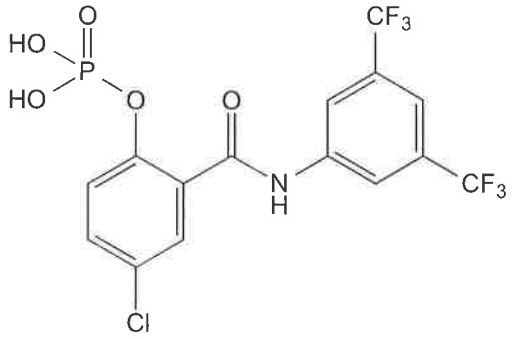
CLAIMS

1. A pharmaceutical composition comprising 2-{[3,5-bis(trifluoromethyl)phenyl]carbamoyl}-4-chlorophenyl dihydrogen phosphate (Formula I)



Formula I

and one or more Bronsted bases, wherein the one or more Bronsted bases is a solid and wherein the composition has < 5% N-[3,5-bis(trifluoromethyl)phenyl]-5-chloro-2-hydroxybenzamide after one week at room temperature and the composition is suitable for dissolution with an aqueous solution to form an injection, wherein upon dissolution the composition comprises a salt of Formula I and the one or more Bronsted bases.

2. The pharmaceutical composition of claim 1, wherein the composition comprises 0.1 mg to 2 g of Formula I.

3. The pharmaceutical composition of claims 1 or 2, wherein upon dissolution of the composition in the aqueous solution the composition has a pH between 7 and 10.5.

4. The pharmaceutical composition of any one of claims 1-3, wherein a conjugate acid of the one or more Bronsted bases has a pKa between 6 and 11.

5. The pharmaceutical composition of any one of claims 1-4, wherein the one or more Bronsted bases are one or more of:

a) a C_{1-8}-alkyl mono-, di-, or tri- carboxylic acid salt,

b) a phosphate salt,

c) an amine and/or a salt thereof,

d) an acetate salt,

e) a hydroxide and/or alkoxide salt,

f) a carbonate and/or bicarbonate salt, and/or

g) a borate salt.

6. The pharmaceutical composition of any one of claims 1-5, wherein the composition comprises 10 to 1500 mg of the one or more Bronsted bases.

7. The pharmaceutical composition of any one of claims 1-6, wherein the one or more Bronsted bases are an amine and/or a salt thereof, optionally wherein the one or more Bronsted bases are H_2NR^{20}, $HNR^{20}R^{21}$, $NR^{20}R^{21}R^{22}$, and/or a salt thereof, wherein each R^{20}, R^{21}, and R^{22} are independently C_{1-8} alkyl optionally substituted with one or more –OH, optionally wherein the one or more Bronsted bases are tris(hydroxymethyl)aminomethane, meglumine, and/or a tris(hydroxymethyl)aminomethane salt.

8. The pharmaceutical composition of any one of claims 1-7, wherein the one or more Bronsted bases is H_2NR^{20}, wherein R^{20} is C_{1-8} alkyl optionally substituted with one or more –OH.

9. The pharmaceutical composition of any one of claims 1-6, wherein the one or more Bronsted bases are an alkali carbonate and/or a sodium phosphate, optionally wherein the sodium phosphate is Na_2HPO_4.

10. The pharmaceutical composition of any one of claims 1-9, wherein the molar ratio of Formula I to the one or more Bronsted bases is at least 1:2.

11. The pharmaceutical composition of any one of claims 1-10, wherein Formula I and the one or more Bronsted bases are milled together.

12. The pharmaceutical composition of any one of claims 1-11, wherein the aqueous solution is sterile water for injection or 0.9% sodium chloride injection, optionally wherein the composition is admixed with 0.5 to 500 mL of the aqueous solution.

13. The pharmaceutical composition of any one of claims 1-12, wherein Formula I is lyophilized.

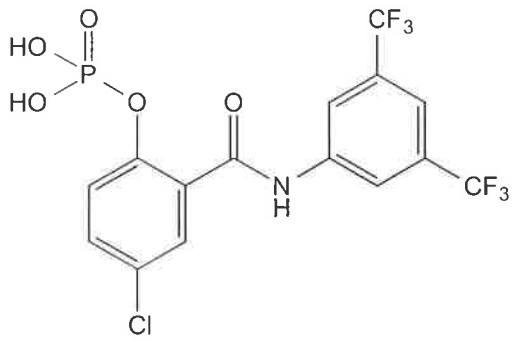
14. The pharmaceutical composition of any one of claims 1-13, wherein Formula I is amorphous.

