cellulose HD90 in an amount of about 36.6% (w/w).~~

~~48. The composition of claim 47, wherein:~~

~~the internal phase comprises:~~

~~a granulated mixture of the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 1.8% (w/w), and sodium caprate in an amount of about 35.7% (w/w);~~

~~a microcrystalline cellulose in an amount of about 3.9% (w/w);~~

~~sorbitol in an amount of about 10.7% (w/w);~~

~~a disintegrant in an amount of about 5.0% (w/w); and~~

~~a hydrophilic silica in an amount of about 0.5% (w/w); and~~

~~the external phase comprises:~~

~~a silicified microcrystalline cellulose in an amount of about 36.6% (w/w);~~

~~a disintegrant in an amount of about 5.0% (w/w);~~

~~a hydrophilic silica in an amount of about 0.5% (w/w); and~~

~~a glidant in an amount of about 0.25% (w/w).~~

~~49. The composition of claim 48, wherein:~~

~~the internal phase comprises:~~

~~a granulated mixture of the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 1.8% (w/w), and sodium caprate in an amount of about 35.7% (w/w);~~

~~a microcrystalline cellulose in an amount of about 3.9% (w/w);~~

~~sorbitol in an amount of about 10.7% (w/w);~~

~~croscarmellose sodium in an amount of about 5.0% (w/w); and~~

~~colloidal anhydrous silica in an amount of about 0.5% (w/w); and~~

~~the external phase comprises:~~

~~a silicified microcrystalline cellulose in an amount of about 36.6% (w/w);~~

~~croscarmellose sodium in an amount of about 5.0% (w/w);~~

~~colloidal anhydrous silica in an amount of about 0.5% (w/w); and~~

~~magnesium stearate in an amount of about 0.25% (w/w).~~

~~50. The composition of claim 48, wherein:~~

~~the internal phase comprises:~~

~~a granulated mixture of the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 1.8% (w/w), and sodium caprate in an amount of about 35.7% (w/w);~~

~~Avicel PH101 in an amount of about 3.9% (w/w);~~

~~sorbitol in an amount of about 10.7% (w/w);~~

~~croscarmellose sodium in an amount of about 5.0% (w/w); and~~

~~Aerosil 200 in an amount of about 0.5% (w/w); and~~

~~the external phase comprises:~~

~~SMCC HD90 in an amount of about 36.6% (w/w);~~

~~croscarmellose sodium in an amount of about 5.0% (w/w);~~

~~Aerosil 200 in an amount of about 0.5% (w/w); and~~

~~magnesium stearate in an amount of about 0.25% (w/w).~~

~~51. The composition of claim 25, wherein:~~

~~the internal phase comprises:~~

~~the acetate form of peptide of SEQ ID NO: 1 in an amount of about 7.1% (w/w); and~~

~~sodium caprate in an amount of about 35.7% (w/w); and~~

~~the external phase comprises:~~

~~silicified microcrystalline cellulose HD90 in an amount of about 30.75% (w/w).~~

~~52. The composition of claim 25, wherein~~

~~the internal phase comprises:~~

~~a granulated mixture of the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 7.1% (w/w), and sodium caprate in an amount of about 35.7% (w/w);~~

~~a microcrystalline cellulose in an amount of about 3.9% (w/w);~~

~~sorbitol in an amount of about 10.7% (w/w);~~

a disintegrant in an amount of about 5.0% (w/w);

a hydrophilic silica in an amount of about 0.5% (w/w); and

a glidant in an amount of about 0.25% (w/w); and

the external phase comprises:

a silicified microcrystalline cellulose in an amount of about 30.75% (w/w);

a disintegrant in an amount of about 5.0% (w/w);

a hydrophilic silica in an amount of about 0.5% (w/w); and

a glidant in an amount of about 0.5% (w/w).

