CLAIMS:

1. A low dose pharmaceutical composition comprising deferasirox or a pharmaceutically acceptable derivative thereof and one or more pharmaceutically acceptable excipients.

2. The low dose pharmaceutical composition according to claim 1, wherein the pharmaceutically acceptable derivative of deferasirox is a salt, solvate, complex, hydrate, isomer, ester, tautomer, anhydrate, enantiomer, polymorph or prodrug.

3. A low dose pharmaceutical composition according to claim 1 or 2, wherein a unit dose of the pharmaceutical composition comprises from about 50 mg to about 100 mg of deferasirox, from about 150 mg to about 200 mg of deferasirox or from about 260 mg to about 350 mg of deferasirox.

4. A low dose pharmaceutical composition according to any preceding claim for use in providing a patient with a daily dose of from about 1 mg/kg to less than about 30 mg/kg of body weight, optionally from about 2 mg/kg to less than about 20 mg/kg of body weight or from about 3 mg/kg to about 10 mg/kg of body weight, or from about 3 mg/kg to less than about 30 mg/kg of body weight, or from about 5 mg/kg to less than about 20 mg/kg of body weight or from about 3 mg/kg to about 15 mg/kg of body weight.

5. A low dose pharmaceutical composition according to any preceding claim, wherein the deferasirox is in the form of particles, and wherein the particles have an average particle size of greater than about 1 μm but less than or equal to about 30 μm, optionally greater than about 1 μm but less than or equal to about 8 μm.

6. A low dose pharmaceutical composition according to any preceding claim, wherein said pharmaceutical composition is for oral administration.

7. A low dose pharmaceutical composition according to claim 6, wherein said pharmaceutical composition is in the form of a tablet.

8. A low dose pharmaceutical composition according to claim 7, wherein the tablet is a dispersible tablet.

9. A low dose pharmaceutical composition according to any preceding claim, wherein the excipients comprise a surface stabilizer.

10. A low dose pharmaceutical composition according to claim 9, wherein the surface stabilizer is an amphoteric, non-ionic, cationic or anionic surfactant or combinations thereof.

11. A low dose pharmaceutical composition according to any preceding claim, wherein the excipients comprise a viscosity enhancing agent.

12. A low dose pharmaceutical composition according to any preceding claim, wherein the excipients comprise one or more of the following: a solubilizer, an anticaking agent, a buffer, a polymer, a sweetener, solvents, co-solvents, a vehicle, a carrier, an adsorbent, a channeling agent, an opacifier, a diluent, a filler, a glidant, an anti-adherent, a binder, a disintegrant and a lubricant.

13. A low dose pharmaceutical composition according to any preceding claim, further comprising at least one additional active ingredient selected from deferiprone, desferrioxamine, leukotriene, probenecid, indomethacin, penicillin G, ritonavir, indinavir, saquinavir, furosemide, methotrexate, sulfinpyrazone, interferon, ribavirin, viramidine, valopicitabine, aromatase inhibitor, antiestrogen, anti-androgen, gonadorelin agonist, topoisomerase I inhibitor, topoisomerase II inhibitor, microtubule active agent, alkylating agent, anti-neoplastic, anti-metabolite, platin compound, anti-angiogenic compound, cyclooxygenase inhibitor, bisphosphonate, heparanase inhibitor, telomerase inhibitor, protease inhibitor, matrix metalloproteinase inhibitor, proteasome inhibitor, somatostatin receptor antagonist, anti-leukemic compound, ribonucleotide reductase inhibitor, S-adenosylmethionine decarboxylase inhibitor; ACE inhibitor, antibiotics such as gentamicin, amikacin, tobramycin, ciprofloxacin, levofloxacin, ceftazidime, cefepime, cefpirome, piperacillin, ticarcillin, meropenem, imipenem, polymyxin B, colistin and aztreonam; cyclosporin A, cyclosporin G, rapamycin, and combinations thereof.

14. A low dose pharmaceutical composition according to any preceding claim for use as a medicament.

15. A low dose pharmaceutical composition according to claim 14 for use in treating chronic iron overload.

16. A low dose pharmaceutical composition according to claim 14 for use in treating lead toxicity.

17. A low dose pharmaceutical composition according to claim 16, wherein the pharmaceutical composition comprises deferasirox and deferiprone for use in treating lead toxicity.

18. A method of treating chronic iron overload comprising administering an effective amount of a low dose pharmaceutical composition according to any one of claims 1 to 13 to a subject in need thereof.

19. A method of treating lead toxicity comprising administering an effective amount of a low dose pharmaceutical composition according to any one of claims 1 to 13 to a subject in need thereof.

20. A method of treating lead toxicity according to claim 19, which comprises administering a low dose pharmaceutical composition comprising deferasirox and deferiprone to a subject in need thereof.

21. A process for preparing a low dose pharmaceutical composition according to any of claims 1 to 13, which process comprises

dissolving or adsorbing or blending deferasirox and at least one excipient to produce a dispersion of deferasirox, and

processing the dispersion to produce a desired dosage form.

