CLAIMS

We claim:

1. An aqueous pharmaceutical composition comprising from 100 to 400 mg/mL acetylcysteine, wherein the composition contains less than 0.05% w/v EDTA, or pharmaceutically acceptable salts thereof, wherein said composition is in a suitable form for intravenous injection, wherein the pH of the composition is from 6 to 8, and wherein said composition is sealed in an airtight container comprising a fill volume of said composition and a headspace volume occupied by a pharmaceutically inert gas.

2. The aqueous pharmaceutical composition of claim 1, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

3. The aqueous pharmaceutical composition of claim 2, wherein the composition contains no EDTA, or pharmaceutically acceptable salts thereof.

4. The aqueous pharmaceutical composition of claim 1, wherein the pH of the composition is from 6.5 to 7.0.

5. The aqueous pharmaceutical composition of claim 4, wherein the pH of the composition is 6.8.

6. The aqueous pharmaceutical composition of claim 1, wherein the composition is stable for at least 12 months at 25°C.

7. The aqueous pharmaceutical composition of claim 1, wherein the composition is stable for at least 6 months at 40°C.

8. An aqueous pharmaceutical composition consisting of from 100 to 400 mg/mL acetylcysteine, dissolved in deaerated water, and wherein the pH of the composition is adjusted with a pH-adjusting agent to a pH of from 6 to 8, wherein

the composition contains less than 0.05% w/v EDTA, wherein said composition is in a suitable form for intravenous injection and wherein said composition is sealed in an airtight container comprising a fill volume of said composition and a headspace volume occupied by a pharmaceutically inert gas.

9. Use of an aqueous composition of from 100 to 400 mg/mL acetylcysteine, wherein said composition contains less than 0.05% w/v EDTA or pharmaceutically acceptable salts thereof, wherein said composition is in a suitable form for intravenous injection, wherein the pH of the composition is from 6 to 8, and wherein said composition is sealed in an airtight container comprising a fill volume of said composition and a headspace volume occupied by a pharmaceutically inert gas, for the preparation of a medicament for the treatment of acetaminophen overdose.

10. The use of claim 9, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

11. The use of claim 10, wherein the composition contains no EDTA, or pharmaceutically acceptable salts thereof.

12. The use of claim 9, wherein the pH of the composition is from 6.5 to 7.0.

13. The use of claim 12, wherein the pH of the composition is 6.8.

14. The use of claim 9, wherein the composition is mixed in an aqueous solution of at least one of dextrose and sodium chloride prior to administration.

15. The use of claim 14, wherein the composition is mixed in an aqueous solution of 5% w/v dextrose prior to administration.

16. The use of claim 14, wherein the composition is mixed in an aqueous solution of 0.45% or 0.90% w/v sodium chloride prior to administration.

17. A method of making an aqueous acetylcysteine pharmaceutical composition, comprising dissolving acetylcysteine in deaerated water; adding a basic agent to achieve a pH of from 6 to 8, wherein the composition contains less than 0.05% w/v EDTA, or pharmaceutically acceptable salts thereof, wherein the composition contains from 100 to 400 mg/mL acetylcysteine, and wherein said composition is in a suitable form for intravenous injection; and passing the solution through a sterilizing filter and filling under an inert atmosphere.

18. The method of claim 17, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

19. The method of claim 18, wherein the composition contains no EDTA, or pharmaceutically acceptable salts thereof.

20. The method of claim 17, wherein the pH of the composition is from 6.5 to 7.0.

21. The method of claim 20, wherein the pH of the composition is 6.8.

22. The method of claim 17, wherein the composition is stable for at least 6 months at 25°C.

23. The method of claim 17, wherein the composition is stable for at least 6 months at 40°C.

24. The method of claim 17, wherein the basic agent is sodium hydroxide.

25. An aqueous pharmaceutical composition comprising from 100 to 400 mg/mL acetylcysteine, wherein chelating agents have not been added to the composition, wherein the pH of the composition is from 6 to 8, wherein said composition is in a suitable form for intravenous injection, and wherein said composition is sealed in an airtight container comprising a fill volume of said composition and a headspace volume occupied by a pharmaceutically inert gas.

26. A container comprising: an aqueous pharmaceutical composition comprising from 100 to 400 mg/mL acetylcysteine, wherein chelating agents have not been added to the composition, wherein the pH of the composition is from 6 to 8, and wherein said composition is in a suitable form for intravenous injection; and a headspace consisting of a pharmaceutically inert gas.

27. A container comprising: an aqueous pharmaceutical composition comprising from 100 to 400 mg/mL acetylcysteine, wherein the composition contains less than 0.05% w/v EDTA, or pharmaceutically acceptable salts thereof, wherein the pH of the composition is from 6 to 8, and wherein said composition is in a suitable form for intravenous injection; and a headspace consisting of a pharmaceutically inert gas.

28. The container of claim 27, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

29. The container of claim 28, wherein the composition contains no EDTA, or pharmaceutically acceptable salts thereof.

30. The container of claim 27, wherein the pH of the composition is from 6.5 to 7.0.

31. The container of claim 30, wherein the pH of the composition is 6.8.

32. Use of an aqueous composition of acetylcysteine, wherein the pH of the composition is from 6 to 8, wherein the composition contains from 100 to 400 mg/mL acetylcysteine, and wherein the composition contains less than 0.05% w/v EDTA or pharmaceutically acceptable salts thereof, for the preparation of a medicament for the treatment of liver failure.

