CLAIMS

What is claimed:

1. Anhydrous sodium thiosulfate characterized by an X-ray powder diffraction (XRPD) pattern comprising at least four peaks selected from 10.52, 15.13, 17.71, 19.70, 21.09, 21.49, 21.84, 27.40, 28.96, 30.46, 31.81, 32.52, 33.15, 37.40, or 38.16 degrees 2 theta (2 θ) ± 0.2, when the XRPD is collected from about 2 to about 40 degrees 2 θ using copper Kα radiation.

2. The anhydrous sodium thiosulfate of claim 1, wherein the anhydrous sodium thiosulfate is characterized by an X-ray powder diffraction (XRPD) pattern comprising at least four peaks selected from 10.52, 15.13, 19.70, 21.49, 21.84, 28.96, 30.46, 33.15, 37.40, and 38.16 degrees 2 theta (2 θ) ± 0.2, when the XRPD is collected from about 2 to about 40 degrees 2 θ using copper Kα radiation.

3. The anhydrous sodium thiosulfate of claim 1 or 2, wherein the anhydrous sodium thiosulfate is characterized by a differential scanning calorimetry melting onset of about 331 °C; and a thermogravimetric analysis showing negligible weight loss from ambient temperature to 162 °C, a weight loss of 14.8% from 162 °C to 309 °C, and an onset of decomposition at 436 °C.

4. Anhydrous sodium thiosulfate comprising:

no greater than 0.1 µg/g of cadmium;

no greater than 0.25 µg/g lead;

no greater than 0.75 µg/g arsenic;

no greater than 0.15 µg/g mercury;

no greater than 0.25 µg/g cobalt;

no greater than 0.5 µg/g vanadium;

no greater than 1.0 µg/g nickel;

no greater than 12.5 µg/g lithium;

no greater than 4.5 µg/g antimony;

no greater than 15.0 µg/g copper;

no greater than 1500 ppm methanol;

no greater than 3% (w/w) water; and

no greater than 1.65% (w/w) of total impurities or related substances.

5. A method for synthesizing sodium thiosulfate comprising reacting sodium sulfite with sulfur in the presence of a surface acting agent.

6. The method of claim 5, wherein the surface acting agent comprises cetylpyridinium chloride.

7. The method of claim 5 or 6, wherein the reaction is aqueous.

8. The method of any one of claims 5–7, wherein the reaction is conducted at about 80 °C to about 100 °C.

9. The method of any one of claims 5–8, wherein the sodium thiosulfate is crystallized and washed with acetone.

10. A method for synthesizing anhydrous sodium thiosulfate comprising reacting sodium sulfite with sulfur in the presence of cetylpyridinium chloride and dehydrating sodium thiosulfate product.

11. The method of claim 10, wherein the reaction comprises 1.0 mole equivalent of sodium sulfite; 1.1 mole equivalents of sulfur; and 0.00013 mole equivalents of cetylpyridinium chloride.

12. The method of claim 10 or 11, wherein the reaction is aqueous.

13. The method of any one of claims 10–12, wherein the reaction is conducted at about 80 °C to about 100 °C.

14. The method of any one of claims 10–13, wherein the sodium thiosulfate is crystallized and washed with acetone.

15. The method of any one of claims 10–14, wherein the sodium thiosulfate is dehydrated and washed with methanol.

16. The method of any one of claims 10–15, wherein the sodium thiosulfate is dried.

17. A method for synthesizing anhydrous sodium thiosulfate comprising:

(a) reacting aqueous sodium sulfite with sulfur and cetylpyridinium chloride;

(b) crystalizing sodium thiosulfate and washing with acetone;

(c) dehydrating the washed sodium thiosulfate with methanol; and

(d) drying the dehydrated sodium thiosulfate.

18. The method of claim 17, wherein the reaction comprises 1.0 mole equivalent of sodium sulfite; 1.1 mole equivalents of sulfur; and 0.00013 mole equivalents of cetylpyridinium chloride.

19. A method for synthesizing anhydrous sodium thiosulfate comprising:

(a) reacting 1.0 mole equivalent of aqueous sodium sulfite with 1.1 mole equivalents of sulfur in the presence of 0.00013 mole equivalents of cetylpyridinium chloride at about 90 °C to about 100 °C;

(b) crystalizing sodium thiosulfate at <2 °C and washing with acetone;

(c) dehydrating the washed sodium thiosulfate with methanol; and

(d) drying the dehydrated sodium thiosulfate at about 25 °C to about 60 °C.

20. Anhydrous sodium thiosulfate synthesized by the method of claim 19.

21. Means for synthesizing anhydrous sodium thiosulfate comprising reacting sodium sulfite with sulfur in the presence of cetylpyridinium chloride, crystalizing the sodium thiosulfate product, and dehydrating sodium thiosulfate product.

22. Anhydrous sodium thiosulfate synthesized by the means of claim 21.

23. Anhydrous sodium thiosulfate comprising essentially no sodium thiosulfate pentahydrate.

24. A method for measuring the binding capacity of sodium thiosulfate for cisplatin comprising:

(a) mixing one or more mole ratios of sodium thiosulfate with a predetermined quantity of cisplatin;

(b) incubating the mixture for a period of time; and

(c) analyzing the apparent concentration of cisplatin.

25. The method of claim 24, wherein the mole ratios of sodium thiosulfate to cisplatin comprise 10:1 to 1:1.

26. The method of claim 24 or 25, wherein the mole ratios of sodium thiosulfate to cisplatin comprise 10:1, 6:1, and 5:1.

27. The method of any one of claims 24–26, wherein the incubation period of time comprises 1 min to 180 min.

28. The method of any one of claims 24–27, wherein the incubation period of time comprises about 5 min; about 35 min, about 65 min; and about 95 min.

29. The method of any one of claims 24–28, wherein the analyzing comprises HPLC and UV detection.

CLAIMS

1. A pharmaceutical composition comprising aqueous anhydrous sodium thiosulfate, wherein the aqueous anhydrous sodium thiosulfate is at a concentration of about 0.5 M and further comprising borate ions wherein the concentration of borate ions is less than 0.05%.

2. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition has a total volume of about 100 mL.

3. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition further comprises hydrochloric acid.

4. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition further comprises sodium hydroxide.

5. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition has a pH between about 5 and about 9.5.

6. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition has a pH between about 8.6 and about 8.8.