Claims

1. Pharmaceutical composition comprising iron oxy-hydroxide in an amount of 10 to 80 % (w/w), expressed in relation to the total weight of the composition, in a form suitable for oral administration, which composition comprises a mixture of native and pregelatinized starch.

2. Pharmaceutical composition according to claim 1, in a form suitable for oral administration as film-coated dosage forms for intact swallowing or as dosage forms capable of disintegration in the oral cavity.

3. The composition according to claim 2, which is a dosage form capable of disintegration in the oral cavity or in a small amount of liquid prior to ingestion.

4. The composition according to claims 2 or 3, wherein dosage form capable of disintegration in the oral cavity is selected from the group consisting of chewable tablets or pills, dry powders, granules, capsules or sachets containing these granules, wafers, or lozenges.

5. The composition according to any of claims 2 to 4, which dosage form capable of disintegration in the oral cavity is selected from chewable tablets.

6. The composition according to any of claims 2 to 5, wherein the oral dosage forms are capable of rapid disintegration in the oral cavity or in a small amount of liquid prior to ingestion and wherein the iron oxy-hydroxide is present in an amount of 700 to 1700 mg per dosage form.

7. The ~~com~~position according to claim 6, wherein the iron oxy-hydroxide is present in an amount of 800 mg per dosage form.

8. The composition according to any preceding claim, which composition comprises saccharose.

9. The composition according to any preceding claim, which composition is consisting of iron oxy-hydroxide, saccharose, a mixture of native and pregelatinized starch, flavour, sweetener, and glidant.

10. The composition according to any preceding claim wherein the iron oxy-hydroxide is containing beta iron oxy-hydroxide.

11. The composition of any preceding claim wherein iron oxy-hydroxide is present in an amount of 30 to 65 % (w/w), expressed in relation to the total weight of the composition.

12. The composition of any preceding claim wherein the carbohydrate and/or humic acid are present in a total amount of 1 to 50 % (w/w), preferably 5 to 30 % (w/w), expressed in relation to the total weight of the composition.

13. The composition of any preceding claim further comprising one or more flavouring agents, sweeteners, taste-enhancing agents, and/or coloring agents.

14. The composition of claim 13, wherein the sweetener is natural or unnatural sweetener selected from a sugar, a polyol, aspartame, sucralose, acesulfamine K, and/or

saccharin and the taste-enhancing agent is selected from glycosides such as neohesperidin dihydrochalcone, glycyrrhizin, glutamate.

15. The composition of claim 13 or 14, wherein the sweetener is present in an amount of 0.01 to 2.5 % (w/w), and the taste-enhancing agent in an amount of 0.1 to 10 ppm, each expressed in relation to the total weight of the composition.

16. The composition of claim 13, wherein the flavouring agent is present in an amount of 0.01 to 10 % (w/w), preferably 0.1 to 5 % (w/w), most preferably 0.1 to 1 % (w/w), expressed in relation to the total weight of the composition.

17. The composition of any preceding claim further comprising one or more excipients, such as superdisintegrants, glidants, antioxidants.

18. The composition of claim 17, wherein the superdisintegrant is selected from the group consisting of cross-linked polyvinylpyrrolidones, modified starches, and modified celluloses.

19. The composition of claims 17 or 18, wherein the superdisintegrant is present in an amount of 0.1 to 10 % (w/w), preferably 0.5 to 8 % (w/w), more preferably 2.5 to 6 % (w/w), expressed in relation to the total weight of the composition.

20. The composition of claim 17, wherein the glidant is selected from the group consisting of magnesium stearate, silica derivatives, such as colloidal silica,

pyrogenic silica, hydrated sodium silicoaluminate, colloidal silicon dioxide, talcum and mixtures thereof, preferably magnesium stearate, colloidal silica or talcum.

21. The composition of claims 17 or 20, wherein the glidant is present in an amount of 0.01 to 10 % (w/w), preferably 0.1 to 5 % (w/w), expressed in relation to the total weight of the composition.

22. The composition of any preceding claim comprising iron oxy-hydroxide in an amount of 10 to 80 % (w/w), at least one carbohydrate and/or humic acid in a total amount of 1.0 to 50 % (w/w), optionally one or more excipients in a total amount of 1.0 to 50 % (w/w), one or more taste-enhancing agents in a total amount of 0.1 to 10 ppm, and/or one or more flavouring agents in a total amount of 0.01 to 10 % (w/w), each expressed in relation to the total weight of the composition.

