[0031] The ability to adjust biological production of energy has applications beyond the diseases described above. Various other disorders can result in suboptimal levels of energy biomarkers (sometimes also referred to as indicators of energetic function), such as ATP levels. Treatments for these disorders are also needed, in order to modulate one or more energy biomarkers to improve the health of the patient. In other applications, it can be desirable to modulate certain energy biomarkers away from their normal values in an individual that is not suffering from disease. For example, if an individual is undergoing an extremely strenuous undertaking, it can be desirable to raise the level of ATP in that individual.

[0032] Certain polymorphic or amorphous forms of a drug can have advantageous characteristics versus other forms; for example, increased stability, increased solubility, better handling properties, lack of associated toxic solvents, and increased purity.

[0033] Example 16 of PCT Application No. PCT/US2008/082374, published as WO 2009/061744 on May 14, 2009, describes a synthesis for racemic 2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide; this Example does not specifically describe the synthesis of any particular polymorphic or amorphous form for (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide or any particular stereoisomer thereof.

SUMMARY

[0034] In one aspect, the present disclosure refers to a polymorph of an anhydrate or a hydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the polymorph is selected from the group consisting of Form I, Form III and Form II; wherein a powder X-ray diffraction pattern for polymorph Form I comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 12.06, 17.03, and 17.26; wherein a powder X-ray diffraction pattern for polymorph Form III comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 14.02, 15.23, and 21.10; wherein a powder X-ray diffraction pattern for polymorph Form II comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.63, 11.33, and 19.33; and wherein the XRPD pattern is generated at 25 °C. In one example, there is disclosed a polymorph of an anhydrate, a hydrate, or a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the polymorph is selected from the group consisting of Forms I-VI as described in Table A or Tables 2-7 respectively. In another aspect, the present disclosure refers to a composition comprising the polymorph as disclosed herein, wherein at least about 95% by mole of the composition is the

polymorph Form I, exclusive of any solvents, carriers or excipients. In yet another aspect, the present disclosure refers to a pharmaceutical composition comprising the polymorph as disclosed herein, or the composition as disclosed herein, and a pharmaceutically acceptable carrier. In another aspect, the present disclosure refers to a composition comprising the polymorph as disclosed herein, wherein the composition is essentially free of Forms II-VI, wherein a powder X-ray diffraction pattern for polymorph Form V comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.61, 11.49, and 15.45; wherein a powder X-ray diffraction pattern for polymorph Form III comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 14.02, 15.23, and 21.10; wherein a powder X-ray diffraction pattern for polymorph Form II comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.63, 11.33, and 19.33; wherein a powder X-ray diffraction pattern for polymorph Form IV comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 4.31, 12.97, and 13.20; and wherein a powder X-ray diffraction pattern for polymorph Form VI comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 6.27, 9.91, and 12.94; and wherein the XRPD pattern is generated at 25 °C. In a further aspect, the present disclosure refers to a composition comprising the polymorph as disclosed herein, wherein at least about 95% by mole of the composition is the

