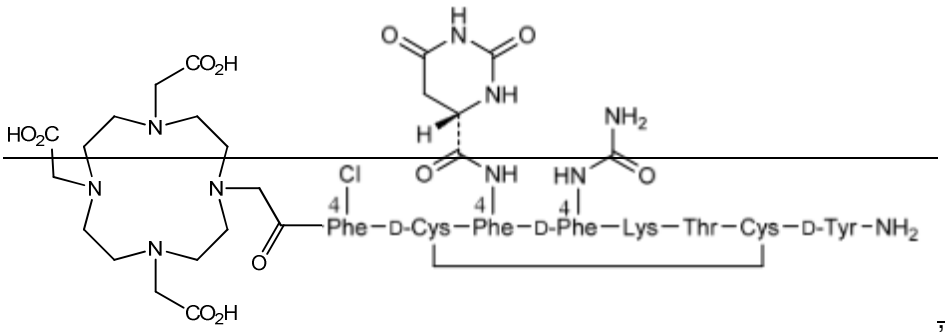
CLAIMS

1. A receptor-selective somatostatin peptide antagonist composition, wherein said composition comprises:

- DOTA-peptide of formula



,

or a salt thereof,

- an antioxidant, and

- a bulking agent.

2. The composition according to claim 1, wherein said composition comprises:

- DOTA-peptide, or a salt thereof,

- an antioxidant,

- a bulking agent,

- a buffering agent, and

- a surfactant.

3. The composition according to claim 1 or 2, wherein the weight ratio of the antioxidant over DOTA-peptide is of at least 20, more preferably comprised from 20 to 60, advantageously comprised from 30 to 50.

4. The composition according to any one of claims 1 to 3, wherein:

- the antioxidant is selected from ascorbic acid or a salt thereof;

- the bulking agent is selected from arginine and histidine, and

- a surfactant is a polysorbate.

5. The composition according to any one of claims 1 to 4, wherein said composition is in a lyophilized form.

6. The composition according to claim 5, wherein the DOTA-peptide is in a salt form and is present in the range of 0.10 % to 3.00 % by weight relative to the total weight of the composition, preferably from 0.50 % to 2.50 %, more preferably from 1.00 % to 2.00 %.

7. The composition according to claim 5 or 6, wherein the antioxidant is present in the range of 40 % to 70 % by weight relative to the total weight of the composition, preferably from 45 % to 65 %, more preferably from 50 % to 60 %.

8. The composition according to claim 7, wherein the antioxidant is ascorbic acid.

9. The composition according to any one of claims 5 to 8, wherein the bulking agent is present in the range of 25 % to 55 % by weight relative to the total weight of the composition, preferably from 30 % to 50 %, more preferably from 35 % to 45 %.

10. The composition according to claim 9, wherein the bulking agent is a basic amino acid, such as arginine, lysine or histidine, and more preferably arginine.

11. The composition according to any one of claims 5 to 10, wherein the surfactant is present in the range of 0.01 % to 0.10% by weight relative to the total weight of the composition, preferably in the range of 0.02 % to 0.08 %.

12. The composition according to claim 11, wherein the surfactant is polysorbate 80.

13. The composition according to any one of claims 5 to 12, wherein said composition comprises:

- DOTA-peptide acetate salt in the range of 0.10 % to 3.00 % by weight,

- ascorbic acid in the range of 40 % and 70 % by weight,

- arginine in the range of 25 % to 55 % by weight, and

- a polysorbate in the range of 0.01 % to 0.10 % by weight,

wherein DOTA-peptide acetate salt, ascorbic acid, the disaccharide and the polysorbate, taken together, represent at least 98 % of the total weight of the lyophilized composition.

14. The composition according to any one of claims 1 to 4, wherein said composition is in a liquid aqueous form.

15. The composition according to claim 14, wherein said composition comprises:

- DOTA-peptide in a salt form,
- ascorbic acid,
- arginine,
- a polysorbate, and
- water for injection.

16. The composition according to any one of claim 14 or 15, wherein the DOTA-peptide in a salt form is at a concentration of 0.1 to 2.0 mg/mL, preferably at a concentration of 0.25 to 1.75 mg/mL, more preferably at a concentration of 0.5 to 1.5 mg/mL, more preferably at a concentration of 0.75 to 1.25 mg/mL.

17. The composition according to any one of claims 1 to 4, wherein said composition a radiolabeled composition.

18. The composition according to claim 17, wherein said composition comprises:

- $^{177}Lu^{3+}$ radiolabeled DOTA-peptide,
- ascorbic acid and a salt thereof,
- arginine,
- a polysorbate,
- DTPA, and
- water for injection.

19. A kit for the preparation of a radiopharmaceutical composition, said kit comprising at least a suitable container containing a composition according to any one of

claims 1 to 16, preferably a lyophilized composition according to according to any one of claims 5 to 13.

20. A kit according to claim 19, said kit comprising:

- a first vial containing a lyophilized composition according to any one of claims 5 to 13, and
- a second vial containing a sterile stabilizing solution comprising an antioxidant.

21. A kit according to claim 20, wherein the sterile stabilizing solution comprises water for injection, sodium ascorbate, DTPA and polysorbate 80.

22. A radiolabeled composition according to any one of claim 17 or 18, for its use for treating a tumor in a mammal, preferably a SSTR2 receptor positive tumor, such as neuroendocrine tumors (NETs), and particularly gastroenteropancreatic neuroendocrine tumors (GEP NETs), or tumors of prostate, breast, lung or lymphoma cancer.

23. A method for treating SSTR2 receptor positive tumors within human body, said method comprising administering to said human an efficient quantity of a radiolabeled composition according to any one of claim 17 or 18.

1. An invention not claimed in any divisional application.