CLAIMS

1. A pharmaceutical formulation suitable for injection, comprising a salt of a dimethyltryptamine compound optionally substituted with deuterium and optionally substituted at position 4 or 5 with acetoxy or methoxy or position 4 with monohydrogen phosphate; a buffer which is separate to the salt; and water, wherein the formulation has a pH of about 3.5 to about 6.5 and an osmolality of about 250 to about 350 mOsm/Kg.

~~2. The formulation of claim 1, wherein the formulation is suitable for injection.~~

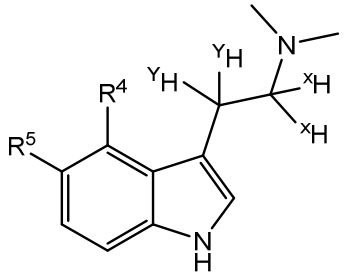
~~3. The formulation of claim 1 or claim 2, wherein the pH is from about 3.75 to about 6.5.~~

4~~2~~. The formulation of claim 1~~ or claim 2~~, wherein the pH is from about 3.75 to about 5.75.

5~~.~~3. The formulation of claim 1~~ or claim 2~~, wherein the pH is from about 3.75 to about 4.25.

6~~4~~. The formulation of ~~any one of claims~~claim 1~~ to 5~~, wherein the formulation has an osmolality of about 275 to about 325 mOsm/Kg.

7~~5~~. The formulation of ~~any one of claims~~claim 1~~ to 6~~, wherein the salt of the dimethyltryptamine compound comprises a Brønsted acid having a pKa of from about 3 to about 5 and a compound of Formula I:



Formula I

wherein:

R^4 and R^5 are both H and each ^xH and each ^YH is independently selected from H and D, or

one of R^4 and R^5 is H and the other is acetoxy or methoxy, each ^YH is H and each ^xH is independently selected from H and D, or

the salt comprises a compound of Formula I wherein R^4 is monohydrogen phosphate, R^5 is H and each ^YH and each ^xH is H.

~~8~~6. The formulation of claim ~~7~~5, wherein

(i) R^4 and R^5 are both H~~.~~; or

~~9. The formulation of claim 7 wherein~~ (ii) R^4 is acetoxy and R^5 is H~~.~~; or

~~10. The formulation of claim 7 wherein~~ (iii) R^4 is H and R^5 is methoxy.

~~11~~7. The formulation of ~~any one of claims~~claim 1 ~~to 8~~, wherein the optionally substituted dimethyltryptamine compound is dimethyltryptamine.

~~12~~8. The formulation of ~~any one of claims~~claim 1 ~~to 11~~, wherein the salt is of an optionally substituted dimethyltryptamine compound and an acid selected from the group consisting of fumaric acid, tartaric acid, citric acid, acetic acid, lactic acid and gluconic acid~~.~~

~~13~~9. The formulation of claim ~~12~~1, wherein the salt is of an optionally substituted dimethyltryptamine compound and wherein the acid is fumaric acid.

~~14~~10. The formulation of ~~any one of claims~~claim 1 ~~to 13 comprising a drug substance which comprises~~, wherein the salt of the dimethyltryptamine compound ~~at~~has a purity of greater than or equal to 99% when measured by HPLC.

~~15~~11. The formulation of ~~any one of claims 1 to 14~~claim 1, wherein the concentration of the optionally substituted dimethyltryptamine is about 2.5 mg/mL.

~~16~~12. The formulation of ~~any one of claims 1 to 15, wherein the buffer comprises an acetate salt and acetic acid.~~

17. The formulation of claim 161, wherein the buffer comprises sodium acetate and acetic acid, or potassium acetate and acetic acid.

18. 13. The formulation of any one of claimsclaim 1 to 17, further comprising a tonicity agent.

14. The formulation of claim 13, wherein the formulation comprises the buffer intonicity agent is sodium chloride at a concentration of about 15120 mM to about 75140 mM.