15. The pharmaceutical composition of any one of claims 1-14, wherein the composition is for injection intravenously.

16. The pharmaceutical composition of any one of claims 1-15, wherein the composition further comprises one or more of mannitol, lactose, sucrose, trehalose, sorbitol, glucose, raffinose, arginine, glycine, histidine, dextran, polyvinylpyrrolidone, polyethylene glycol, polypropylene glycol, a lactate salt, polysorbate 80, and ethylenediamine tetraacetic acid (EDTA) or a salt thereof.

17. The pharmaceutical composition of any one of claims 1-16, wherein the composition has < 2% N-[3,5-bis(trifluoromethyl)phenyl]-5-chloro-2-hydroxybenzamide after one week at room temperature.

18. A kit comprising Formula I



Formula I

and one or more Bronsted bases, wherein the one or more Bronsted bases is a solid and wherein the kit has < 5% N-[3,5-bis(trifluoromethyl)phenyl]-5-chloro-2-hydroxybenzamide after one week at room temperature and Formula I and the one or more Bronsted bases are suitable for dissolution with an aqueous solution to form an injection comprising a salt of Formula I and the one or more Bronsted bases.

19. The kit of claim 18, wherein a conjugate acid of the one or more Bronsted bases has a pKa between 6 and 11.

20. The kit of claims 18 or 19, wherein the one or more Bronsted bases are one or more of:

a) a C_{1-8}-alkyl mono-, di-, or tri- carboxylic acid salt,
b) a phosphate salt,
c) an amine and/or a salt thereof,
d) an acetate salt,
e) a hydroxide and/or alkoxide salt,
f) a carbonate and/or bicarbonate salt, and/or
g) a borate salt.

21. The kit of any one of claims 18-20, wherein the one or Bronsted bases are an amine and/or a salt thereof, optionally wherein the one or more Bronsted bases are H_2NR^{20}, $HNR^{20}R^{21}$, $NR^{20}R^{21}R^{22}$, and/or a salt thereof, wherein each R^{20}, R^{21}, and R^{22} are independently C_{1-8} alkyl optionally substituted with one or more –OH, optionally wherein the one or more Bronsted bases are tris(hydroxymethyl)aminomethane, meglumine, and/or a tris(hydroxymethyl)aminomethane salt.

22. The kit of any one of claims 18-21, wherein the one or more Bronsted bases is H_2NR^{20} and/or a salt thereof, wherein R^{20} is C_{1-8} alkyl optionally substituted with one or more –OH.

23. The kit of any one of claims 18-20, wherein the one or more bases are an alkali carbonate and/or a sodium phosphate, optionally wherein the sodium phosphate is Na_2HPO_4.

24. The kit of any one of claims 18-23, wherein Formula I is lyophilized.

25. The kit of any one of claims 18-24, wherein Formula I is amorphous.

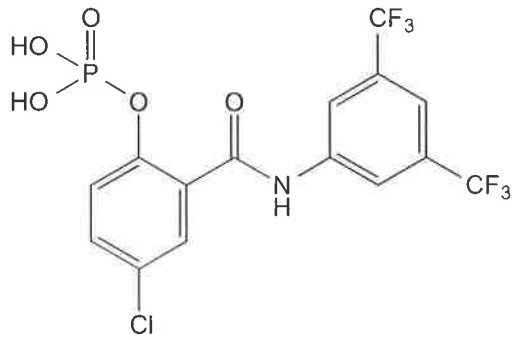
26. The kit of any one of claims 18-25, wherein Formula I and the one or more bases are in the same container or in one or more different containers.

27. The kit of any one of claims 18-26, wherein the kit further comprises the aqueous solution.

28. The kit of claim 27, wherein the aqueous solution is sterile water for injection or 0.9% sodium chloride injection.

29. The kit of any one of claims 18-28, wherein the kit comprises instructions for administering Formula I to a patient in need thereof.

