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 $\mu$m but less than or equal to about 30 $\mu$m, optionally greater than about 1 $\mu$m but less than or equal to about 8 $\mu$m.

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.

CLAIMS:

1. A low dose pharmaceutical composition for oral administration to a patient comprising deferasirox or a pharmaceutically acceptable derivative thereof and one or more pharmaceutically acceptable excipients, which composition is in a unit dosage form that enables the patient to be provided with from 0.1 mg/kg bodyweight to less than 20 mg/kg bodyweight of deferasirox.

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 50 mg to 100 mg of deferasirox, from 150 mg to 200 mg of deferasirox or from 260 mg to 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 2 mg/kg to less than 20 mg/kg of body weight or from 3 mg/kg to 10 mg/kg of body weight, or from 3 mg/kg to less than 30 mg/kg of body weight, or from 5 mg/kg to less than 20 mg/kg of body weight or from 3 mg/kg to 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 1 µm but less than or equal to 0 µm, optionally greater than 1 µm but less than or equal to 8 µm.

6. A low dose pharmaceutical composition according to claim 5, wherein said pharmaceutical composition is in the form of a tablet.

7. A low dose pharmaceutical composition according to claim 6, wherein the tablet is a dispersible tablet or a film-coated tablet.

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

9. A low dose pharmaceutical composition according to claim 8, wherein the surface stabilizer is an amphoteric, non-ionic, cationic or anionic surfactant or combinations thereof.

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

11. 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.

12. A low dose pharmaceutical composition according to any preceding claim, comprising: sodium docusate, hydroxypropylmethylcellulose, sodium lauryl sulphate, monohydrated lactose, crospovidone, sodium chloride, silicified microcrystalline cellulose, silica, magnesium stearate and water.

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

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

15. The use of an effective amount of a low dose pharmaceutical composition according to any one of claims 1 to 14 to a subject in need thereof.

16 A process for preparing a low dose pharmaceutical composition according to any of claims 1 to 14, which process comprises

(a) dissolving or adsorbing or blending the deferasirox or pharmaceutically acceptable derivative thereof in an amount that enables the patient to be provided with from about 0.1

mg/kg bodyweight to less than about 20 mg/kg bodyweight of deferasirox, and at least one excipient; and

(b) processing the resulting mixture to produce a desired dosage form.

17. A process according to claim 16, comprising

(a) solubilizing docusate sodium, hydroxypropylmethylcellulose, sodium lauryl sulphate and lactose in water; dispersing the deferasirox in the solution thus obtained to produce a dispersion of deferasirox;

(b) nanomilling the dispersion and spraying it onto a hydrated lactose and crospovidone mixture to form granules;

(c) blending the resulting granules with sodium chloride, crospovidone, silicified microcrystalline cellulose and magnesium stearate; and

(d) compressing the resulting blend into tablets.

18. A process according to claim 16, comprising

(a) mixing the deferasirox with sodium lauryl sulphate, hydrated lactose and copovidone to produce a blend;

(b) hot melt extruding the blend and sizing the extrudes to form granules;

(c) blending the resulting granules with sodium chloride, crospovidone, silicified microcrystalline cellulose and magnesium stearate; and

(d) compressing the resulting blend into tablets.