Claims

1. A pharmaceutical aqueous solution comprising:

(a) a complex comprising

(ai) the radionuclide ^{177}Lu, and

(aii) DOTA-TATE; and

(b) at least one stabilizer(s) against radiolytic degradation;

wherein:

the at least one stabilizer(s) against radiolytic degradation is/are present in a total concentration of 0.5 mg/mL to 10.0 mg/mL;

the activity of the pharmaceutical aqueous solution is 7.4 GBq ±10%;

the volume of the pharmaceutical aqueous solution is 20.5 mL to 25 mL; and

the pharmaceutical aqueous solution comprises less than 1% ethanol, wherein the radiochemical purity of the pharmaceutical aqueous solution as determined by HPLC can be maintained at ≥95% for at least 72 hours when stored at 25 °C.

2. The pharmaceutical aqueous solution of claim 1, wherein the pharmaceutical aqueous solution is a ready-to-use single dose pharmaceutical aqueous solution.

3. The pharmaceutical aqueous solution of claim 1, wherein the at least one stabilizer(s) against radiolytic degradation is/are present in a total concentration of 1.0 mg/mL to 5.0 mg/mL.

4. The pharmaceutical aqueous solution of claim 1, wherein the at least one stabilizer(s) against radiolytic degradation comprises ascorbic acid or a salt thereof.

5. The pharmaceutical aqueous solution of claim 1, wherein the pharmaceutical aqueous solution is free of ethanol.

6. The pharmaceutical aqueous solution of claim 1, further comprising a sequestering agent.

7. The pharmaceutical aqueous solution of claim 6, wherein the sequestering agent is diethylentriaminepentaacetic acid (DTPA) or a salt thereof; and the DTPA or a salt thereof is present in an amount to result in a concentration of 0.01 mg/mL to 0.10 mg/mL.

8. A dose unit container enclosing the pharmaceutical aqueous solution of claim 1.

9. A lead container enclosing the dose unit container of claim 8.

10. A dose unit container comprising a dose unit comprising 20.5 to 25 mL of a pharmaceutical aqueous solution, the pharmaceutical aqueous solution comprising:

(a) a complex comprising

(ai) the radionuclide ^{177}Lu, and

(aii) DOTA-TATE; and

(b) at least one stabilizer(s) against radiolytic degradation;

wherein:

the at least one stabilizer(s) against radiolytic degradation is/are present in a total concentration of 0.5 mg/mL to 10.0 mg/mL; and

the activity of the pharmaceutical aqueous solution is 7.4 GBq ±10%; and

the pharmaceutical aqueous solution comprises less than 1% ethanol, wherein the radiochemical purity of the pharmaceutical aqueous solution as determined by HPLC can be maintained at ≥95% for at least 72 hours when stored at 25 °C.

11. The dose unit container of claim 10, wherein the pharmaceutical aqueous solution is a ready-to-use single dose pharmaceutical aqueous solution.

12. The dose unit container of claim 10, wherein the container comprises a stoppered vial comprising the pharmaceutical aqueous solution.

13. A lead container enclosing the dose unit container of claim 10.

14. A lead container enclosing the dose unit container of claim 12.

15. Use of the dose unit container of claim 10 in the manufacture of a medicament for the treatment of a neuroendocrine tumor (NET) in a patient in need thereof, wherein the dose unit in the dose unit container of claim 14 is to be administered to the patient.

16. Use of the pharmaceutical aqueous solution of claim 1 in the manufacture of a medicament for the treatment of a neuroendocrine tumor (NET) in a patient in need thereof, wherein the medicament is to be administered to the patient.

17. The use of claim 16, wherein the medicament is to be administered by injection or infusion.

18. Use of a pharmaceutical aqueous solution in the manufacture of a medicament for the treatment of a neuroendocrine tumor (NET) in a patient in need thereof, the pharmaceutical aqueous solution comprising:

(a) a complex comprising

(ai) the radionuclide ^{177}Lu, and

(aii) DOTA-TATE; and

(b) at least one stabilizer(s) against radiolytic degradation;

wherein:

the at least one stabilizer(s) against radiolytic degradation is/are present in a total concentration of 0.5 mg/mL to 10.0 mg/mL; and

the pharmaceutical aqueous solution comprises less than 1% ethanol,

wherein a volume of the pharmaceutical aqueous solution to be administered to the patient is 20.5 mL to 25 mL and a dose to be administered to the patient is 7.4 GBq ±10%, wherein the radiochemical purity of the pharmaceutical aqueous solution as determined by HPLC can be maintained at ≥95% for at least 72 hours when stored at 25 °C.

19. The use of claim 18, wherein the tumor is selected from the group consisting of gastroenteropancreatic neuroendocrine tumor, neuroendocrine carcinoid tumor, neuroendocrine small cell lung cancer, neuroendocrine glioma, neuroendocrine prostate cancer, neuroendocrine meningioma, neuroendocrine neuroblastoma, neuroendocrine paraganglioma, neuroendocrine pheochromocytoma, pulmonary NET, neuroendocrine medullary thyroid cancer, neuroendocrine breast cancer, neuroendocrine head & neck tumor and pancreatic NET, neuroendocrine thymic cancer and lung NET.

20. The use of claim 18, wherein the administering is by injection or infusion.

21. The use of claim 18, wherein the pharmaceutical aqueous solution is to be administered to the patient within a period of 20 minutes to 30 minutes by infusion.

22. The pharmaceutical aqueous solution of claim 7, wherein the DTPA or a salt thereof is present in an amount to result in a concentration of 0.01 mg/mL to 0.10 mg/mL.

23. The use of claim 19, wherein the tumor is a gastroenteropancreatic neuroendocrine tumor.

24. The pharmaceutical aqueous solution of any one of claims 1 to 7 and 22, the dose unit container of any one of claims 8 and 10 to 12, and the lead container of any one of claims 9, 13 and 14, for use in therapy.