CLAIMS

What is claimed is:

1. A pharmaceutical formulation for intranasal administration, formulated as an aqueous solution, comprising:

a) about 1% (w/v) to about 4% (w/v) naltrexone or a pharmaceutically acceptable salt, hydrate, or solvate thereof;

b) about 0.1% (w/v) to about 0.5% (w/v) of dodecyl maltoside;

c) about 0.2% (w/v) to about 1.2% (w/v) of sodium chloride;

d) about 0.005% (w/v) to about 0.1% (w/v) of benzalkonium chloride;

e) about 0.2% (w/v) to about 0.3% (w/v) of disodium edetate; and

f) water in an amount sufficient to achieve a final volume of about 0.05 mL to about 0.2 mL;

wherein the pH of the formulation is about 3.5 to about 5.4.

2. The pharmaceutical formulation as recited in claim 1, wherein the formulation comprises about 0.25% (w/v) of dodecyl maltoside.

3. The pharmaceutical formulation as recited in claim 1, comprising about 3% (w/v) naltrexone or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

4. The pharmaceutical formulation as recited in claim 1, wherein the total volume of the formulation comprises between about 0.05 mL to about 0.2 mL.

5. The pharmaceutical formulation as recited in claim 1, wherein the total volume of the formulation comprises about 0.1 mL.

6. A pharmaceutical composition for intranasal administration to a human subject in need thereof, comprising:

a) about 3 mg to about 4 mg of naltrexone or a pharmaceutically acceptable salt, hydrate, or solvate thereof;

b) about 0.25 mg of dodecyl maltoside;

c) water in an amount sufficient to total about 0.1 mL;

wherein the pH of the composition is between about 3.5 to about 5.4.

7. The pharmaceutical composition of claim 6, further comprising a preservative and an isotonicity agent.

8. The pharmaceutical composition of claim 6, wherein upon administration to the subject of the pharmaceutical composition, the Tmax is 25 minutes or less.

9. The pharmaceutical composition of claim 6, wherein upon administration to the subject of the pharmaceutical composition, the Tmax is 20 minutes or less.

10. The pharmaceutical composition of claim 6, wherein upon administration to the subject of the pharmaceutical composition, the Tmax is 15 minutes or less.

11. The pharmaceutical composition of claim 6, wherein upon administration to the subject of the pharmaceutical composition, the AUC0-inf after administration of the composition is higher than the AUC0-inf of an intranasal formulation of about 3 mg to about 4 mg naltrexone or a pharmaceutically acceptable salt, hydrate, or solvate thereof that does not contain dodecyl maltoside.

12. The pharmaceutical composition of claim 6, wherein upon administration to the subject of the pharmaceutical composition, the AUC0-inf is about 50% higher than the AUC0-inf of the intranasal formulation of about 3 mg to about 4 mg naltrexone or a pharmaceutically acceptable salt, hydrate, or solvate thereof that does not contain dodecyl maltoside.

13. The pharmaceutical composition of claim 6, wherein upon administration to the subject of the pharmaceutical composition, the AUC0-inf is about 50% to about 60% higher than the AUC0-inf of an intranasal formulation of about 3 mg to about 4 mg naltrexone or a pharmaceutically acceptable salt, hydrate, or solvate thereof that does not contain dodecyl maltoside.

14. The pharmaceutical composition of claim 6, wherein upon administration to the subject of the pharmaceutical composition, the Cmax is about 2 to about 3 times higher than the Cmax of an intranasal formulation of about 3 mg to about 4 mg naltrexone or a pharmaceutically acceptable salt, hydrate, or solvate thereof that does not contain dodecyl maltoside.

15. The pharmaceutical composition of claim 6, wherein upon administration to a population of subjects of the pharmaceutical composition, the mean plasma concentration of naltrexone at about 5 minutes post-dose is about 12 ng/mL.

16. The pharmaceutical composition of claim 6, wherein upon administration to a population of subjects of the pharmaceutical composition, the mean plasma concentration of naltrexone at about 15 minutes post-dose is about 10 ng/mL.

17. The pharmaceutical composition of claim 6, wherein upon administration to a population of subjects of the pharmaceutical composition, the mean plasma concentration of naltrexone at about 30 minutes post-dose is about 7 ng/mL.

18. The pharmaceutical composition of claim 6, wherein the total volume of the pharmaceutical composition comprises about 0.1 mL.