53. The composition of claim 52, wherein

the internal phase comprises:

a granulated mixture of the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 7.1% (w/w), and sodium caprate in an amount of about 35.7% (w/w);

Avicel PH101 in an amount of about 3.9% (w/w);

sorbitol in an amount of about 10.7% (w/w);

croscarmellose sodium in an amount of about 5.0% (w/w);

Aerosil 200 in an amount of about 0.5% (w/w); and

magnesium stearate in an amount of about 0.25% (w/w); and

the external phase comprises:

SMCC HD90 in an amount of about 30.75% (w/w);

a croscarmellose sodium in an amount of about 5.0% (w/w);

Aerosil in an amount of about 0.5% (w/w); and

magnesium stearate in an amount of about 0.5% (w/w).

54. The composition of claim 25, wherein

the internal phase comprises:

a granulated mixture of the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 7.1% (w/w), and sodium caprate in an amount of about 35.7% (w/w);

microcrystalline cellulose in an amount of about 3.9% (w/w);
sorbitol in an amount of about 10.7% (w/w);
croscarmellose sodium in an amount of about 5.0% (w/w);
colloidal anhydrous silica in an amount of about 0.5% (w/w); and
magnesium stearate in an amount of about 0.25% (w/w); and
the external phase comprises:
silicified microcrystalline cellulose in an amount of about 31.0% (w/w);
a croscarmellose sodium in an amount of about 5.0% (w/w);
colloidal anhydrous silica in an amount of about 0.5% (w/w); and
magnesium stearate in an amount of about 0.25% (w/w).

55. The composition of claim 25, wherein
the internal phase comprises:
a granulated mixture of the acetate form of the peptide of SEQ ID NO: 1 in an amount of about 10.7% (w/w), and sodium caprate in an amount of about 35.7% (w/w);
microcrystalline cellulose in an amount of about 3.9% (w/w);
sorbitol in an amount of about 10.7% (w/w);
croscarmellose sodium in an amount of about 5.0% (w/w); and
colloidal anhydrous silica in an amount of about 0.5% (w/w); and
the external phase comprises:
silicified microcrystalline cellulose in an amount of about 27.7% (w/w);
a croscarmellose sodium in an amount of about 5.0% (w/w);
colloidal anhydrous silica in an amount of about 0.5% (w/w); and
magnesium stearate in an amount of about 0.25% (w/w).

56. The composition of claim 1, wherein the compostion comprises:
the acetate form of peptide of SEQ ID NO: 1 in an amount of about 16.3% (w/w), and
sodium caprate in an amount of about 50.0% (w/w).

~~57. The composition of claim 56, further comprising:~~

~~a poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) in an amount of about 6.0% (w/w);~~

~~mannitol in an amount of about 15.2% (w/w);~~

~~a disintegrant in an amount of about 10.0% (w/w);~~

~~a hydrophilic silica in an amount of about 1.0% (w/w); and~~

~~a glidant in an amount of about 1.5% (w/w).~~

~~58. The composition of claim 57, further comprising:~~

~~Kolliphor P188 in an amount of about 6.0% (w/w);~~

~~mannitol in an amount of about 15.2% (w/w);~~

~~croscarmellose sodium in an amount of about 10.0% (w/w);~~

~~Aerosil 200 in an amount of about 1.0% (w/w); and~~

~~magnesium stearate in an amount of about 1.5% (w/w).~~

~~59. The composition of claim 1, wherein~~

~~the internal phase comprises:~~

~~the acetate form of peptide of SEQ ID NO: 1 in an amount of about 1.8% (w/w), and~~

~~microcrystalline cellulose in an amount of about 21.3% (w/w);~~

~~sorbitol in an amount of about 10.7% (w/w);~~

~~croscarmellose sodium in an amount of about 2.5% (w/w);~~

~~hydrophilic silica in an amount of about 0.5% (w/w); and~~

~~magnesium stearate in an amount of about 0.25% (w/w); and~~

~~the external phase comprises:~~

~~silicified microcrystalline cellulose HD90 in an amount of about 59.6% (w/w);~~

~~crocarmellose sodium in an amount of about 2.5% (w/w);~~

~~hydrophilic silica in an amount of about 0.5% (w/w); and~~

~~magnesium stearate in an amount of about 0.25% (w/w).~~

60. The composition of any one of claims 1 to 59, further comprising a subcoating of a PVA-PEG graft co-polymer disposed over the composition.

