between about 200 and about 550 nm. In one embodiment, the dye is selected from the group consisting of a black dye, a blue dye, a green dye, a red dye, an orange dye, a yellow dye, and combinations thereof. In another embodiment, the dye is selected from the group consisting of a red dye, an orange dye, a yellow dye, and combinations thereof.

[0007] In one embodiment, the dye is selected from the group consisting of Allura Red AC, Allura Red AC aluminum lake, iron oxide red, iron oxide yellow, Sunset Yellow FCF, Sunset Yellow FCF aluminum lake, Indigotine, Indigotine aluminum lake, and combinations thereof.

[0008] In one embodiment, the pharmaceutical formulation comprises from about 20 mg to about 200 mg of [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid. In another embodiment, the pharmaceutical formulation comprises about 20 mg, about 50 mg, or about 100 mg of [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid.

[0009] In one embodiment, a solid dosage form comprises the pharmaceutical formulation and the solid dosage form is selected from a capsule, tablet, bead, granule, pellet, lozenge, pill, or gum. In another embodiment, the solid dosage form is a tablet. In another embodiment, the solid dosage form is a capsule.

[0010] In an embodiment, there is provided a tablet comprising [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, a pharmaceutically acceptable excipient and an effective amount of a photostabilizing agent. In one embodiment, the tablet comprises a tablet core and a coating. In some embodiments, the photostabilizing agent is blended into the tablet or the tablet core. In other embodiments, the tablet core comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and the pharmaceutically acceptable excipient, and the coating comprises the photostabilizing agent.

[0010a] In an aspect, there is provided a tablet comprising a tablet core and a coating, wherein the tablet core comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and at least one pharmaceutically acceptable excipient, and the coating comprises at least one photostabilizing agent, wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, Allura Red AC aluminum lake, iron oxide red, iron oxide yellow, Sunset Yellow FCF, Sunset Yellow FCF aluminum lake, Indigotine, and Indigotine aluminum lake, or any combination thereof.

[0011] In one embodiment, the coating is present in the tablet in an amount that is from about 3% to about 8% w/w based on the weight of the tablet core. In another embodiment, the tablet core comprises from about 22% to about 28% w/w [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid (based on the weight of the tablet core). In yet another embodiment, the pharmaceutically acceptable excipient comprises lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate.

[0011a] In another aspect, there is provided a tablet comprising a tablet core and a coating, wherein the tablet core comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and a pharmaceutically acceptable excipient, and the coating comprises a photostabilizing agent, wherein the coating is present in an amount from 3%± 3%x10% to 8%± 8%x10% w/w (based on the weight of the tablet core), wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, Allura Red AC aluminum lake, iron oxide red, iron oxide yellow, Sunset Yellow FCF, Sunset Yellow FCF aluminum lake, Indigotine, and Indigotine aluminum lake, or any combination thereof.

[0012] In one embodiment, the coating comprises from about 0.1% to about 50% w/w photostabilizing agent (based on coating weight). In some embodiments, the photostabilizing agent

comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, Allura Red AC aluminum lake, iron oxide red, iron oxide yellow, Sunset Yellow FCF, Sunset Yellow FCF aluminum lake, Indigotine, Indigotine aluminum lake, and combinations thereof. In another embodiment, the photostabilizing agent comprises titanium dioxide and Allura Red AC aluminum lake.

[0013] In an embodiment, there is provided a capsule comprising [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, a pharmaceutically acceptable excipient and an effective amount of a photostabilizing agent. In one embodiment, the capsule comprises a capsule fill and a capsule shell. In one embodiment, the capsule fill comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and the pharmaceutically acceptable excipient, and the capsule shell comprises the photostabilizing agent.

[0013] In an aspect, there is provided a capsule comprising a capsule fill and a capsule shell, wherein the capsule fill comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and a pharmaceutically acceptable excipient and the capsule shell comprises a photostabilizing agent, wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, iron oxide red, and iron oxide yellow, or any combination thereof.

