CLAIMS

1. High-purity iron(III) citrate substantially free of beta-iron hydroxide oxide, wherein the beta-iron hydroxide oxide content is less than 6% by weight based on the total weight thereof.

2. The high-purity iron(III) citrate according to claim 1, wherein the beta-iron hydroxide oxide content is less than 2.5% by weight.

3. The high-purity iron(III) citrate according to claim 1, wherein the beta-iron hydroxide oxide content is less than 1.0% by weight.

4. The high-purity iron(III) citrate according to any one of claims 1 to 3, wherein the molar ratio of iron(III) to citric acid is from 1:0.75 to 1:1.10.

5. The high-purity iron(III) citrate according to claim 4, wherein the molar ratio of iron(III) to citric acid is from 1:0.80 to 1:0.92.

6. The high-purity iron(III) citrate according to any one of claims 1 to 5, wherein the percentage of iron(III) citrate dissolved within 15 minutes is 80% or more in dissolution testing conducted with the use of the first fluid of dissolution testing of the Japanese Pharmacopoeia, Fifteenth Edition as a test liquid via the paddle method at 100 rpm in accordance with the Japanese Pharmacopoeia, Fifteenth Edition.

7. A pharmaceutical composition comprising, as an active ingredient, the high-purity iron(III) citrate according to any one of claims 1 to 6.

8. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the high-purity iron(III) citrate according to any one of claims 1 to 6.

9. Powder of the high-purity iron(III) citrate according to any one of claims 1 to 6, which has an amorphous structure.

10. Powder of the high-purity iron(III) citrate according to any one of claims 1 to 6, which has a specific surface area of 20 to 45 m^2/g.

11. Powder of the high-purity iron(III) citrate according to claim 9, which has a specific surface area of 20 to 45 m^2/g.

12. A pharmaceutical composition comprising, as an active ingredient, the powder according to any one of claims 9 to 11.

13. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the powder according to any one of claims 9 to 11.

14. A method for producing iron(III) citrate comprising:

a step of forming an iron-containing precipitate comprising bringing ferric chloride into contact with sodium hydroxide for a short period of time at low temperature in an aqueous medium to form an iron-containing precipitate;

a step of generating an aqueous solution of iron(III) citrate comprising bringing citric acid into contact with the iron-containing precipitate in an aqueous medium and generating an aqueous solution of iron(III) citrate via heating; and

a step of precipitating iron(III) citrate comprising bringing the aqueous solution of iron(III) citrate into contact with an organic solvent to precipitate the iron(III) citrate.

15. The method according to claim 14, wherein the step of forming iron-containing precipitate comprises bringing ferric chloride into contact with sodium hydroxide within 2 hours at a liquid temperature of 0°C to 10°C.

16. The method according to claim 14 or 15, wherein the step of generating an aqueous solution of iron(III) citrate comprises bringing citric acid into contact with the iron-containing precipitate at a liquid temperature of 60°C to 100°C.

17. The method according to any one of claims 14 to 16, wherein the iron-containing precipitate is ferrihydride.

18. Iron(III) citrate produced by the method according to any one of claims 14 to 17.

19. A pharmaceutical composition comprising, as an active ingredient, the iron(III) citrate according to claim 18.

20. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the iron(III) citrate according to claim 18.

21. Powder of the iron(III) citrate according to claim 18, which has an amorphous structure.

22. Powder of the iron(III) citrate according to claim 18, which has a specific surface area of 20 to 45 m^2/g.

23. Powder of the iron(III) citrate according to claim 21, which has a specific

surface area of 20 to 45 m^2/g.

24. A pharmaceutical composition comprising, as an active ingredient, the powder according to any one of claims 21 to 23.

25. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the powder according to any one of claims 21 to 23.