[0044] In another examples, there is described a method of treating or suppressing an oxidative stress disorder, modulating one or more energy biomarkers, normalizing one or more energy biomarkers, or enhancing one or more energy biomarkers, comprising administering to an individual in need thereof a therapeutically effective amount or effective amount of a polymorphic or amorphous form of an anhydrate, a hydrate, or a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, or composition comprising such form, as described herein, including any of the foregoing or hereafter examples. The method can use any individual polymorphic or amorphous form as described herein, or a combination of such. In some examples, the form is polymorph Form I. In some examples, the form is polymorph Form II. In some examples, the form is polymorph Form III. In some examples, the form is polymorph Form IV. In some examples, the form is polymorph Form V. In some examples, the form is polymorph Form VI. In some examples, the form is amorphous. In some examples, including any of the foregoing examples, the anhydrate, hydrate, or solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide is administered in a pharmaceutical composition comprising the polymorphic or amorphous form and a pharmaceutically acceptable carrier. In some examples, including any of the foregoing examples, the pharmaceutical composition comprises an active agent consisting essentially of the polymorphic or amorphous form of the anhydrate, hydrate, or solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide. In one aspect, the present disclosure refers to use of the polymorph as disclosed herein, the composition as disclosed herein, or the pharmaceutical composition as disclosed herein in the manufacture of a medicament for treating or suppressing an oxidative stress disorder. In some examples, including any of the foregoing examples, the method is a method of treating or suppressing an oxidative stress disorder. In some examples, including any of the foregoing examples, the method is a method of treating an oxidative stress disorder. In some examples, including any of the foregoing examples, the method is a method of suppressing an oxidative stress disorder. In some examples, including any of the foregoing examples, the oxidative stress disorder is selected from the group consisting of: a mitochondrial disorder; an inherited mitochondrial disease; Alpers Disease; Barth syndrome; a Beta-oxidation Defect; Carnitine-Acyl-Carnitine Deficiency; Carnitine Deficiency; a Creatine Deficiency Syndrome; Co-Enzyme Q10 Deficiency; Complex I Deficiency; Complex II Deficiency; Complex III

[0045] In another example, there is described the use of a polymorphic or amorphous form of an anhydrate, a hydrate, or a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide as described herein, including any of the foregoing or hereafter described examples, for treating or suppressing an oxidative stress disorder. In some examples, the form is polymorph Form I. In some examples, the form is polymorph Form II. In some examples, the form is polymorph Form III. In some examples, the form is polymorph Form IV. In some examples, the form is polymorph Form V. In some examples, the form is polymorph Form VI. In some examples, the form is amorphous. In another example, there is described the use of a polymorphic or amorphous form of an anhydrate, a hydrate, or a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide as described herein, including any of the foregoing or hereafter described examples, in the manufacture of a medicament for use in treating or suppressing an oxidative stress disorder. In some examples, the form is polymorph Form I. In some examples, the form is polymorph Form II. In some examples, the form is polymorph Form III. In some examples, the form is polymorph Form IV. In some examples, the form is polymorph Form V. In some examples, the form is polymorph Form VI. In some examples, the form is amorphous.

[0046] For all compositions described herein, and all methods using a composition described herein, the compositions can either comprise the listed components or steps, or can "consist essentially of" the listed components or steps. When a composition is described as "consisting essentially of" the listed components, the composition contains the components listed, and may contain other components which do not substantially affect the condition being treated, but do not contain any other components which substantially affect the condition being treated other than those components expressly listed; or, if the composition does contain extra components other than those listed which substantially affect the condition being treated, the composition does not contain a sufficient concentration or amount of the extra components to substantially affect the condition being treated. When a method is described as "consisting essentially of" the listed steps, the method contains the steps listed, and may contain other steps that do not substantially affect the condition being treated, but the method does not contain any other steps which substantially affect the condition being treated other than those steps expressly listed. As a non-limiting specific example, when a composition is described as 'consisting essentially of' a component, the composition may additionally contain any amount of pharmaceutically acceptable carriers, vehicles, or diluents and other such components which do not substantially affect the condition being treated.

[0047] The present disclosure refers to a process for the preparation of a polymorph of anhydrous (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the process comprises the steps: (a) contacting (R)-2-hydroxy-2-methyl-

4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide with a liquid comprising IPA; and (b) removing the liquid. In another example, there is described a process for the preparation of polymorph Form I of an anhydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the process comprises the steps: (a) contacting (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide with a liquid comprising IPA; and (b) removing the liquid. In some examples, step (a) comprises dissolving the (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide in the liquid. In some examples, step (a) comprises slurrying the (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide in the liquid. In some examples, the slurrying in step (a) may be performed for at least about 24 hours. In some examples, including any of the foregoing examples, the liquid is 100% IPA In some examples, including any of the foregoing examples, the liquid is 98% IPA/2% water (v/v). In some examples, including any of the foregoing examples, the process further comprises step (a)(i): adding heptane to the liquid. In some examples, including any of the foregoing embodiments, step (b) comprises filtering the (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide. In some examples, including any of the foregoing examples, the mixture in step (a) or step (a)(i) may be seeded with Form I crystals. In some examples, including any of the foregoing examples, the (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide in step (a) is at least about 95% pure. In various examples, including any of the foregoing examples, the (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide in step (a) is at least about 96%, at least about 97%, at least about 98%, at least about 99%, at least about 99.5%, at least about 99.9% pure. In another example, there is described an anhydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide prepared by the above described process.