33. The use of claim 32, wherein the composition contains less than 0.05% w/v chelating agents or pharmaceutically acceptable salts thereof.

34. The use of claim 33, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

35. The use of claim 32, wherein the pH of the composition is from 6.5 to 7.0.

36. The use of claim 35, wherein the pH of the composition is 6.8.

37. The use of claim 32 wherein the liver failure is acute liver failure.

38. Use of an aqueous composition of acetylcysteine, wherein the pH of the composition is from 6 to 8, wherein the composition contains from 100 to 400 mg/mL acetylcysteine, and wherein the composition contains less than 0.05% w/v EDTA, or pharmaceutically acceptable salts thereof, for the preparation of a medicament for the treatment of radiocontrast-induced nephropathy.

39. The use of claim 38, wherein the composition contains less than 0.05% w/v chelating agents or pharmaceutically acceptable salts thereof.

40. The use of claim 39, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

41. The use of claim 38, wherein the pH of the composition is from 6.5 to 7.0.

42. The use of claim 41, wherein the pH of the composition is 6.8.

43. The aqueous pharmaceutical composition of claim 1, wherein the composition contains 200 mg/mL acetylcysteine.

44. The use of claim 9, wherein the composition contains 200 mg/mL acetylcysteine.

45. The method of claim 17, wherein the composition contains 200 mg/mL acetylcysteine.

46. The container of claim 27, wherein the composition contains 200 mg/mL acetylcysteine.

CLAIMS

We claim:

1. An aqueous pharmaceutical composition comprising acetylcysteine, wherein the composition is substantially free of EDTA or pharmaceutically acceptable salts thereof.

2. An aqueous pharmaceutical composition comprising acetylcysteine, wherein the composition contains less than 0.05% w/v EDTA, or pharmaceutically acceptable salts thereof.

3. The aqueous pharmaceutical composition of claim 2, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

4. The aqueous pharmaceutical composition of claim 3, wherein the composition contains no EDTA, or pharmaceutically acceptable salts thereof.

5. The aqueous pharmaceutical composition of claim 1 or 2, wherein the pH of the composition is from 6 to 8.

6. The aqueous pharmaceutical composition of claim 5, wherein the pH of the composition is from 6.5 to 7.0.

7. The aqueous pharmaceutical composition of claim 6, wherein the pH of the composition is 6.8.

8. The aqueous pharmaceutical composition of claim 1 or 2, wherein the composition is stable for at least 12 months at 25°C.

9. The aqueous pharmaceutical composition of claim 1 or 2, wherein the composition is stable for at least 6 months at 40°C.

10. An aqueous pharmaceutical composition consisting of from 10 to 400 mg/mL acetylcysteine, dissolved in deaerated water, and wherein the pH of the composition is adjusted with a pH-adjusting agent to a pH of from 6 to 8.

11. A method of treating acetaminophen overdose, comprising administering to a patient in need thereof an effective amount of an aqueous composition of acetylcysteine, wherein said composition is substantially free of EDTA or pharmaceutically acceptable salts thereof.

12. A method of treating acetaminophen overdose, comprising administering to a patient in need thereof an effective amount of an aqueous composition of acetylcysteine, wherein said composition contains less than 0.05% w/v EDTA or pharmaceutically acceptable salts thereof.

13. The method of claim 12, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

14. The method of claim 13, wherein the composition contains no EDTA, or pharmaceutically acceptable salts thereof.

15. The method of claim 11 or 12, wherein the pH of the composition is from 6 to 8.

16. The method of claim 15, wherein the pH of the composition is from 6.5 to 7.0.

17. The method of claim 16, wherein the pH of the composition is 6.8.

18. The method of claim 11 or 12, wherein the administration occurs via intravenous injection, orally, or by inhalation.

19. The method of claim 18 wherein the method of administration occurs via intravenous injection.

20. The method of claim 11 or 12, wherein the composition is mixed in an aqueous solution of at least one of dextrose and sodium chloride prior to administration.

21. The method of claim 20, wherein the composition is mixed in an aqueous solution of 5% w/v dextrose prior to administration.

22. The method of claim 20, wherein the composition is mixed in an aqueous solution of 0.45% or 0.90% w/v sodium chloride prior to administration.

23. A method of making an aqueous acetylcysteine pharmaceutical composition, comprising dissolving acetylcysteine in deaerated water and adding a basic agent to achieve a pH of 6 to 8, wherein the composition is substantially free of EDTA or pharmaceutically acceptable salts thereof.

24. A method of making an aqueous acetylcysteine pharmaceutical composition, comprising dissolving acetylcysteine in deaerated water and adding a basic agent to achieve a pH of 6 to 8, wherein the composition contains less than 0.05% w/v EDTA, or pharmaceutically acceptable salts thereof.

25. The method of claim 23 or 24, wherein the method further comprises passing the solution through a sterilizing filter and filling under an inert atmosphere.

26. The method of claim 24, wherein the composition contains less than 0.02% w/v EDTA, or pharmaceutically acceptable salts thereof.

27. The method of claim 26, wherein the composition contains no EDTA, or pharmaceutically acceptable salts thereof.

28. The method of claim 23 or 24, wherein the pH of the composition is from 6.5 to 7.0.

29. The method of claim 28, wherein the pH of the composition is 6.8.

30. The method of claim 23 or 24, wherein the composition is stable for at least 6 months at 25°C.

31. The method of claim 23 or 24, wherein the composition is stable for at least 6 months at 40°C.

32. The method of claim 23 or 24, wherein the basic agent is sodium hydroxide.