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15. The formulation of any one of claimsclaim 1 to 18, wherein the formulation further comprises a tonicity agent.

20. The formulation of any one of claims 1 to 19, wherein the formulation consists essentially of the salt, the buffer, water, and optionally a tonicity agent.

21. The formulation of any one of claims 1 to 20, wherein the formulation consists of the salt, the buffer, 16water, and optionally a tonicity agent.

22. The formulation of any one of claims 19 to 21, wherein the tonicity agent is sodium chloride.

23. The formulation of claim 221, wherein the formulation comprises sodium chloride at a concentration of about 120 mM to about 140 mM.

24. The formulation of any one of claims 1 to 23, havinghas an oxygen content of less than 2ppm.

25. The formulation of any one of claims 1 to 24, stored in a container adapted to prevent penetration of ultraviolet light.

26. A kit 17. The pharmaceutical formulation suitable for preparing a formulation of any one of claims 1 to 25, said kitinjection of claim 1, comprising:

a salt of a dimethyltryptamine compound optionally substituted with deuterium and optionally substituted at position 4 or 5 with acetoxy or methoxy

or position 4 with monohydrogen phosphate; and a buffer which is separate to the salt.

a buffer which is separate to the salt; and

water,

27. A method of preparing a pharmaceutical formulation as defined in any one of claims 1 to 25, comprising contacting the salt, buffer, water and optionally a tonicity agent.

28. The method of claim 27

wherein an aqueous solution of the buffer is contacted with the salt, wherein the aqueous solution formulation has a pH as defined in any one of claims 1of about 3.75 to about 6.5 and an osmolality of about 250 mOsm/Kg to about 350 mOsm/Kg.

2918. The methodpharmaceutical formulation suitable for injection of claim 27 or 28, wherein the method comprises contacting the optionally substituted1, comprising:

a salt of a dimethyltryptamine in free base form with the buffer, water and optionally a tonicity agent.

30. The method of any one of claims 27 to 29, further comprising adjusting the pH of the solution resultant from the contacting.

31. The method of claim 30 wherein the pH is adjusted with sodium hydroxide or potassium hydroxide.

32. The method of any one of claims 27 to 31 further comprising sparging the solution resultant from the contacting with an inert gas.

33. Use of a buffer to ameliorate degradation of an injectable pharmaceutical formulation of a salt of a dimethyltryptaminecompound optionally substituted with deuterium and optionally substituted at position 4 or 5 with acetoxy or methoxy or position 4 with monohydrogen phosphate.;

34. Use of a container adapted to prevent penetration of ultraviolet light to ameliorate degradation of an injectable pharmaceutical formulation of a salt of a dimethyltryptamine optionally substituted with deuterium and optionally

substituted at position 4 or 5 with acetoxy or methoxy or position 4 with monohydrogen phosphate.

35. The use of claim 33 or claim 34, wherein the salt is as defined in any one of claims 7 to 14.

36. A a buffer which is separate to the salt; and

water,

wherein the formulation has a pH of about 3.75 to about 6.5 and an osmolality of about 250 mOsm/Kg to about 350 mOsm/Kg.

19. The formulation as defined in any one of claimsclaim 1 to 25 or the kit of claim 26 for use in therapy.

37. A formulation as defined in any one of claims 1 to 25 or the kit of claim 26 for use in a method of treating a psychiatric or neurological disorder in a patient.

38. The formulation for the use of claim 37, wherein the psychiatric or neurological disorderpH is selected from the group consisting of (i) an obsessive compulsive disorder, (ii) a depressive disorder, (iii) an anxiety disorder, (iv) substance abuse, and (v) an avolition disorderabout 4.0 to about 6.5.

39. A method of treating a psychiatric or neurological disorder comprising administering to a patient in need thereof a formulation as defined in any one of claims 1 to 25.

40. The method of claim 3920. The formulation of claim 5, wherein the psychiatric or neurological disorderpH is as defined in claim 38.from about 4.0 to about 6.5.