In another example, there is described a process for the preparation of polymorph Form II of an anhydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the process comprises the steps: (a) dissolving the (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide in EtOAc, (b) rapidly cooling the mixture from (a), and (c) isolating the (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide. In some examples, the initial (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide is Form I. In some examples, including any of the foregoing examples, step (a) is at about 60°C. In some examples, including any of the foregoing examples, step (b) comprises rapidly cooling the mixture in an ice bath. In some examples, including any of the foregoing examples, the mixture in step (b) may be seeded with Form II

crystals. In another example, there is described an anhydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide prepared by the above described process.

[0048] In another example, there is described a process for the preparation of polymorph Form III of a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the process comprises the steps: (a) combining (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide and 0.5% MC/2%Tween 80 in water to create a slurry; (b) slurrying the mixture from (a), and (c) removing the 0.5% MC/2%Tween 80 in water. As used herein "MC" refers to methyl cellulose and "Tween 80" refers to a commercially available polysorbate nonionic surfactant In some examples, the initial (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide is Form I. In some examples, including any of the foregoing examples, step (b) is performed for at least about 24 hours. In some examples, including any of the foregoing examples, step (b) is at room temperature. In some examples, including any of the foregoing examples, the mixture in step (b) may be seeded with Form III crystals. In another example, there is described a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide prepared by the above described process.

[0049] In another example, there is described a process for the preparation of polymorph Form III of a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the process comprises the steps: (a) combining (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide and 0.5% MC in water to create a slurry; (b) slurrying the mixture from (a), and (c) removing the 0.5% MC in water. In some examples, the initial (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide is Form I, II, IV, V or VI. In some examples, including any of the foregoing examples, step (b) is performed at room temperature. In some examples, including any of the foregoing examples, step (b) may be performed for at least about 7 days. In some examples, including any of the foregoing examples, the mixture in step (b) may be seeded with Form III crystals. In another example, there is described a solvate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide prepared by the above described process.

The present disclosure refers to a polymorph produced by the process comprising the steps: (a) contacting (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide with a liquid comprising IPA; and (b) removing the liquid.

BRIEF DESCRIPTION OF THE FIGURES

[0050] Figure 1 shows a XRPD stack plot of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide short term slurry experiments, a) Pattern C, from slurry in 0.5% Methyl Cellulose/2% Tween 80, b) Pattern B, from slurry in tetrahydrofuran (THF), and c) starting material, Pattern A.

CLAIMS

What is claimed is:

1. A polymorph of an anhydrate or a hydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, wherein the polymorph is selected from the group consisting of Form I, Form III and Form II; wherein a powder X-ray diffraction pattern for polymorph Form I comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 12.06, 17.03, and 17.26; wherein a powder X-ray diffraction pattern for polymorph Form III comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 14.02, 15.23, and 21.10; wherein a powder X-ray diffraction pattern for polymorph Form II comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.63, 11.33, and 19.33; and wherein the XRPD pattern is generated at 25 °C.

2. The polymorph of claim 1, wherein the polymorph is Form I, wherein a powder X-ray diffraction pattern for the polymorph comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 12.06, 17.03, and 17.26.

3. The polymorph of claim 1, wherein the polymorph is Form I, wherein a powder X-ray diffraction pattern for the polymorph comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 12.06, 15.33, 17.03, 17.26, and 18.72.

