CLAIMS

1. A process for manufacturing a pharmaceutical aqueous solution, comprising:

providing a solution comprising a complex of the radionuclide ^{177}Lu (Lutetium-177) and DOTA-TATE; a first stabilizer against radiolytic degradation selected from gentisic acid or a salt thereof and ascorbic acid or a salt thereof in an amount to result in a concentration of 0.5 to 2 mg/mL in the pharmaceutical aqueous solution, and optionally a second stabilizer against radiolytic degradation different from the first stabilizer; and

diluting the solution comprising the complex with an aqueous dilution solution comprising at least one second stabilizer against radiolytic degradation which is ascorbic acid or a salt thereof to obtain the pharmaceutical aqueous solution, wherein the second stabilizer is in an amount to result in a concentration of 2.2 to 3.4 mg/mL in the pharmaceutical aqueous solution;

wherein, in the obtained pharmaceutical aqueous solution, the radionuclide ^{177}Lu is present in a concentration that it provides a volumetric radioactivity of from 250 to 500 MBq/mL, the stabilizer(s) is/are present in a total concentration of from 1.0 to 5.0 mg/mL, and ethanol is present in a concentration of less than 1%.

2. The process according to claim 1, comprising:

(1) forming a complex of the radionuclide ^{177}Lu and a somatostatin receptor binding peptide linked to the chelating agent DOTA by

(1.1) providing an aqueous solution comprising the radionuclide;

(1.2) providing an aqueous solution comprising the somatostatin receptor binding peptide linked to the chelating agent, and a first stabilizer against radiolytic degradation selected from gentisic acid or a salt thereof and ascorbic acid or salt thereof and optionally a second stabilizer against radiolytic degradation different from the first stabilizer; and

(1.3) mixing the solutions provided in steps (1.1) and (1.2) and heating the resulting mixture to form a solution comprising the complex;

(2) diluting the solution comprising the complex obtained by step (1) by

(2.1) providing an aqueous dilution solution comprising at least one stabilizer against radiolytic degradation selected from gentisic acid or a salt thereof and; and

(2.2.) mixing the solution comprising the complex obtained by step (1) with the dilution solution provided in step (2.1) to obtain the pharmaceutical aqueous solution.

3. The process according to claim 2, wherein the stabilizer/stabilizers provided in step (1.2) is/are present during the complex formation in step (1.3) in a total concentration of from 15 to 50 mg/mL.

4. The process according to claim 3, wherein the stabilizer/stabilizers provided in step (1.2) is/are present during the complex formation in step (1.3) in a total concentration of from 20 to 40 mg/mL.

5. The process according to claim 2, wherein in step (1.3) the resulting mixture is heated to a temperature of from 70 to 99 °C, for from 2 to 59 min.

6. The process according to claim 5, wherein in step (1.3) the resulting mixture is heated to a temperature of from 90 to 98 °C for from 5 to 15 min.

7. The process according to claim 2, wherein the solution provided in step (2.1) further comprises diethylentriaminepentaacetic acid (DTPA) or a salt thereof.

8. The process according to claim 2, further comprising the process steps:

(3) filtering the solution obtained by step (2) through 0.2 µm; and

(4) dispensing the filtered solution obtained by step (3) into dose unit containers in a volume required to deliver the radioactive dose of 7.4 GBq ± 10 %.

9. The process according to claim 2, wherein the solution of step (1.1) comprises $LuCl_3$ and HCl.

10. The process according to claim 2, wherein the solution of step (2.1) comprises DTPA and ascorbic acid.

11. The process according to claim 8, wherein the dose unit containers in step (4) are stoppered vials, enclosed within a lead container.

12. The process according to claim 1, which is free of ethanol.

13. The process according to claim 1, for which the radiochemical purity of the pharmaceutical aqueous solution as determined by HPLC is maintained at ≥ 95% for at least 72 h when stored at 25 °C.