CLAIMS

WHAT IS CLAIMED IS:

1. A pharmaceutical spray formulation, comprising:

(a) from about 1% to about 25% (w/w) of epinephrine, or a pharmaceutically acceptable salt thereof, in water, ethanol, propylene glycol, or a combination thereof; and

(b) one or more of an antioxidant, an antimicrobial preservative, an isotonicity agent, an absorption enhancer, a viscosity modifier, or a buffering agent;

wherein the formulation is configured to be administered into a nostril of a subject as a nasal spray that yields a plasma concentration of at least 0.4 ng/mL within 1 minute of administration.

2. The pharmaceutical spray formulation of claim 1, wherein the pH of the formulation is from about 4.0 to about 6.5.

3. The pharmaceutical spray formulation of claim 1, wherein the antioxidant comprises sodium bisulfite or sodium metabisulfite at a concentration from about 0.01% to about 0.1% (w/w).

4. The pharmaceutical spray formulation of claim 1, wherein the antimicrobial preservative comprises chlorobutanol or chlorobutanol hemihydrate at a concentration from about 0.1% to about 1% (w/w).

5. The pharmaceutical spray formulation of claim 1, wherein the isotonicity agent comprises sodium chloride at a concentration from about 0.1% to about 1% (w/w).

6. The pharmaceutical spray formulation of claim 1, wherein the viscosity modifier comprises hypromellose at a concentration from about 0.01% to about 0.2% (w/w).

7. The pharmaceutical spray formulation of claim 1, wherein the buffering agent comprises citric acid or citric acid monohydrate at a concentration from about 0.1% to about 1% (w/w).

8. The pharmaceutical spray formulation of claim 1, comprising about 2% or about 5% (w/w) of epinephrine, or a pharmaceutically acceptable salt thereof.

9. The pharmaceutical spray formulation of claim 1, wherein the pharmaceutical spray formulation comprises sodium metabisulfite, sodium chloride, hypromellose, citric acid monohydrate, diethylene glycol monoethyl ether, and chlorobutanol hemihydrate.

10. The pharmaceutical spray formulation of claim 9, comprising from about 1% to about 10% (w/w) of epinephrine, or a pharmaceutically acceptable salt thereof, from about 0.01% to about 0.1% (w/w) of sodium metabisulfite, from about 0.1% to about 1% (w/w) sodium chloride, from about 0.01% to about 0.2% (w/w) hypromellose, from about 0.1% to about 1% (w/w) citric

acid monohydrate, from about 0.1% to about 5% (w/w) diethylene glycol monoethyl ether, and from about 0.1% to about 1% (w/w) chlorobutanol hemihydrate.

11. A stable pharmaceutical spray formulation, comprising:

(a) from about 1% to about 25% (w/w) of epinephrine, or a pharmaceutically acceptable salt thereof, in water, ethanol, propylene glycol, or a combination thereof; and

(b) one or more of an antioxidant, an antimicrobial preservative, an isotonicity agent, an absorption enhancer, a viscosity modifier, or a buffering agent;

wherein the formulation is stable for a period of at least about one month at a temperature of at least about 20 °C.

12. The pharmaceutical spray formulation of claim 11, wherein the formulation is stable for a period of at least one month at a temperature of at least about 40 °C.

13. The pharmaceutical spray formulation of claim 11, wherein the formulation has no more than about 2% total impurities after storage for a period of at least about one month at a temperature of at least about 40 °C.

14. The pharmaceutical spray formulation of claim 11, wherein the antioxidant comprises sodium bisulfite or sodium metabisulfite at a concentration from about 0.01% to about 0.1% (w/w).

15. The pharmaceutical spray formulation of claim 11, wherein the antimicrobial preservative comprises chlorobutanol or chlorobutanol hemihydrate at a concentration from about 0.1% to about 1% (w/w).

16. The pharmaceutical spray formulation of claim 11, wherein the isotonicity agent comprises sodium chloride at a concentration from about 0.1% to about 1% (w/w).

17. The pharmaceutical spray formulation of claim 11, wherein the buffering agent comprises citric acid or citric acid monohydrate at a concentration from about 0.1% to about 1% (w/w).

18. A pharmaceutical spray formulation, comprising:

(a) from about 1% to about 25% (w/w) of epinephrine, or a pharmaceutically acceptable salt thereof, in water, ethanol, propylene glycol, or a combination thereof; and

(b) one or more of an antioxidant, an antimicrobial preservative, an isotonicity agent, an absorption enhancer, a viscosity modifier, or a buffering agent;

wherein the absorption enhancer is diethylene glycol monoethyl ether.

19. The pharmaceutical spray formulation of claim 1, wherein the formulation comprises diethylene glycol monoethyl ether at a concentration from about 0.1% to about 5% (w/w).

20. The pharmaceutical spray formulation of claim 1, wherein the absorption enhancer comprises diethylene glycol monoethyl ether at a concentration of about 1% (w/w).