4. The polymorph of claim 1, wherein the polymorph is Form I, wherein the polymorph has a powder x-ray diffraction pattern substantially as shown in Figure 10.

5. A composition comprising the polymorph of any one of claims 2-4, wherein the composition is essentially free of Forms II-VI, wherein a powder X-ray diffraction pattern for polymorph Form V comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.61, 11.49, and 15.45; wherein a powder X-ray diffraction pattern for polymorph Form III comprises characteristic peaks at least at the

following angular positions, wherein the angular positions may vary by ± 0.2: 14.02, 15.23, and 21.10; wherein a powder X-ray diffraction pattern for polymorph Form II comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.63, 11.33, and 19.33; wherein a powder X-ray diffraction pattern for polymorph Form IV comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 4.31, 12.97, and 13.20; and wherein a powder X-ray diffraction pattern for polymorph Form VI comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 6.27, 9.91, and 12.94; and wherein the XRPD pattern is generated at 25 °C.

6. A composition comprising the polymorph of any one of claims 2-4, wherein at least about 95% by mole of the composition is the polymorph Form I, exclusive of any solvents, carriers or excipients.

7. A pharmaceutical composition comprising the polymorph of any one of claims 2 to 4, or the composition of any one of claims 5-6, and a pharmaceutically acceptable carrier.

8. The pharmaceutical composition of claim 7, wherein the pharmaceutical composition has an HPLC purity of more than about 95% for the anhydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, exclusive of any solvents, carriers or excipients.

9. The pharmaceutical composition of claim 7, wherein the pharmaceutical composition has an HPLC purity of more than about 99% for the anhydrate of (R)-2-hydroxy-2-methyl-4-(2,4,5-trimethyl-3,6-dioxocyclohexa-1,4-dienyl)butanamide, exclusive of any solvents, carriers or excipients.

10. Use of the polymorph of any one of claims 2-4, the composition of any one of claims 5-6, or the pharmaceutical composition of any one of claims 7-9 in the manufacture of a medicament for treating or suppressing an oxidative stress disorder.

11. The use of claim 10, wherein the medicament is for treating or suppressing an oxidative stress disorder selected from the group consisting of: a mitochondrial disorder; an inherited mitochondrial disease; Alpers Disease; Barth syndrome; a Beta-oxidation Defect; Carnitine-Acyl-Carnitine Deficiency; Carnitine Deficiency; a Creatine Deficiency Syndrome; Co-Enzyme Q10 Deficiency; Complex I Deficiency; Complex II Deficiency; Complex III Deficiency; Complex IV Deficiency; Complex V Deficiency; COX Deficiency; chronic progressive external ophthalmoplegia (CPEO); CPT I Deficiency; CPT II Deficiency; Friedreich's Ataxia (FA); Glutaric Aciduria Type II; Kearns-Sayre Syndrome (KSS); Lactic Acidosis; Long-Chain Acyl-CoA Dehydrogenase Deficiency (LCAD); LCHAD; Leigh Syndrome; Leigh-like Syndrome; Leber's Hereditary Optic Neuropathy (LHON); Lethal Infantile Cardiomyopathy (LIC); Luft Disease; Multiple Acyl-CoA Dehydrogenase Deficiency (MAD); Medium-Chain Acyl-CoA Dehydrogenase Deficiency (MCAD); Mitochondrial Myopathy, Encephalopathy, Lactacidosis, Stroke (MELAS); Myoclonic Epilepsy with Ragged Red Fibers (MERRF); Mitochondrial Recessive Ataxia Syndrome (MIRAS); Mitochondrial Cytopathy, Mitochondrial DNA Depletion; Mitochondrial Encephalopathy; Mitochondrial Myopathy; Myoneurogastrointestinal Disorder and Encephalopathy (MNGIE); Neuropathy, Ataxia, and Retinitis Pigmentosa (NARP); Pearson Syndrome; Pyruvate Carboxylase Deficiency; Pyruvate Dehydrogenase Deficiency; a POLG Mutation; a Respiratory Chain Disorder; Short-Chain Acyl-CoA Dehydrogenase Deficiency (SCAD); SCHAD; Very Long-Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD); a myopathy; cardiomyopathy; encephalomyopathy; a neurodegenerative disease; Parkinson's disease; Alzheimer's disease; amyotrophic lateral sclerosis (ALS); a motor neuron disease; a neurological disease; epilepsy; an age-associated disease; macular degeneration; diabetes; metabolic syndrome; cancer; brain cancer; a genetic disease; Huntington's Disease; a mood disorder; schizophrenia; bipolar disorder; a pervasive developmental disorder; autistic disorder; Asperger's syndrome; childhood disintegrative disorder (CDD); Rett's disorder; PDD-not otherwise specified (PDD-NOS); a cerebrovascular accident; stroke; a vision impairment; optic neuropathy; dominant inherited juvenile optic atrophy; optic neuropathy caused by a toxic agent; glaucoma; Stargardt's macular dystrophy; diabetic retinopathy; diabetic maculopathy; retinopathy of prematurity; ischemic reperfusion-related retinal injury; oxygen poisoning; a haemoglobinopathy; thalassemia; sickle cell anemia; seizures; ischemia; renal tubular acidosis; attention deficit/hyperactivity disorder (ADHD); a neurodegenerative disorder resulting in hearing or balance impairment; Dominant