[0014] In one embodiment, the capsule fill comprises from about 12% to about 15% w/w [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid (based on the weight of the capsule fill). In another embodiment, the pharmaceutically acceptable excipient comprises lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate.

[0014a] In another aspect, there is provided a capsule comprising a capsule fill and a capsule shell, wherein the capsule fill comprises from 12%± 12%x10% to 15% ± 15%x10% w/w [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid (based on the weight of the capsule fill) and a pharmaceutically acceptable excipient, and wherein the capsule shell comprises a photostabilizing agent, wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, iron oxide red, and iron oxide yellow, or any combination thereof.

[0015] In one embodiment, the capsule shell comprises the photostabilizing agent in an amount of from about 1.8% to about 6% w/w (based on the weight of the capsule shell). In some embodiments, the

photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, iron oxide red, iron oxide yellow, and combinations thereof.

[0016] In a separate embodiment, a method of inhibiting the photodegradation of [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid is provided. The method comprises formulating [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid with an effective amount of a photostabilizing agent. In another embodiment, the photostabilizing agent comprises titanium dioxide and at least one additional dye.

[0017] In yet another embodiment, a method for treating, pretreating, or delaying onset or progression of a condition mediated at least in part by hypoxia inducible factor (HIF) is provided. The method comprises administering to a patient in need thereof, a pharmaceutical formulation, a tablet, or a capsule as described herein.

[0018] In still yet another embodiment, a method for treating, pretreating, or delaying onset or progression of anemia is provided. The method comprises administering to a patient in need thereof, a pharmaceutical formulation, a tablet, or a capsule as described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1 illustrates the HPLC chromatograms of Compound A powders before and after exposure to sunlight. See Example 1 for details.

[0020] FIG. 2A and 2B illustrates the amount of photodegradation product in tablets containing either 20 mg (FIG. 2A) or 100 mg (FIG. 2B) of Compound A upon light exposure. The tablets are coated with a coating formula containing Allura Red AC/Indigotine /titanium dioxide (labeled as Allura Red AC/Indigotine in figures), Allura Red AC/titanium dioxide (labeled as Allura Red AC in figures), or red iron oxide/titanium dioxide (labeled as Red Iron Oxide in figures). See Example 2 for details.

[0021] FIG. 3A and 3B illustrates the amount of photodegradation product in tablets containing either 20 mg (FIG. 3A) or 100 mg (FIG. 3B) of Compound A upon light exposure. The tablets are coated with a variety of pink/peach coating formulas. See Example 2 for details.

[0022] FIG. 4 demonstrates the amount of photodegradation product in capsules covered with gelatin films containing various photostabilizing agents upon light exposure. See Example 3 for details.

DETAILED DESCRIPTION

Definitions

[0023] As used herein, the following terms have the following meanings.

WHAT IS CLAIMED IS:

1. A tablet comprising a tablet core and a coating, wherein the tablet core comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and at least one pharmaceutically acceptable excipient, and the coating comprises at least one photostabilizing agent, wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, Allura Red AC aluminum lake, iron oxide red, iron oxide yellow, Sunset Yellow FCF, Sunset Yellow FCF aluminum lake, Indigotine, and Indigotine aluminum lake, or any combination thereof.

2. The tablet of claim 1, wherein the photostabilizing agent is blended into the tablet or the tablet core.

3. The tablet of claim 1, wherein the photostabilizing agent comprises titanium dioxide and Allura Red AC aluminum lake.

4. The tablet of claim 1, wherein the photostabilizing agent comprises at least 0.1 ± 0.1x10% mg/cm^2 titanium dioxide and at least one additional dye selected from the group consisting of:

at least 0.1 ± 0.1x10% mg/cm^2 Allura Red AC;
at least 0.1 ± 0.1x10% mg/cm^2 Allura Red AC in aluminum lake;
at least 0.004 ± 0.004x10% mg/cm^2 iron oxide red;
at least 0.009 ± 0.009x10% mg/cm^2 iron oxide yellow;
at least 0.01 ± 0.01x10% mg/cm^2 Sunset Yellow FCF; and
at least 0.01 ± 0.01x10% mg/cm^2 Sunset Yellow FCF in aluminum lake;
wherein the amount of photostabilizing agent is based on surface area of the tablet core.

