CLAIMS

1. An oral spray formulation for the treatment of pulmonary arterial hypertension and/or SSRI-induced sexual dysfunction, comprising sildenafil base or a pharmaceutically acceptable salt thereof, in which the pH of the formulation is about 1.5 to less than 3.0.

2. Use of sildenafil in the preparation of a medicament for the treatment of pulmonary arterial hypertension and/or SSRI-induced sexual dysfunction, in which the medicament comprises an oral spray formulation comprising sildenafil base or a pharmaceutically acceptable salt thereof, in which the pH of the formulation is about 1.5 to less than 3.0.

3. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the sildenafil base is present in an amount of about 7 to about 9 % w/v of the formulation.

4. An oral spray formulation or use according to Claim 3, in which the sildenafil base is present in an amount of about 8.31 % w/v of the formulation.

5. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the sildenafil salt is present in an amount of about 10 to about 12 % w/v of the formulation.

6. An oral spray formulation or use according to Claim 5, in which the sildenafil salt is present in an amount of about 11.67 % w/v of the formulation.

7. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the sildenafil salt is sildenafil citrate.

8. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation comprises a polar solvent.

9. An oral spray formulation or use according to Claim 8, in which the polar solvent comprises propylene glycol and ethyl alcohol.

10. An oral spray formulation or use according to Claim 9, in which the ratio of propylene glycokethyl alcohol is about 62.5:37.5 % v/v.

11. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation comprises one or more pH- adjusting agents.

12. An oral spray formulation or use according to Claim 11, in which the pH-adjusting agents are acidifying agents, alkalizing agents or combinations thereof.

13. An oral spray formulation or use according to Claim 12, in which the acidifying agent is HCl.

14. An oral spray formulation or use according to Claim 13, in which the HCl is present in an amount of about 10 % v/v of the formulation.

15. The oral spray formulation or use according to Claim 12, in which the alkalizing agent is NaOH.

16. An oral spray formulation or use according to Claim 15, in which the NaOH is present in an amount of about 2.1 % v/v of the formulation.

17. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation further comprises a taste-masking agent and/or a flavour.

18. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation comprises one or more pharmaceutically acceptable excipients, carriers or a combination thereof.

19. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the pH of the formulation is about 2.2 +- 0.5

20. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the amount of sildenafil administered per spray is between 10 mg and 30 mg.

21. An oral spray formulation or use according to Claim 20, in which the sildenafil exposure in the patient results in a ln-transformed dose-adjusted to 25 mg geometric mean AUC_{0-t}(ng-hr/mL) of approximately 299.36, 323.16 or 304.98.

22. An oral spray formulation or use according to Claim 20, in which the sildenafil exposure in the patient results in a ln-transformed dose-adjusted to 25 mg geometric mean AUC_{0-inf}(ng-hr/mL) of approximately 310.60, 331.22 or 311.05.

23. An oral spray formulation according to Claim 1 or a use according to Claim 2, further comprising a sweetener.

24. An oral spray formulation or use according to Claim 23, in which the sweetener is sucralose.

25. An oral spray formulation or use according to Claim 17 in which the taste-masking agent is chosen from the list comprising: mint; and the flavour is chosen from the list comprising: a fruit and/or chocolate flavour.

CLAIMS

1. An oral spray formulation for use in the treatment of pulmonary arterial hypertension and/or SSRI-induced sexual dysfunction, comprising sildenafil base or a pharmaceutically acceptable salt thereof, in which the pH of the formulation is 1.5 to 2.4.

2. Use of sildenafil in the preparation of a medicament for the treatment of pulmonary arterial hypertension and/or SSRI-induced sexual dysfunction, in which the medicament comprises an oral spray formulation comprising sildenafil base or a pharmaceutically acceptable salt thereof, in which the pH of the formulation is 1.5 to 2.4.

3. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the sildenafil base is present in an amount of 7 to 9 % w/v of the formulation.

4. An oral spray formulation or use according to Claim 3, in which the sildenafil base is present in an amount of 8.31 % w/v of the formulation.

5. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the sildenafil salt is present in an amount of 10 to 12 % w/v of the formulation.

6. An oral spray formulation or use according to Claim 5, in which the sildenafil salt is present in an amount of 11.67 % w/v of the formulation.

7. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the sildenafil salt is sildenafil citrate.

8. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation comprises a polar solvent.

9. An oral spray formulation or use according to Claim 8, in which the polar solvent comprises propylene glycol and ethyl alcohol.

10. An oral spray formulation or use according to Claim 9, in which the ratio of propylene glycol : ethyl alcohol is 62.5:37.5 % v/v.

11. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation comprises one or more pH- adjusting agents.

12. An oral spray formulation or use according to Claim 11, in which the pH-adjusting agents are acidifying agents, alkalizing agents or combinations thereof.

13. An oral spray formulation or use according to Claim 12, in which the acidifying agent is HCl.

14. An oral spray formulation or use according to Claim 13, in which the HCl is present in an amount of 10 % v/v of the formulation.

15. The oral spray formulation or use according to Claim 12, in which the alkalizing agent is NaOH.

16. An oral spray formulation or use according to Claim 15, in which the NaOH is present in an amount of 2.1 % v/v of the formulation.

17. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation further comprises a taste-masking agent and/or a flavour.

18. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the formulation comprises one or more pharmaceutically acceptable excipients, carriers or a combination thereof.

19. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the pH of the formulation is 2.2.

20. An oral spray formulation according to Claim 1 or a use according to Claim 2, in which the amount of sildenafil administered per spray is between 10 mg and 30 mg.

21. An oral spray formulation according to Claim 1 or a use according to Claim 2, further comprising a sweetener.

22. An oral spray formulation or use according to Claim 21, in which the sweetener is sucralose.

23. An oral spray formulation or use according to Claim 17 in which the taste-masking agent is chosen from the list comprising: mint; and the flavour is chosen from the list comprising: a fruit and/or chocolate flavour.