26. The pharmaceutical composition according to claim 7, 12, 19, or 24 for use in treatment of hyperphosphatemia.

CLAIMS

1. High-purity iron(III) citrate substantially free of beta-iron hydroxide oxide, wherein the beta-iron hydroxide oxide content is less than 6% by weight based on the total weight thereof, and is produced by a method comprising:

a step of forming an iron-containing precipitate comprising bringing ferric chloride into contact with sodium hydroxide for a short period of time at low temperature in an aqueous medium to form an iron-containing precipitate;

a step of generating an aqueous solution of iron(III) citrate comprising bringing citric acid into contact with the iron-containing precipitate in an aqueous medium and generating an aqueous solution of iron(III) citrate via heating; and

a step of precipitating iron(III) citrate comprising bringing the aqueous solution of iron(III) citrate into contact with an organic solvent to precipitate the iron(III) citrate;

wherein the step of forming iron-containing precipitate comprises bringing ferric chloride into contact with sodium hydroxide within 2 hours at a liquid temperature of 0 °C to 10 °C.

2. The high-purity iron(III) citrate according to claim I, wherein the beta-iron hydroxide oxide content is less than 2.5% by weight.

3. The high-purity iron(III) citrate according to claim I, wherein the beta-iron hydroxide oxide content is less than 1.0% by weight.

4. The high-purity iron(III) citrate according to any one of claims 1 to 3, wherein the molar ratio of iron(III) to citric acid is from 1: 0.75 to 1: 1.10.

5. The high-purity iron(III) citrate according to claim 4, wherein the molar ratio of iron(III) to citric acid is from 1:0.80 to 1:0.92.

6. The high-purity iron(III) citrate according to any one of claims 1 to 5, wherein the percentage of iron(III) citrate dissolved within 15 minutes is 80% or more in dissolution testing conducted with the use of the first fluid of dissolution testing of the Japanese Pharmacopoeia, Fifteenth Edition as a test liquid via the paddle method at 100 rpm in accordance with the Japanese Pharmacopoeia, Fifteenth Edition.

7. A pharmaceutical composition comprising, as an active ingredient, the high-purity iron(III) citrate according to any one of claims 1 to 6.

8. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the high-purity iron(III) citrate according to any one of claims 1 to 6.

9. Powder of the high-purity iron(III) citrate according to any one of claims 1 to 6, which has an amorphous structure.

10. Powder of the high-purity iron(III) citrate according to any one of claims 1 to 6, which has a specific surface area of 20 to 45 m^2/g.

11. Powder of the high-purity iron(III) citrate according to claim 9, which has a specific surface area of 20 to 45 m^2/g.

12. A pharmaceutical composition comprising, as an active ingredient, the powder according to any one of claims 9 to 11.

13. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the powder according to any one of claims 9 to 11.

14. A method for producing iron(III) citrate comprising:

a step of forming an iron-containing precipitate comprising bringing ferric chloride into contact with sodium hydroxide for a short period of time at low temperature in an aqueous medium to form an iron-containing precipitate;

a step of generating an aqueous solution of iron(III) citrate comprising bringing citric acid into contact with the iron-containing precipitate in an aqueous medium and generating an aqueous solution of iron(III) citrate via heating; and

a step of precipitating iron(III) citrate comprising bringing the aqueous solution of iron(III) citrate into contact with an organic solvent to precipitate the iron(III) citrate;

wherein the step of forming iron-containing precipitate comprises bringing ferric chloride into contact with sodium hydroxide within 2 hours at a liquid temperature of 0 °C to 10 °C.

15. The method according to claim 14, wherein the step of generating an aqueous solution of iron(III) citrate comprises bringing citric acid into contact with the iron-containing precipitate at a liquid temperature of 60 °C to 100 °C.

16. The method according to any one of claims 14 to 15, wherein the iron-containing precipitate is ferrihydride.

17. Iron(III) citrate produced by the method according to any one of claims 14 to 16.

18. A pharmaceutical composition comprising, as an active ingredient, the iron(III) citrate according to claim 17.

19. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the iron(III) citrate according to claim 17.

20. Powder of the iron(III) citrate according to claim 17, which has an amorphous structure.

21. Powder of the iron(III) citrate according to claim 17, which has a specific surface area of 20 to 45 m^2/g.

22. Powder of the iron(III) citrate according to claim 20, which has a specific surface area of 20 to 45 m^2/g.

23. A pharmaceutical composition comprising, as an active ingredient, the powder according to any one of claims 20 to 22.

24. An agent for treatment or amelioration of hyperphosphatemia comprising, as an active ingredient, the powder according to any one of claims 20 to 22.

25. The pharmaceutical composition according to claim 7, 12, 18, or 23 for use in treatment of hyperphosphatemia.