5. The tablet of claim 1, wherein the photostabilizing agent comprises, from 0.1 ± 0.1x10% to 2 ± 2x10% mg/cm^2 titanium dioxide and at least one additional dye selected from the group consisting of:

from 0.1 ± 0.1x10% to 0.4 ± 0.4x10% mg/cm^2 Allura Red AC;
from 0.1 ± 0.1x10% to 0.4 ± 0.4x10% mg/cm^2 Allura Red AC in aluminum lake;
from 0.004 ± 0.004x10% to 0.4 ± 0.4x10% mg/cm^2 iron oxide red;
from 0.009 ± 0.009x10% to 0.2 ± 0.2x10% mg/cm^2 iron oxide yellow;
from 0.01 ± 0.01x10% to 0.03 ± 0.03x10% mg/cm^2 Sunset Yellow FCF; and
from 0.01 ± 0.01x10% to 0.03 ± 0.03x10% mg/cm^2 Sunset Yellow FCF in aluminum lake;
wherein the amount of photostabilizing agent is based on surface area of the tablet core.

6. A tablet comprising a tablet core and a coating, wherein the tablet core comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and a pharmaceutically acceptable excipient, and the coating comprises a photostabilizing agent, wherein the coating is present in an amount from 3% ± 3%x10% to 8% ± 8%x10% w/w (based on the weight of the tablet core), wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, Allura Red AC aluminum lake, iron oxide red, iron oxide yellow, Sunset Yellow FCF, Sunset Yellow FCF aluminum lake, Indigotine, and Indigotine aluminum lake, or any combination thereof.

7. The tablet of claim 6, wherein the tablet core comprises from 22% ± 22%x10% to 28% ± 28%x10% w/w [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid (based on the weight of the tablet core) and a pharmaceutically acceptable excipient.

8. The tablet of claim 7, wherein the pharmaceutically acceptable excipient comprises lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate.

9. The tablet of claim7 or 8, wherein the tablet core comprises from 20 ± 20x10% mg to 200 ± 200x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid.

10. The tablet of claim 9, wherein the tablet core comprises 20 ± 20x10% mg, 50± 50x10% mg or 100 ± 100x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid.

11. The tablet of claim 6, wherein the photostabilizing agent comprises titanium dioxide and Allura Red AC aluminum lake.

12. The tablet of claim 6, wherein the coating comprises from 0.1± 0.1x10% to 0.4 ± 0.4x10% mg/cm^2 titanium dioxide and from 0.1 ± 0.1x10% to 0.4 ± 0.4x10% mg/cm^2 Allura Red AC in aluminum lake wherein the amount of titanium dioxide and Allura Red AC in aluminum lake is based on surface area of the tablet core.

13. The tablet of claim 6, wherein the tablet core comprises 20 ± 20x10% mg, 50 ± 50x10% mg or 100 ± 100x10% mg of [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the photostabilizing agent comprises 0.1 ± 0.1x10% to 0.4 ± 0.4x10% mg/cm^2 titanium dioxide and from 0.1 ± 0.1x10% to 0.4 ± 0.4x10% mg/cm^2 Allura Red AC in aluminum lake wherein the amount of titanium dioxide and Allura Red AC in aluminum lake is based on surface area of the tablet core.

14. A capsule comprising a capsule fill and a capsule shell, wherein the capsule fill comprises [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid and a pharmaceutically acceptable excipient and the capsule shell comprises a photostabilizing agent, wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, iron oxide red, and iron oxide yellow, or any combination thereof.

15. The capsule of claim 14, wherein the photostabilizing agent comprises iron oxide red and titanium dioxide.

16. The capsule of claim 14, wherein the photostabilizing agent comprises Allura Red AC, iron oxide yellow, and titanium dioxide.

17. The capsule of claim 14, wherein the photostabilizing agent comprises iron oxide red, Allura Red AC, iron oxide yellow, and titanium dioxide.