23. The composition of claim 22 comprising one or more superdisintegrants in a total amount of 0.1 to 10 % by weight (w/w).

24. The composition of any preceding claim in form a form for intact swallowing or in a form capable of rapid disintegration such as chewable tablets or pills, dry powders, granules, capsules or sachets containing these granules, wafers, or lozenges.

25. Use of the compositions of any preceding claim for the manufacture of a medicament for the treatment of hyperphosphataemia.

26. Use of the compositions of any preceding claim for the manufacture of a medicament for the treatment of patients with chronic renal insufficiency.

27. A method for preparing the composition according to any preceding claim in form of a tablet by direct compression or dry granulation.

28. A method for preparing the composition according to any preceding claim in form of a tablet, wherein an aqueous suspension, comprising at least 90 % (w/w) of the ingredients based on the total weight of the final composition, is prepared, which is then subjected to spray-drying to obtain a flowable powder, which is optionally mixed with the remaining ingredients and subsequently compressed to obtain a tablet.

29. A tablet, as obtainable by the method of claim 28.

30. A tablet comprising iron oxy-hydroxide in an amount of 30 to 65 % (w/w), saccharose in an amount of 5 to 30 % (w/w), and starch in an amount of 5 to 30 % (w/w), expressed in relation to the total weight of the tablet composition, excluding the weight of an optionally present tablet coating.

Claims

1. Pharmaceutical composition comprising iron oxy-hydroxide in an amount of 10 to 80 % (w/w), expressed in relation to the total weight of the composition, in a form suitable for oral administration, which composition comprises saccharose and a mixture of native and pregelatinized starch.

2. The pharmaceutical composition according to claim 1, which comprises a mixture of native and pregelatinized starch having a ratio (native : pregelatinized) in the range of 10:1 to 0.5:1, preferably in the range of 3:1 to 0.5:1 more preferably in the range of 2:1 to 1:1.

3. Pharmaceutical composition according to claim 1 or 2, in a form suitable for oral administration as film-coated dosage forms for intact swallowing or as dosage forms capable of disintegration in the oral cavity.

4. The pharmaceutical composition according to any of claims 1 to 3, which is a tablet.

5. The composition according to claim 3, which is a dosage form capable of disintegration in the oral cavity or in a small amount of liquid prior to ingestion.

6. The composition according to claims 2 or 3, wherein dosage form capable of disintegration in the oral cavity is selected from the group consisting of chewable tablets or pills, dry powders, granules, capsules or sachets containing these granules, wafers, or lozenges.

7. The composition according to any of claims 2 to 4, which dosage form capable of disintegration in the oral cavity is selected from chewable tablets.

8. The pharmaceutical composition according to any of claims 1 to 7, comprising iron oxy-hydroxide in an amount of > 300 mg per dosage form.

9. The pharmaceutical composition according to any of claims 1 to 8, comprising iron oxy-hydroxide in an amount of 300 to 2000 mg per dosage form.

10. The pharmaceutical composition according to any of claims 1 to 9, wherein the oral dosage is a tablet for intact swallowing, which comprises iron oxy-hydroxide in an amount of 350 to 850 mg.

11. The composition according to any of claims 1 to 9, wherein the oral dosage forms are capable of rapid disintegration in the oral cavity or in a small amount of liquid prior to ingestion and wherein the iron oxy-hydroxide is present in an amount of 700 to 1700 mg per dosage form.

12. The composition according to claim 6, wherein the iron oxy-hydroxide is present in an amount of 800 mg per dosage form.

13. The composition according to any preceding claim, which composition is consisting of iron oxy-hydroxide, saccharose, a mixture of native and pregelatinized starch, flavour, sweetener, and glidant.

14. The composition according to any preceding claim wherein the iron oxy-hydroxide is containing beta iron oxy-hydroxide.

15. The composition of any preceding claim wherein iron oxy-hydroxide is present in an amount of 10 to 65 % (w/w), expressed in relation to the total weight of the composition.

16. The composition of any preceding claim further comprising one or more flavouring agents, sweeteners, taste-enhancing agents, and/or coloring agents.

17. The composition of claim 16, wherein the sweetener is natural or unnatural sweetener selected from a sugar, a polyol, aspartame, sucralose, acesulfamine K, and/or saccharin and the taste-enhancing agent is selected from glycosides such as neohesperidin dihydrochalcone, glycyrrhizin, glutamate.

18. The composition of claim 16 or 17, wherein the sweetener is present in an amount of 0.01 to 2.5 % (w/w), and the taste-enhancing agent in an amount of 0.1 to 10 ppm, each expressed in relation to the total weight of the composition.

