CLAIMS

1. Use of ferric citrate in the manufacture of a medicament for reducing mortality and morbidity related to adverse cardiac events in a human non-dialysis chronic kidney disease patient, wherein said medicament is to be administered orally to said patient as a tablet, and the ferric citrate is to be administered in an amount ranging from 1 g to 18 g, wherein the adverse cardiac event is selected from the group consisting of: heart failure, ventricular arrhythmias, myocardial infarction, decreased left ventricular (LV) ejection fraction, sudden cardiac death, aortic root dilation, and a cerebrovascular event, wherein each tablet comprises 80% to 92% by weight of ferric citrate, 5% to 15% by weight of pregelatinized starch, and 0.5% to 2% by weight of a lubricant; and wherein at least 80% of the ferric citrate in the tablet is dissolved in less than or equal to 60 minutes as measured by test method USP <711>, and the water content of the tablet is less than 11% by loss on drying (LOD).

2. The use of claim 1, wherein the ferric citrate raises the hemoglobin level of the patient to a level above 10 g/dL.

3. The use of claim 1, wherein the ferric citrate reduces FGF-23 levels of the patient by at least 30% compared to baseline.

4. Use of ferric citrate in the manufacture of a medicament for reducing incidence or risk of adverse cardiac events in a human non-dialysis chronic kidney disease patient, wherein said medicament is to be administered orally to said patient as a tablet, and the ferric citrate is to be administered in an amount ranging from 1 g to 18 g, and wherein the adverse cardiac event is selected from the group consisting of: heart failure, ventricular arrhythmias, myocardial infarction, decreased left ventricular (LV) ejection fraction, sudden cardiac death, aortic root dilation, and a cerebrovascular event, wherein each tablet comprises 80% to 92% by weight of ferric citrate, 5% to 15% by weight of pregelatinized starch, and 0.5% to 2% by weight of a lubricant; and wherein at least 80% of the ferric citrate in the tablet is dissolved in less than or equal to 60 minutes as measured by test method USP <711>, and the water content of the tablet is less than 11% by loss on drying (LOD).

5. Use of ferric citrate in the manufacture of a medicament for reducing incidence or risk of hospitalizations related to adverse cardiac events in a human non-dialysis chronic kidney disease patient, wherein said medicament is to be administered orally to said patient as a tablet, and the ferric citrate is to be administered in an amount ranging from 1 g to 18 g, wherein each tablet comprises 80% to 92% by weight of ferric citrate, 5% to 15% by weight of pregelatinized starch, and 0.5% to 2% by weight of a lubricant; and wherein at least 80% of the ferric citrate in the tablet is dissolved in less

than or equal to 60 minutes as measured by test method USP <711>, and the water content of the tablet is less than 11% by loss on drying (LOD).

6. Use of ferric citrate in the manufacture of a medicament for reducing incidence or risk of sudden cardiac death in a human non-dialysis chronic kidney disease patient, wherein said medicament is to be administered orally to said patient as a tablet, and the ferric citrate is to be administered in an amount ranging from 1 g to 18 g, wherein each tablet comprises 80% to 92% by weight of ferric citrate, 5% to 15% by weight of pregelatinized starch, and 0.5% to 2% by weight of a lubricant; and wherein at least 80% of the ferric citrate in the tablet is dissolved in less than or equal to 60 minutes as measured by test method USP <711>, and the water content of the tablet is less than 11% by loss on drying (LOD).

7. Use of ferric citrate in the manufacture of a medicament for treating left ventricular hypertrophy (LVH) in a human non-dialysis chronic kidney disease patient, wherein said medicament is to be administered orally to said patient as a tablet, and the ferric citrate is to be administered in an amount ranging from 1 g to 18 g, wherein each tablet comprises 80% to 92% by weight of ferric citrate, 5% to 15% by weight of pregelatinized starch, and 0.5% to 2% by weight of a lubricant; and wherein at least 80% of the ferric citrate in the tablet is dissolved in less than or equal to 60 minutes as measured by test method USP <711>, and the water content of the tablet is less than 11% by loss on drying (LOD).

8. The use of claim 5, wherein the adverse cardiac event is selected from the group consisting of: heart failure, ventricular arrhythmias, myocardial infarction, decreased left ventricular (LV) ejection fraction, sudden cardiac death, aortic root dilation, and a cerebrovascular event.

9. The use of any one of claims 1-8, wherein the ferric citrate is a complex comprising iron(III) and citric acid with a molar ratio of 1:0.69 to 1:0.87.

10. The use of any one of claims 1-9, wherein the lubricant is calcium stearate.

11. The use of any one of claims 1-10, wherein the tablet is coated.

12. The use of any one of claims 1-11, wherein the water content of the tablet is between 5% and 10% by loss on drying (LOD).

13. The use of any one of claims 1-12, wherein the patient to be treated has serum phosphate levels within the normal range for non-chronic kidney disease patients.

14. The use of any one of claim 1-13, wherein the patient to be treated has FGF-23 levels that are elevated relative to the normal range in healthy humans.

15. The use of claim 14, wherein the FGF-23 levels measured are intact FGF-23 and C-terminal FGF-23 fragments.

16. The use of claim 15, wherein the patient's intact FGF-23 levels in serum are between 250 pg/mL and 350 pg/mL or 250 pg/mL and 500 pg/mL prior to administration of said medicament.

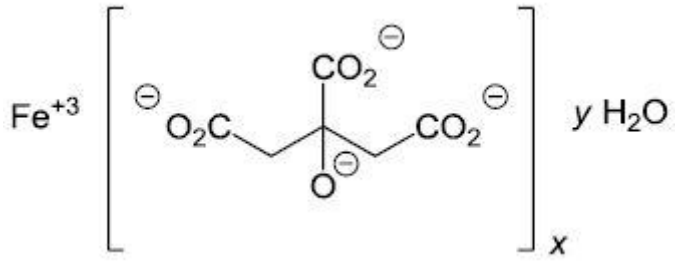
17. The use of claim 15 or 16, wherein the patient's C-terminal FGF-23 levels in serum are between 60 RU/mL and 100 RU/mL or 100 RU/mL and 200 RU/mL.

18. The use of any one of claims 1-17, wherein the use further comprises monitoring the patient for (i) hemoglobin concentration; (ii) FGF-23 levels; and (iii) phosphate levels.

19. The use of any one of claims 1-18, wherein the patient is not receiving IV iron.

20. The use of any one of claims 1-18, wherein the patient is not receiving EPO.

21. The use of any one of claims 1-20, wherein the ferric citrate is iron (+3), *x* (1, 2, 3-propanetricarboxylic acid, 2-hydroxy-), *y* (H_2O)



x=0.70 – 0.87, y = 1.9 – 3.3.