30. A kit comprising Formula I



Formula I,

in a first container and further comprising one or more Bronsted bases dissolved in an aqueous solution in a second container, wherein Formula I and the aqueous solution are suitable to be admixed to form an injection comprising a salt of Formula I and the one or more Bronsted bases

and wherein the kit has < 5% N-[3,5-bis(trifluoromethyl)phenyl]-5-chloro-2-hydroxybenzamide after one week at room temperature.

31. The kit of claim 30, wherein a conjugate acid of the one or more Bronsted bases has a pKa between 6 and 11.

32. The kit of claims 30 or 31, wherein the one or more Bronsted bases are one or more of:

a) a C_{1-8}-alkyl mono-, di-, or tri- carboxylic acid salt,
b) a phosphate salt,
c) an amine and/or a salt thereof,
d) an acetate salt,
e) a hydroxide and/or alkoxide salt,
f) a carbonate and/or bicarbonate salt, and/or
g) a borate salt.

33. The kit of any one of claims 30-32, wherein the one or Bronsted bases are an amine and/or a salt thereof, optionally wherein the one or more Bronsted bases are H_2NR^{20}, $HNR^{20}R^{21}$, $NR^{20}R^{21}R^{22}$, and/or a salt thereof, wherein each R^{20}, R^{21}, and R^{22} are independently C_{1-8} alkyl optionally substituted with one or more –OH, optionally wherein the one or more Bronsted bases are tris(hydroxymethyl)aminomethane, meglumine, and/or a tris(hydroxymethyl)aminomethane salt.

34. The kit of any one of claims 30-33, wherein the one or more Bronsted bases is H_2NR^{20} and/or a salt thereof, wherein R^{20} is C_{1-8} alkyl optionally substituted with one or more –OH, optionally wherein the one or more Bronsted bases is ethanolamine.

35. The kit of any one of claims 30-32, wherein the one or more bases are an alkali carbonate and/or a sodium phosphate, optionally wherein the sodium phosphate is Na_2HPO_4.

36. The kit of any one of claims 30-35, wherein Formula I is lyophilized.

37. The kit of any one of claims 30-36, wherein Formula I is amorphous.

38. The kit of any one claims 30-37, wherein the aqueous solution is sterile water for injection or 0.9% sodium chloride injection.

39. The kit of any one of claims 30-38, wherein the kit comprises instructions for administering Formula I to a patient in need thereof.

40. The kit of any one of claims 18-39, wherein the kit has < 2% N-[3,5-bis(trifluoromethyl)phenyl]-5-chloro-2-hydroxybenzamide after one week at room temperature.

41. The kit of any one of claims 18-40, wherein the kit has < 1% N-[3,5-bis(trifluoromethyl)phenyl]-5-chloro-2-hydroxybenzamide after one week at room temperature.

42. The pharmaceutical composition of any one of claims 1-17 or the kit of any one of claims 18-41 for use in treating or controlling edema.

43. The pharmaceutical composition or kit of claim 42, wherein the edema is cerebral edema.

44. The pharmaceutical composition or kit of claim 43, wherein the cerebral edema is consequent to a stroke, traumatic brain injury, or closed head trauma.

45. The pharmaceutical composition or kit of claim 44, wherein the cerebral edema is consequent to an ischemic stroke.

46. The pharmaceutical composition or kit of claim 43, wherein the cerebral edema is consequent to hypoxia, optionally wherein the hypoxia is caused by cardiac arrest, stroke, or other interruption of perfusion to the brain.

47. The pharmaceutical composition or kit of any one claims 42-46, wherein the edema is cytotoxic cerebral edema.

48. Use of the pharmaceutical composition of any one of claims 1-17 or the kit of any one of claims 18-41 in the manufacture of a medicament for treating or controlling edema.

49. The use of claim 48, wherein the edema is cerebral edema.

50. The use of claim 49, wherein the cerebral edema is consequent to a stroke, traumatic brain injury, or closed head trauma.

51. The use of claim 50, wherein the cerebral edema is consequent to an ischemic stroke.

52. The use of claim 49, wherein the cerebral edema is consequent to hypoxia, optionally wherein the hypoxia is caused by cardiac arrest, stroke, or other interruption of perfusion to the brain.

53. The use of any one of claims 48-52, wherein the edema is cytotoxic cerebral edema.