19. The composition of claim 16, wherein the flavouring agent is present in an amount of 0.01 to 10 % (w/w), preferably 0.1 to 5 % (w/w), most preferably 0.1 to 1 % (w/w), expressed in relation to the total weight of the composition.

20. The composition of any preceding claim further comprising one or more excipients, such as superdisintegrants, glidants, antioxidants.

21. The composition of claim 20, wherein the superdisintegrant is selected from the group consisting of cross-linked polyvinylpyrrolidones, modified starches, and modified celluloses.

22. The composition of claims 20 or 21, wherein the superdisintegrant is present in an amount of 0.1 to 10 % (w/w), preferably 0.5 to 8 % (w/w), more preferably 2.5 to 6 % (w/w), expressed in relation to the total weight of the composition.

23. The composition of claim 20, wherein the glidant is selected from the group consisting of magnesium stearate, silica derivatives, such as colloidal silica, pyrogenic silica, hydrated sodium silicoaluminate, colloidal silicon dioxide, talcum and mixtures thereof, preferably magnesium stearate, colloidal silica or talcum.

24. The composition of claims 20 or 23, wherein the glidant is present in an amount of 0.01 to 10 % (w/w), preferably 0.1 to 5 % (w/w), expressed in relation to the total weight of the composition.

25. The composition of any preceding claim comprising iron oxy-hydroxide in an amount of 10 to 80 % (w/w), at least one carbohydrate and/or humic acid in a total amount of 1.0 to 50 % (w/w), optionally one or more excipients in a total amount of 1.0 to 50 % (w/w), one or more taste-enhancing agents in a total amount of 0.1 to 10 ppm, and/or one or more flavouring agents in a total amount of 0.01 to 10 % (w/w), each expressed in relation to the total weight of the composition.

26. The composition of claim 25 comprising one or more superdisintegrants in a total amount of 0.1 to 10 % by weight(w/w).

27. Use of the compositions of any preceding claim for the manufacture of a medicament for the treatment of hyperphosphataemia.

28. Use of the compositions of any preceding claim for the manufacture of a medicament for the treatment of patients with chronic renal insufficiency.

29. A method for preparing the composition according to any preceding claim in form of a tablet by direct compression or dry granulation.

30. A method for preparing the composition according to any preceding claim in form of a tablet, wherein an aqueous suspension, comprising at least 90 % (w/w) of the ingredients based on the total weight of the final composition, is prepared, which is then subjected to spray-drying to obtain a flowable powder, which is optionally mixed with the remaining

ingredients and subsequently compressed to obtain a tablet.

31. A tablet, as obtainable by the method of claim 29 or 30.

32. A tablet comprising iron oxy-hydroxide in an amount of 30 to 65 % (w/w), saccharose in an amount of 5 to 30 % (w/w), and starch in an amount of 5 to 30 % (w/w), expressed in relation to the total weight of the tablet composition, excluding the weight of an optionally present tablet coating.

33. A composition comprising iron oxy-hydroxide in an amount of 10 to 80 % (w/w), expressed in relation to the total weight of the composition, saccharose and a mixture of native and pregelatinized starch.

34. Iron oxy-hydroxide, stabilized with saccharose and a mixture of native and pregelatinized starch.

35. A stabilized iron oxy-hydroxide according to claim 34, wherein the mixture of native and pregelatinized starch has a ratio (native : pregelatinized) in the range of 10:1 to 0.5:1, preferably in the range of 3:1 to 0.5:1 more preferably in the range of 2:1 to 1:1.

36. Use of the composition of claim 33 or the stabilized iron oxy-hydroxides of claims 34 or 35 as a phosphate binder for oral administration.

37. The composition of claim 33 or the stabilized iron oxy-hydroxides of claims 34 or 35 as flowable powder.

38. The use of a mixture of native and pregelatinized starch for the manufacture of a pharmaceutical composition in the form of a tablet, comprising iron oxy-hydroxide in an amount of 10 to 80 % (w/w), expressed in relation to the total weight of the composition.

39. Use of the compositions of any preceding claims or the

stabilized iron oxy-hydroxides of claims 34 or 35 for the manufacture of a medicament for the treatment of hyperphosphataemia.

40. Use of the compositions of any preceding claims or the stabilized iron oxy-hydroxides of claims 34 or 35 for the manufacture of a medicament for the treatment of patients with chronic renal insufficiency.