61. The composition of claim 60, wherein the subcoating is present in an amount from about 1% to about 10% (w/w).

62. The composition of claim 60 or 61, further comprising an enteric coating disposed over the subcoating.

63. The composition of claim 62, wherein the enteric coating is present in an amount from about 1% to about 15% (w/w).

64. The composition of any one of claims 1 to 63, wherein the composition has a bioavailability of at least about 1 to about 10% (w/w).

65. The composition of any one of claims 1 to 63, wherein the composition has a bioavailability in a range from about 10% to about 50% (w/w).

66. A composition comprising:

a peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof; and

a 50 mM pH 7.4 phosphate buffered aqueous solution.

67. A tablet made by the process of:

granulating a mixture comprising:

a peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof; and

sodium caprate;

adding to the granulated mixture:

a microcrystalline cellulose;

sorbitol;

a disintegrant; and

a hydrophilic silica, to form an internal phase;

compressing an external phase over the internal phase, wherein the external phase comprises a silicified microcrystalline cellulose;

applying a subcoating over the external phase; and

applying an enteric coating over the subcoating to form a tablet.

68. A method comprising:

granulating a mixture comprising:

a peptide of SEQ ID NO: 1 or a pharmaceutically acceptable salt or solvate form thereof; and

sodium caprate;

adding to the granulated mixture:

a microcrystalline cellulose;

sorbitol;

a disintegrant; and

a hydrophilic silica, to form an internal phase;

compressing an external phase over the internal phase, wherein the external phase comprises a silicified microcrystalline cellulose;

applying a subcoating over the external phase; and

applying an enteric coating over the subcoating to form a tablet.

69. A method of treating an inflammatory disease in a subject comprising administering to the subject a therapeutically effective amount of a composition according to any one of claims 1 to 66 or a tablet according to claim 67.

70. The method of claim 69, wherein the inflammatory disease is inflammatory bowel disease (IBD), Crohn's disease, ulcerative colitis, psoriasis, or psoriatic arthritis.

71. A method of treating an inflammatory bowel disease (IBD) in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a composition according to any one of claims 1 to 66 or a tablet according to claim 67.

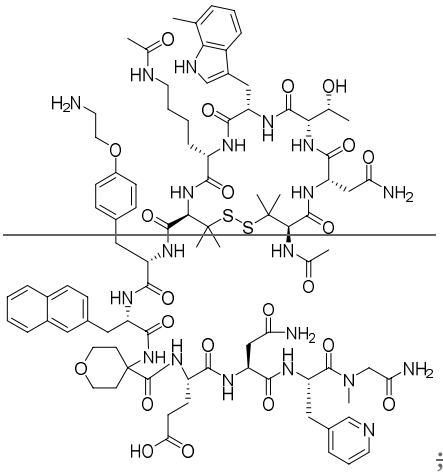
72. The method of claim 71, wherein the IBD is Crohn's disease or ulcerative colitis.

73. Use of a composition of any one of claims 1 to 66 or a tablet according to claim 67 in pharmaceutical composition of claim 11 for the manufacture of a medicament for treating an inflammatory bowel diseases (IBD).

74. A method of treating psoriasis or psoriatic arthritis in a subject in need thereof comprising administering to the subject a therapeutically effective amount of a composition according to any one of claims 1 to 66 or a tablet according to claim 67.

75. Use of a composition of any one of claims 1 to 66 or a tablet according to claim 67, in the manufacture of a medicament for treating psoriasis or psoriatic arthritis.