Optic Atrophy (DOA); Maternally inherited diabetes and deafness (MIDD); chronic fatigue; contrast-induced kidney damage; contrast-induced retinopathy damage; Abetalipoproteinemia; retinitis pigmentosum; Wolfram's disease; Tourette syndrome; cobalamin c defect; methylmalonic aciduria; glioblastoma; Down's syndrome; acute tubular necrosis; a muscular dystrophy; a leukodystrophy; Progressive Supranuclear Palsy; spinal muscular atrophy; hearing loss; noise induced hearing loss; traumatic brain injury; Juvenile Huntington's Disease; Multiple Sclerosis; NGLY1; Multiple System Atrophy; Adrenoleukodystrophy; and Adrenomyeloneuropathy.

12. The use of claim 11, wherein the oxidative stress disorder is amyotrophic lateral sclerosis (ALS).

13. The use of claim 11, wherein the oxidative stress disorder is Parkinson's disease.

14. The polymorph of claim 1, wherein the polymorph is Form I, having a differential scanning calorimetry (DSC) thermogram substantially as shown in Figure 12.

15. The polymorph of claim 14, wherein the DSC thermogram has a single endothermic peak at about 152.9 °C.

16. The polymorph of claim 1, wherein the polymorph is Form I, having a thermogravimetric analysis (TGA) thermogram substantially as shown in Figure 13.

17. The polymorph of claim 1, wherein the polymorph is Form I, having a ^{1}H NMR spectrum substantially as shown in Figure 40.

18. A composition comprising the polymorph of any one of claims 14-17, wherein the composition is essentially free of Forms II-VI wherein a powder X-ray diffraction pattern for polymorph Form V comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.61, 11.49, and 15.45; wherein a powder X-ray diffraction pattern for polymorph Form III comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 14.02, 15.23, and 21.10; wherein a powder X-ray diffraction pattern for polymorph Form II comprises

characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 9.63, 11.33, and 19.33; wherein a powder X-ray diffraction pattern for polymorph Form IV comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 4.31, 12.97, and 13.20; and wherein a powder X-ray diffraction pattern for polymorph Form VI comprises characteristic peaks at least at the following angular positions, wherein the angular positions may vary by ± 0.2: 6.27, 9.91, and 12.94; and wherein the XRPD pattern is generated at 25 °C.

19. A composition comprising the polymorph of any one of claims 14-17, wherein at least about 95% by mole of the composition is the polymorph Form I, exclusive of any solvents, carriers or excipients.

20. The polymorph of claim 1, wherein the DSC thermogram has a single endothermic peak.

21. The use of claim 11, wherein the oxidative stress disorder is Huntington's Disease.