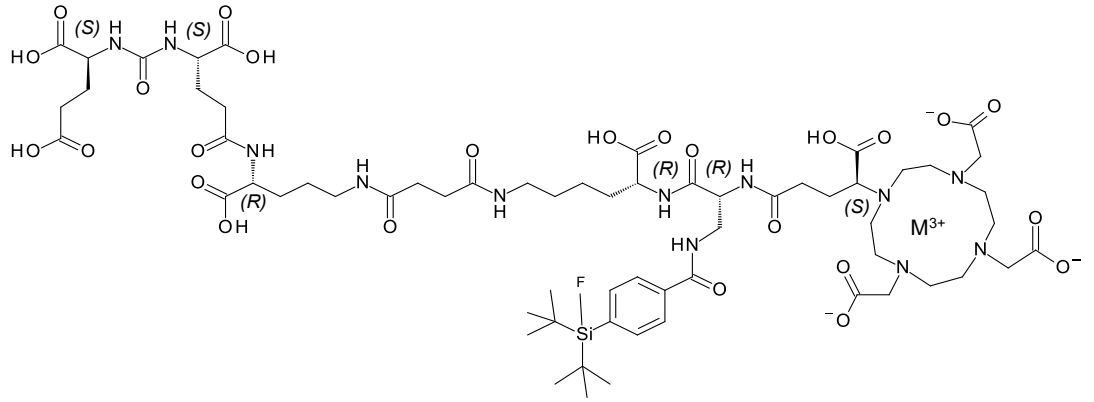
Claims

1. A pharmaceutical composition comprising a radiohybrid agent containing a silicon-fluoride and a chelating group wherein either the fluorine is ^{18}F or the chelating group contains a chelated radioactive metal, wherein the radiohybrid agent is:



or an isomer or salt thereof, wherein M^{3+} is a chelated radioactive or non-radioactive metal, and wherein the composition has a pH of 4.0-6.0 and further comprises:

a) 0.1-200 mM citrate buffer; and

b) 1-100 mg/mL ethanol; and

c) 5-10 mg/mL sodium chloride.

2. The pharmaceutical composition as defined in claim 1 comprising 1-15 mM citrate buffer.

3. The pharmaceutical composition as defined in claim 1 comprising 1-10 mM (±10%) citrate buffer.

4. The pharmaceutical composition as defined in any one of claims 1 to 3 comprising 5-50 mg/mL (±10%) ethanol.

5. The pharmaceutical composition as defined in claim 4 comprising 5-50 mg/mL ethanol.

6. The pharmaceutical composition as defined in any one of claims 1 to 5 that has a pH of 4.5 to 5.5.

7. The pharmaceutical composition as defined in any one of claims 1 to 6, wherein the composition comprises 6-9 mg/mL sodium chloride.

8. The pharmaceutical composition as defined in any one of claims 1 to 7 wherein the citrate buffer

is prepared from citric acid and sodium hydroxide, or sodium citrate and hydrochloric acid.

9. The pharmaceutical composition as defined in claim 8, wherein 1-3 mg/mL citric acid and 0.5-1.0 mg/mL sodium hydroxide are used to prepare the citrate buffer.

10. The pharmaceutical composition as defined in claim 8, wherein 1.9 mg/mL citric acid and 0.75 mg/mL sodium hydroxide are used to prepare the citrate buffer.

11. The pharmaceutical composition as defined in any one of claims 1 to 10 wherein the metal is radioactive and the fluoride is ^{19}F.

12. The pharmaceutical composition as defined in any one any one of claims 1 to 11 wherein the chelated metal is selected from the cations of: Sc, Cu, Ga, Y, In, Tb, Ho, Lu, Re, Pb, Bi, Ac, Th or Er.

13. The pharmaceutical composition as defined in any one of claims 1 to 10 wherein the fluoride is ^{18}F and the metal is non-radioactive.

14. The pharmaceutical composition as defined in claim 12 wherein the chelated radioactive metal cation is a positron emitting isotope.

15. The pharmaceutical composition as defined in any one of claims 1-14 that has an end of synthesis (EOS) radioactive concentration (RAC) of 5-200 mCi/mL.

16. The pharmaceutical composition as defined in any one preceding claim comprising 1-10 mM (±10%) citrate buffer, 5-50 mg/mL (±10%) ethanol, 6-9 mg/mL sodium chloride and that has a pH of 4.5 to 5.5.

17. The pharmaceutical composition as defined in any one preceding claim comprising 10 mM citrate buffer, 50 mg/mL ethanol, 7.2 mg/mL sodium chloride, and that is pH 5.

18. The pharmaceutical composition as defined in any one of claims 1 to 17, which is diluted with sodium chloride solution prior to administration.

19. The pharmaceutical composition as defined in claim 18 comprising 1.1 mM (±10%) citrate buffer, 5.3 mg/mL (±10%) ethanol, 8.8 mg/mL (±10%) sodium chloride, and which has a pH of 4.5 to 5.5.