76 A method for IL-23 receptor inhibition for treating inflammatory diseases or disorders by delivering a systemically active peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):

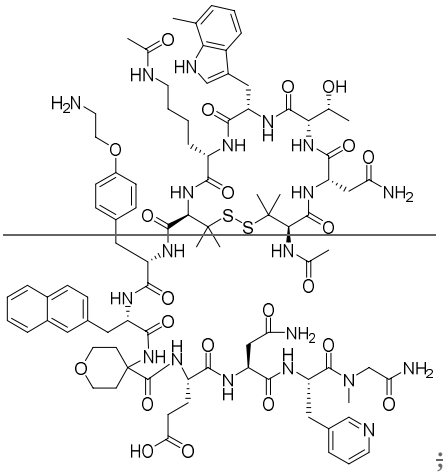


; or

a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

77. A method for IL-23 receptor inhibition for treating inflammatory diseases or disorders by delivering a pharmaceutical composition, which comprises:

[a] a therapeutically effective amount of a systemically active peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



; or

a pharmaceutically acceptable salt or solvate form thereof;

[b] optionally with or without an absorption enhancer; and

[c] at least one pharmaceutically acceptable excipient;

to a patient in need thereof.

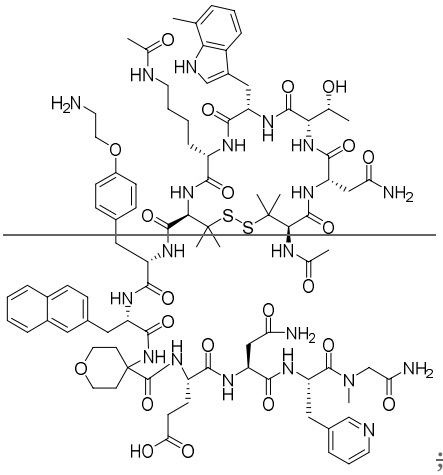
78. The method for IL-23 receptor inhibition for treating inflammatory diseases or disorders according to any one of claims 76 or 77, wherein the systemically active peptide or pharmaceutically acceptable salt thereof or pharmaceutical composition is orally administered.

79. The method for IL-23 receptor inhibition for treating inflammatory diseases or disorders according to any one of claims 76 or 77, wherein the systemically the active peptide compound or a pharmaceutically acceptable salt thereof or corresponding pharmaceutical composition thereof is or delivered directly via or to blood, blood circulation, tissue, skin or joints for the treatment of an inflammatory diseases or disorders.disease.

80. A method for systemically inhibiting or pharmacologically blocking:

- IL-23 receptor;
- IL-23 signalling through IL-23 receptor; or
- IL-23 pathway,

for treatment of inflammatory diseases or disorders, which comprises orally administering a therapeutically effective amount of a systemically active peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



; or

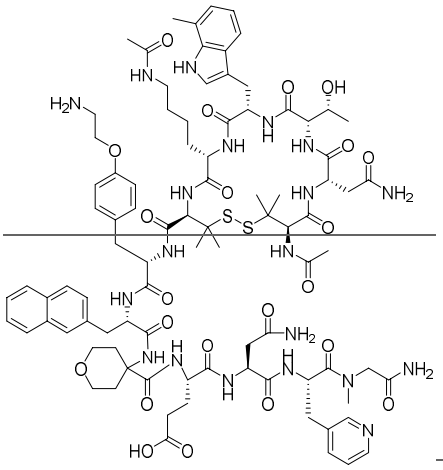
a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

81. A method for systemically inhibiting or pharmacologically blocking:

- IL-23 receptor,
- IL-23 signalling through IL-23 receptor; or
- IL-23 pathway,

for treatment of inflammatory diseases or disorders, which comprises orally administering a pharmaceutical composition, which comprises:

[a] a therapeutically effective amount of a systemically active peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



, or

a pharmaceutically acceptable salt or solvate form thereof;

[b] optionally with or without an absorption enhancer; and

[c] at least one pharmaceutically acceptable excipient

to a patient in need thereof.

82. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 80 or 81, wherein the inflammatory diseases or disorders are psoriasis, psoriatic arthritis, inflammatory bowel disease, ulcerative colitis or Crohn's disease.

77. The method for systemically inhibiting or pharmacologically blocking according to claim 82, wherein the inflammatory diseases or disorders are characterized as moderate to severe in degree.

78. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 80 or 81, which comprises administering the therapeutically effective amount of the systemically active peptide in a dose range from about 1 mg to about 1000 mg.

79. The method for systemically inhibiting or pharmacologically blocking: according to claim 84, which comprises administering the amount of the systemically active peptide in dose range from about 25 mg to about 100 mg.

80. The method for systemically inhibiting or pharmacologically blocking: according to any one of claims 83 to 85, which comprises administering the amount of the systemically active peptide in specific doses of 10 mg, 25 mg or 50 mg once daily or twice daily as needed.

81. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 83 to 86, which comprises administering 10 mg once daily.

82. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 83 to 86, which comprises administering 10 mg twice daily.

89. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 83 to 86, which comprises administering 25 mg once daily.

90. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 83 to 86, which comprises administering 25 mg twice daily.

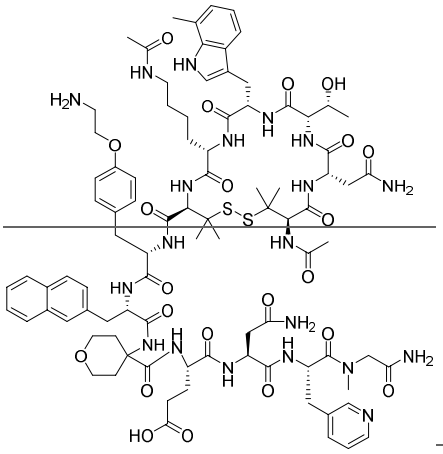
91. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 83 to 86, which comprises administering 50 mg once daily.

92. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 83 to 86, which comprises administering 50 mg twice daily.

93. The method for systemically inhibiting or pharmacologically blocking according to any one of claims 80 to 92, wherein after the amount of the systemically active peptide is dosed 50 mg once or twice daily greater than 50 % inhibition over a 24 hour period is observed.

94. A method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders, which comprises administering:

an oral dose of therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2-(*Pen-Pen form disulfide bond) (SEQ ID NO: 1):

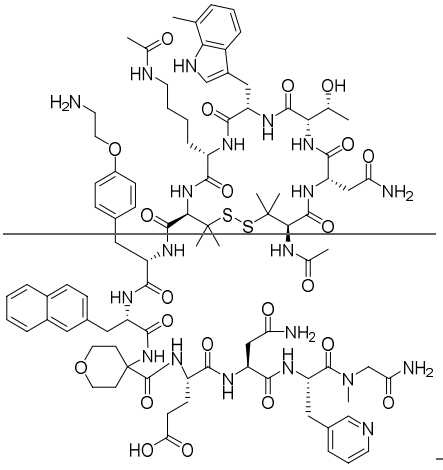


, or

a pharmaceutically acceptable salt or solvate form thereof.

95. A method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders, which comprises administering an oral dose of therapeutically effective amount of a pharmaceutical composition, which comprises:

[a] a therapeutically effective amount of a systemically active peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1);



, or

a pharmaceutically acceptable salt or solvate form thereof;

[b] optionally with or without an absorption enhancer; and

[c] at least one pharmaceutically acceptable excipient

to a patient in need thereof.

96. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to anyone of claims 94 or 95, wherein inhibition or blocking IL-23 receptor (IL23R) occurs in tissues including and beyond the gastrointestinal tract

97. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to any one of claims 94 or 95, wherein inflammatory diseases or disorders are selected from psoriasis, psoriatic arthritis, inflammatory bowel disease, ulcerative colitis, or Crohn's disease.

98. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to claim 97, wherein inflammatory diseases or disorders are moderate to severe in degree.

99. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to anyone of claims 94 to 98, wherein systemic pharmacodynamic activity in blood is directly proportional to the systemic exposure in human subjects.

100. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to anyone of claims 94 to 98, wherein level of target blockade is predicted by IC50 value.

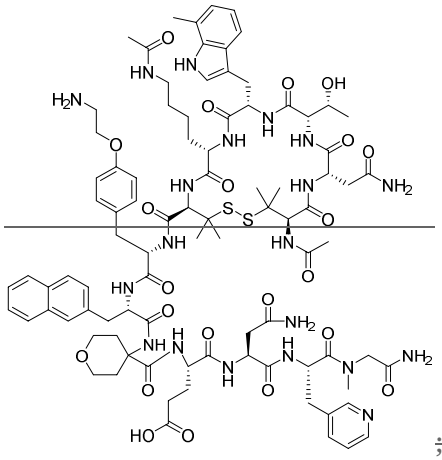
101. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to

anyone of claims 94 to 98, wherein sufficient exposure of the systemically active peptide level is at least above IC_{50} for 24 hours.

102. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to anyone of claims 94 to 98, wherein a level of target blockade is determined by IC_{50} values in picomolar range.

103. The method for inhibition or blocking of IL-23 receptor in blood, blood circulation, tissue, skin or joints for treatment of inflammatory diseases or disorders according to anyone of claims 94 to 98, wherein systemic exposure is required for inhibitory activity in the blood.

104. A method for inhibiting IL-23 receptor in a tissue selected from blood, skin, cartilage, or synovial membrane comprising administering an oral dose of a therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



; or

a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

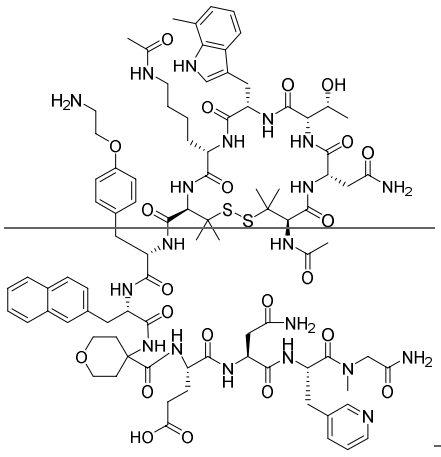
105. The method of claim 104, wherein the tissue is blood.

106. The method of claim 104, wherein the tissue is skin.

107. The method of claim 104, wherein the tissue is cartilage.

108. The method of claim 104, wherein the tissue is synovial membrane.

109. A method for inhibiting IL-23 receptor in a digestive tract tissue comprising administering an oral dose of a therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH_2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



, or a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

110. The method of claim 109, wherein the tissue is selected from the group consisting of mouth, esophagus, stomach, small intestine, large intestine, duodenum, and anus.

111. The method of claim 109, wherein the tissue is mouth.

112. The method of claim 109, wherein the tissue is esophagus.

113. The method of claim 109, wherein the tissue is stomach.

114. The method of claim 109, wherein the tissue is small intestine.

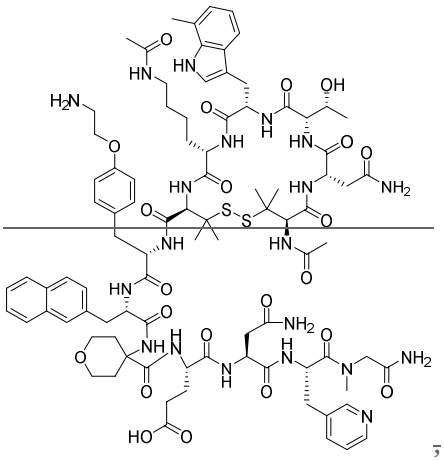
115. The method of claim 109, wherein the tissue is large intestine.