18. The capsule of claim 14, wherein the photostabilizing agent comprises iron oxide red, iron oxide yellow, and titanium dioxide.

19. The capsule of claim 14, wherein the photostabilizing agent comprises iron oxide yellow and titanium dioxide.

20. The capsule of claim 14, wherein the capsule shell comprises from 1.8% ± 1.8%x10% to 6% ± 6%x10% w/w photostabilizing agent (based on the weight of the capsule shell).

21. The capsule of claim 14, wherein the capsule shell comprises from 2% ± 2%x10% to 3.5% ± 3.5%x10% w/w photostabilizing agent (based on the weight of the capsule shell).

22. The capsule of claim 14, wherein the capsule shell is a gelatin shell.

23. A capsule comprising a capsule fill and a capsule shell, wherein the capsule fill comprises from 12% ± 12%x10% to 15% ± 15%x10% w/w [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid (based on the weight of the capsule fill) and a pharmaceutically acceptable excipient, and wherein the capsule shell comprises a photostabilizing agent, wherein the photostabilizing agent comprises titanium dioxide and at least one additional dye selected from the group consisting of Allura Red AC, iron oxide red, and iron oxide yellow, or any combination thereof.

24. The capsule of claim 23, wherein the pharmaceutically acceptable excipient comprises lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate.

25. The capsule of claim 23 or 24, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid.

26. The capsule of claim 23, wherein the capsule shell comprises from 2% ± 2%x10% w/w to 3.5% ± 3.5%x10% w/w photostabilizing agent (based on the weight of the capsule shell).

27. The capsule of claim 23, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, and pharmaceutically acceptable excipients comprising lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the capsule shell is a gelatin shell comprising 2% ± 2%x10% w/w iron oxide red and 0.9% ± 0.9%x10% w/w titanium dioxide (based on the weight of the capsule shell).

28. The capsule of claim 23, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, and pharmaceutically acceptable excipients comprising lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the capsule shell is a gelatin shell comprising 0.3% ± 0.3%x10% w/w Allura Red AC, 1% ± 1%x10% w/w iron oxide yellow, and 1% ± 1%x10% w/w titanium dioxide (based on the weight of the capsule shell).

29. The capsule of claim 23, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, and pharmaceutically acceptable excipients comprising lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the capsule shell is a gelatin shell comprising 0.7% ± 0.7%x10% w/w iron oxide red, 0.3% ± 0.3%x10% w/w Allura Red AC, 1% ± 1%x10% w/w iron oxide yellow, and 1% ± 1%x10% w/w titanium dioxide (based on the weight of the capsule shell).

30. The capsule of claim 23, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, and pharmaceutically acceptable excipients comprising lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the capsule shell is a gelatin shell comprising 1% ± 1%x10% w/w iron oxide red, 1% ± 1%x10% w/w iron oxide yellow, and 1% ± 1%x10% w/w titanium dioxide (based on the weight of the capsule shell).

31. The capsule of claim 23, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, and pharmaceutically acceptable excipients comprising lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the capsule shell is a gelatin shell comprising 1% ± 1%x10% w/w Allura Red AC, 1% ± 1%x10% w/w iron oxide yellow, and 1% ± 1%x10% w/w titanium dioxide (based on the weight of the capsule shell).

32. The capsule of claim 23, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, and pharmaceutically acceptable excipients comprising lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the capsule shell is a gelatin shell comprising 2% ± 2%x10% w/w iron oxide red, and 1% ± 1%x10% w/w titanium dioxide (based on the weight of the capsule shell).

33. The capsule of claim 23, wherein the capsule fill comprises 20 ± 20x10% mg or 50 ± 50x10% mg [(4-hydroxy-1-methyl-7-phenoxy-isoquinoline-3-carbonyl)-amino]-acetic acid, and pharmaceutically

acceptable excipients comprising lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, and magnesium stearate; and wherein the capsule shell is a gelatin shell comprising 2% ± 2%x10% w/w iron oxide yellow, and 1% ± 1%x10% w/w titanium dioxide (based on the weight of the capsule shell).