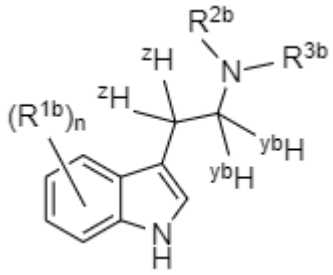
CLAIMS

1. A pharmaceutical formulation suitable for intramuscular injection, comprising a salt of a compound of Formula IB:



Formula IB

wherein:

n is 0;

R^{1b} is independently selected from $–R^{4b}$, -OH, $-OR^{4b}$, $-O(CO)R^{4b}$, monohydrogen phosphate, -F, -Cl, -Br or –I;

R^{2b} is $C(^{xb}H)_3$;

R^{3b} is $C(^{xb}H)_3$;

each R^{4b} is independently selected from C_1-C_4alkyl; and

each ^{xb}H, ^{yb}H and ^{z}H is independently selected from protium or deuterium;

and a Brønsted acid having a pKa of from 3 ± 5% to 5 ± 5%;

a base agent, water, and optionally a buffer which is separate to the salt;

wherein the formulation has a pH of from 5 ± 5% to 6.5 ± 5%, a concentration of the compound of Formula IB of 10 ± 5% mg/ml or greater as the freebase equivalent, and an osmolality of from 250 ± 5% to 350 ± 5% mOsm/Kg; and

wherein the formulation comprises a dose of the compound of Formula IB within a volume of 5 ml or less.

2. The formulation of claim 1, wherein the formulation has a pH of from 5 ± 5% to 6 ± 5%.

3. The formulation of claim 1, wherein the formulation comprises a dose of the compound of Formula IB within a volume of 3 ml or less.

4. The formulation of claim 1, wherein R^{2b} is CD_3 and R^{3b} is CD_3; and/or wherein each ^{yb}H is D.

5. The formulation of claim 1, wherein the compound of Formula IB is N,N-dimethyltryptamine.

6. The formulation of claim 1, wherein the compound of Formula IB is selected from the group consisting of α,α-dideutero-N,N-dimethyltryptamine, α,α-dideutero-N,N-di(trideuteromethyl)tryptamine, α,α,β,β-tetradeutero-N,N-dimethyltryptamine, and α,α,β,β-tetradeutero-N,N-di(trideuteromethyl)tryptamine.

7. The formulation of claim 1, wherein the Brønsted acid is selected from the group consisting of fumaric acid, tartaric acid, citric acid, acetic acid, lactic acid and gluconic acid.

8. The formulation of claim 1, wherein the concentration of the compound of Formula IB is from 20 ± 5% mg/mL to 40 ± 5% mg/mL (as the freebase equivalent).

9. The formulation of claim 1, wherein the formulation comprises the buffer which is separate to the salt, optionally wherein the buffer comprises an acetate salt and acetic acid; or a citrate salt and citric acid; or a phosphate salt and phosphoric acid; or the buffer comprises an acetate salt, a citrate salt, or a phosphate salt.

10. The formulation of claim 1, wherein the formulation further comprises a tonicity agent and/or a pH adjuster.

11. The formulation of claim 1, wherein the formulation consists of the salt of the compound of Formula IB, water, the base agent and optionally the buffer and/or a tonicity agent and/or pH adjuster.

12. The formulation of claim 1, having an oxygen content of less than 5 ppm, or less than 2 ppm.

13. The formulation of claim 1, comprising the salt of the compound of Formula IB, the base agent, water, the buffer which is separate to the salt, and a tonicity agent or pH adjuster.

14. The formulation of claim 13, comprising a salt of the compound of Formula IB; the base agent which is selected from potassium hydroxide or sodium hydroxide; water; the buffer which is a citrate salt; and the tonicity agent or pH adjuster which is an acid.

15. A kit suitable for preparing the formulation of claim 1, said kit comprising the salt of the compound of Formula IB; optionally a tonicity agent and/or a pH adjuster; the base agent and optionally the buffer which is separate to the salt.

16. A lyophilised powder formulation comprising the formulation according to claim 1 which has been lyophilised.

17. The formulation of claim 1, wherein the concentration of the compound of Formula IB is 25 ± 5% mg/mL (as the freebase equivalent).

18. The formulation of claim 1, wherein the compound of Formula IB is a deuterated N,N-dimethyltryptamine.

19. The formulation of claim 18, wherein the deuterated N,N-dimethyltryptamine is selected from the group consisting of α,α-dideutero-N,N-dimethyltryptamine, α,α-dideutero-N,N-di(trideuteromethyl)tryptamine, α,α,β,β-tetradeutero-N,N-dimethyltryptamine, and α,α,β,β-tetradeutero-N,N-di(trideuteromethyl)tryptamine.

20. A pharmaceutical formulation suitable for intramuscular injection, comprising:

a fumarate salt of deuterated N,N-dimethyltryptamine selected from the group consisting of α,α-dideutero-N,N-dimethyltryptamine, α,α-dideutero-N,N-di(trideuteromethyl)tryptamine, α,α,β,β-tetradeutero-N,N-dimethyltryptamine, and α,α,β,β-tetradeutero-N,N-di(trideuteromethyl)tryptamine;

a base agent selected from potassium hydroxide and sodium hydroxide;

water; and

a buffer which comprises an acetate salt, a citrate salt, or a phosphate salt;

wherein the formulation has a pH of from 5 ± 5% to 6.5 ± 5%, a concentration of the deuterated N,N-dimethyltryptamine from 20 ± 5% mg/mL to 40 ± 5% mg/mL as the freebase equivalent, and an osmolality of from 250 ± 5% to 350 ± 5% mOsm/Kg; and

wherein the formulation comprises a dose of the deuterated N,N-dimethyltryptamine within a volume of 5 ml or less.

21. A formulation according claim 20, comprising a fumarate salt of α,α,β,β-tetradeutero-N,N-di(trideuteromethyl)tryptamine.