116. The method of claim 109, wherein the tissue is duodenum.

117. The method of claim 109, wherein the tissue is anus.

118. A method inhibiting the production of IL-17A in a tissue selected from blood, skin, cartilage, or synovial membrane comprising administering an oral dose of a

~~therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):~~



~~or a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.~~

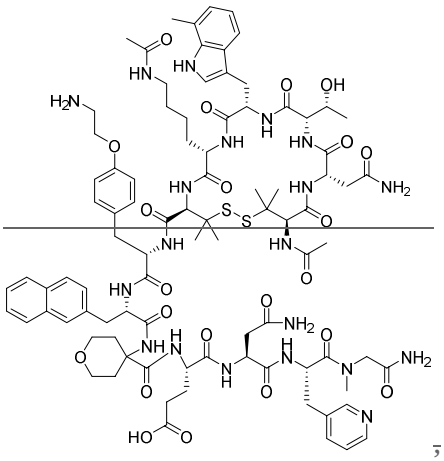
~~119. The method of claim 118, wherein the tissue is blood.~~

~~120. The method of claim 118, wherein the tissue is skin.~~

~~121. The method of claim 118, wherein the tissue is cartilage.~~

~~122. The method of claim 118, wherein the tissue is synovial membrane.~~

~~123. A method inhibiting the production of IL-17A in a digestive tract tissue comprising administering an oral dose of a therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):~~



~~or a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.~~

124. The method of claim 123, wherein the tissue is selected from the group consisting of mouth, esophagus, stomach, small intestine, large intestine, duodenum, and anus.

125. The method of claim 123, wherein the tissue is mouth.

126. The method of claim 123, wherein the tissue is esophagus.

127. The method of claim 123, wherein the tissue is stomach.

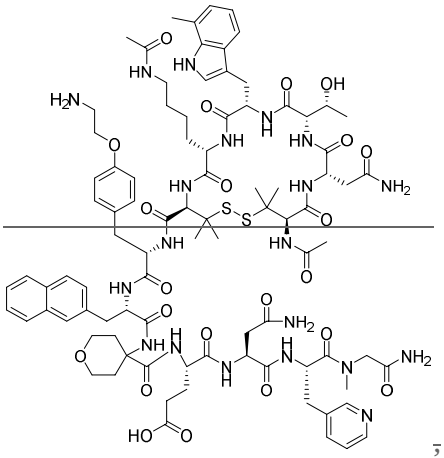
128. The method of claim 123, wherein the tissue is small intestine.

129. The method of claim 123, wherein the tissue is large intestine.

130. The method of claim 123, wherein the tissue is duodenum.

131. The method of claim 123, wherein the tissue is anus.

132. A method inhibiting the production of IL-17F in a tissue selected from blood, skin, cartilage, or synovial membrane comprising administering an oral dose of a therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



;

or a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

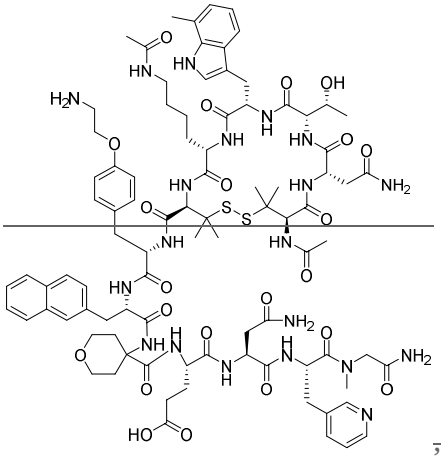
133. The method of claim 132, wherein the tissue is blood.

134. The method of claim 132, wherein the tissue is skin.

135. The method of claim 132, wherein the tissue is cartilage.

136. The method of claim 132, wherein the tissue is synovial membrane.

137. A method inhibiting the production of IL-17F in a digestive tract tissue comprising administering an oral dose of a therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



or a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

138. The method of claim 137, wherein the tissue is selected from the group consisting of mouth, esophagus, stomach, small intestine, large intestine, duodenum, and anus.