22. A low dose pharmaceutical composition substantially as described herein with reference to the examples.

23. A process substantially as described herein with reference to the examples.

CLAIMS:

1. A low dose pharmaceutical composition comprising deferasirox or a pharmaceutically acceptable derivative thereof and one or more pharmaceutically acceptable excipients.

2. The low dose pharmaceutical composition according to claim 1, wherein the pharmaceutically acceptable derivative of deferasirox is a salt, solvate, complex, hydrate, isomer, ester, tautomer, anhydrate, enantiomer, polymorph or prodrug.

3. A low dose pharmaceutical composition according to claim 1 or 2, wherein a unit dose of the pharmaceutical composition comprises from about 50 mg to about 100 mg of deferasirox, from about 150 mg to about 200 mg of deferasirox or from about 260 mg to about 350 mg of deferasirox.

4. A low dose pharmaceutical composition according to any preceding claim for use in providing a patient with a daily dose of from about 1 mg/kg to less than about 30 mg/kg of body weight, optionally from about 2 mg/kg to less than about 20 mg/kg of body weight or from about 3 mg/kg to about 10 mg/kg of body weight, or from about 3 mg/kg to less than about 30 mg/kg of body weight, or from about 5 mg/kg to less than about 20 mg/kg of body weight or from about 3 mg/kg to about 15 mg/kg of body weight.

5. A low dose pharmaceutical composition according to any preceding claim, wherein the deferasirox is in the form of particles, and wherein the particles have an average particle size of greater than about 1 μm but less than or equal to about 30 μm, optionally greater than about 1 μm but less than or equal to about 8 μm.

6. A low dose pharmaceutical composition according to any preceding claim, wherein said pharmaceutical composition is for oral administration.

7. A low dose pharmaceutical composition according to claim 6, wherein said pharmaceutical composition is in the form of a tablet.

8. A low dose pharmaceutical composition according to claim 7, wherein the tablet is a dispersible tablet.

9. A low dose pharmaceutical composition according to any preceding claim, wherein the excipients comprise a surface stabilizer.

10. A low dose pharmaceutical composition according to claim 9, wherein the surface stabilizer is an amphoteric, non-ionic, cationic or anionic surfactant or combinations thereof.

11. A low dose pharmaceutical composition according to any preceding claim, wherein the excipients comprise a viscosity enhancing agent.

12. A low dose pharmaceutical composition according to any preceding claim, wherein the excipients comprise one or more of the following: a solubilizer, an anticaking agent, a buffer, a polymer, a sweetener, solvents, co-solvents, a vehicle, a carrier, an adsorbent, a channeling agent, an opacifier, a diluent, a filler, a glidant, an anti-adherent, a binder, a disintegrant and a lubricant.

13. A low dose pharmaceutical composition according to any preceding claim, further comprising at least one additional active ingredient selected from deferiprone, desferrioxamine, leukotriene, probenecid, indomethacin, penicillin G, ritonavir, indinavir, saquinavir, furosemide, methotrexate, sulfinpyrazone, interferon, ribavirin, viramidine, valopicitabine, aromatase inhibitor, antiestrogen, anti-androgen, gonadorelin agonist, topoisomerase I inhibitor, topoisomerase II inhibitor, microtubule active agent, alkylating agent, anti-neoplastic, anti-metabolite, platin compound, anti-angiogenic compound, cyclooxygenase inhibitor, bisphosphonate, heparanase inhibitor, telomerase inhibitor,

protease inhibitor, matrix metalloproteinase inhibitor, proteasome inhibitor, somatostatin receptor antagonist, anti-leukemic compound, ribonucleotide reductase inhibitor, Sadenosylmethionine decarboxylase inhibitor; ACE inhibitor, antibiotics such as gentamicin, amikacin, tobramycin, ciprofloxacin, levofloxacin, ceftazidime, cefepime, cefpirome, piperacillin, ticarcillin, meropenem, imipenem, polymyxin B, colistin and aztreonam; cyclosporin A, cyclosporin G, rapamycin, and combinations thereof.

14. A low dose pharmaceutical composition according to any preceding claim for use as a medicament.

15. A low dose pharmaceutical composition according to claim 14 for use in treating chronic iron overload.

16. A low dose pharmaceutical composition according to claim 14 for use in treating lead toxicity.

17. A low dose pharmaceutical composition according to claim 16, wherein the pharmaceutical composition comprises deferasirox and deferiprone for use in treating lead toxicity.

18. The use of an effective amount of a low dose pharmaceutical composition according to any one of claims 1 to 13 in the manufacture of a medicament for the treatment of chronic iron overload.

19. The use of an effective amount of a low dose pharmaceutical composition according to any one of claims 1 to 13 in the manufacture of a medicament for the treatment of lead toxicity.

20. The use of a low dose pharmaceutical composition comprising deferasirox and deferiprone in the manufacture of a medicament for the treatment of lead toxicity.

21. A process for preparing a low dose pharmaceutical composition according to any of claims 1 to 13, which process comprises

dissolving or adsorbing or blending deferasirox and at least one excipient to produce a dispersion of deferasirox; and

processing the dispersion to produce a desired dosage form.