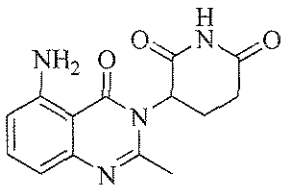
Lafayette). Moreover, multiple-component crystal forms may potentially be susceptible to polymorphism, wherein a given multiple-component composition may exist in more than one three-dimensional crystalline arrangement. The preparation of solid forms is of great importance in the development of a safe, effective, stable and marketable pharmaceutical compound.

[0016] Provided herein are embodiments addressing a need for solid forms of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione ("Compound A"). Compound A was described in U.S. Pat. No. 7,635,700, the disclosure of which is incorporated herein by reference in its entirety.

3. SUMMARY

[0017] This disclosure relates to methods of treating diseases and disorders utilizing a solid form of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione or a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

[0018] Provided herein are solid forms of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione or a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof. In one embodiment, the solid form is crystalline Form A. In another embodiment, the solid form is crystalline Form B. In yet another embodiment, the solid form is crystalline Form C. In yet another embodiment, the solid form is Form D. In yet another embodiment, the solid form is crystalline Form E. In yet another embodiment, the solid form is crystalline Form F. In yet another embodiment, the solid form is a solid form of a hydrochloride salt of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione. In one aspect, there is provided a solid form comprising a hydrochloride salt of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione:



having an X-ray powder diffraction pattern comprising: peaks at approximately 8.6 °2θ, 13.1 °2θ, 20.5 °2θ and 26.3 °2θ. In still another embodiment, the solid form is crystalline

Form A1.

[0019] Further provided herein are pharmaceutical compositions, single unit dosage forms, dosing regimens, and kits, which comprise a solid form of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione or a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof; and a pharmaceutically acceptable carrier.

[0019a] In another aspect, there is provided a pharmaceutical composition comprising the solid form as defined herein and a pharmaceutical acceptable carrier, diluent or excipient.

[0020] Additionally provided herein are methods of treating and managing various diseases or disorders, which comprise administering to a patient a therapeutically effective amount of a solid form of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-

piperidine-2,6-dione or a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

[0021] Also provided herein are methods of preventing various diseases and disorders, which comprise administering to a patient a prophylactically effective amount of a solid form of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione or a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

[0021a] In another aspect, there is provided the use of a solid form as defined herein, or a composition as defined herein in the manufacture of a medicament for treating a disease or disorder, wherein the disease or disorder is selected from the group consisting of cancer, a disorder associated with angiogenesis, pain, macular degeneration or a related syndrome, a skin disease, a pulmonary disorder, an asbestos-related disorder, a parasitic disease, an immunodeficiency disorder, a CNS disorder, CNS injury, atherosclerosis or a related disorder, dysfunctional sleep or a related disorder, hemoglobinopathy or a related disorder, and a TNFα related disorder.

[0022] In certain embodiments, the solid forms are single-component crystal forms of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione. In certain embodiments, the solid forms are multiple-component crystal forms of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, including, but not limited to, salts, co-crystals and/or solvates (including hydrates) comprising 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione. In certain embodiments, the solid forms are single-component amorphous forms of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione. In certain embodiments, the solid forms are multiple-component amorphous forms of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione. Without intending to be limited by any particular theory, certain solid forms provided herein have particular advantageous physical and/or chemical properties making them useful, *e.g.*, for manufacturing, processing, formulation and/or storage, while also possessing particularly advantageous biological properties, such as, *e.g.*, bioavailability and/or biological activity.

[0023] In certain embodiments, solid forms provided herein include solid forms comprising 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, including, but not limited to, single-component and multiple-component solid forms comprising 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione. In certain embodiments, solid forms provided herein include salts, polymorphs, solvates (including hydrates), and co-crystals comprising 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione. Certain embodiments herein provide methods of making, isolating and/or characterizing the solid forms provided herein.

[0024] The solid forms provided herein are useful as active pharmaceutical ingredients for the preparation of formulations for use in patients. Thus, embodiments herein encompass the use of these solid forms as a final drug product. Certain embodiments provide solid forms useful in making final dosage forms with improved properties, *e.g.*, powder flow properties, compaction properties, tableting properties,