139. The method of claim 137, wherein the tissue is mouth.

140. The method of claim 137, wherein the tissue is esophagus.

141. The method of claim 137, wherein the tissue is stomach.

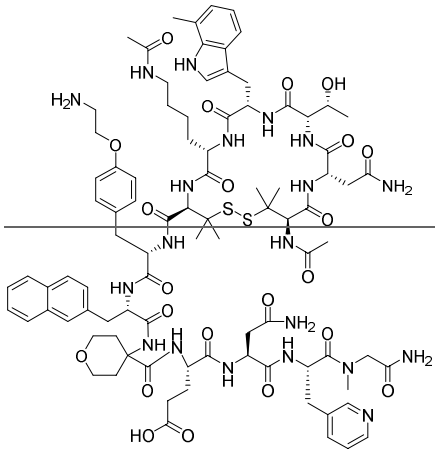
142. The method of claim 137, wherein the tissue is small intestine.

143. The method of claim 137, wherein the tissue is large intestine.

144. The method of claim 137, wherein the tissue is duodenum.

145. The method of claim 137, wherein the tissue is anus.

146. A method inhibiting the production of IL-22 in a tissue selected from blood, skin, cartilage, or synovial membrane comprising administering an oral dose of a therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



or a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

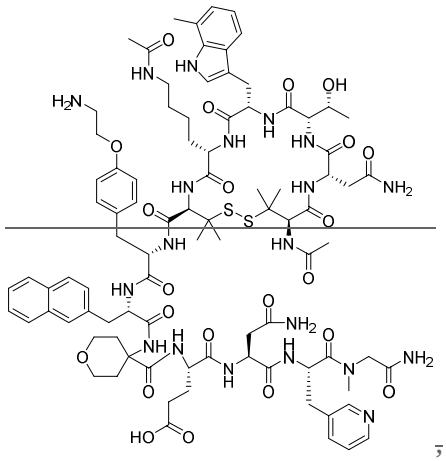
147. The method of claim 146, wherein the tissue is blood.

148. The method of claim 146, wherein the tissue is skin.

149. The method of claim 146, wherein the tissue is cartilage.

150. The method of claim 146, wherein the tissue is synovial membrane.

151. A method inhibiting the production of IL-22 in a digestive tract tissue comprising administering an oral dose of a therapeutically effective amount of a peptide Ac-[Pen]*-N-T-[W(7-Me)]-[Lys(Ac)]-[Pen]*-Phe[4-(2-aminoethoxy)]-[2-Nal]-[THP]-E-N-[3-Pal]-Sarc-NH2 (*Pen-Pen form disulfide bond) (SEQ ID NO: 1):



or a pharmaceutically acceptable salt or solvate form thereof to a patient in need thereof.

152. The method of claim 151, wherein the tissue is selected from the group consisting of mouth, esophagus, stomach, small intestine, large intestine, duodenum, and anus.

153. The method of claim 151, wherein the tissue is mouth.

~~154. The method of claim 151, wherein the tissue is esophagus.~~

~~155. The method of claim 151, wherein the tissue is stomach.~~

~~156. The method of claim 151, wherein the tissue is small intestine.~~

~~157. The method of claim 151, wherein the tissue is large intestine.~~

~~158. The method of claim 151, wherein the tissue is duodenum.~~

~~159. The method of claim 151, wherein the tissue is anus.~~

~~160. The method of any of claims 104 to 108, 118 to 122, 132 to 136, or 146 to 150 wherein the oral dose is 10 mg to 25 mg.~~

~~161. The method of any of claims 109 to 117, 123 to 131, 137 to 145, or 151 to 159 wherein the oral dose is 25 mg to 50 mg.~~

~~162. The method of claim 160, wherein the oral dose is 10 mg.~~

~~163. The method of claim 160, wherein the oral dose is 25 mg.~~

~~164. The method of claim 161, wherein the oral dose is 25 mg.~~

~~165. The method of claim 161, wherein the oral dose is 50 mg.s~~