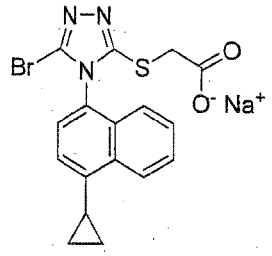
WHAT IS CLAIMED IS:

1. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



a) characterized by peaks at 4.90, 9.83, and 25.29 °2θ±0.1°2θ;

b) characterized by peaks at 4.90, 9.83, and 25.29 °2θ±0.1°2θ, further characterized by at least two further peaks at 6.86, 8.41, 10.13, 17.92, and 23.10 °2θ±0.1°2θ;

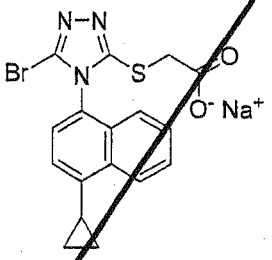
c) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 1;

d) characterized by an endothermic point onset, as determined by differential scanning calorimetry at about 62°C;

e) characterized by a differential scanning calorimetry pattern substantially the same as the differential scanning calorimetry pattern shown in FIGURE 2; or

f) characterized as crystalline polymorph Form A of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate..

2. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



a) characterized by peaks at 4.22, 8.51, and 16.95 °2θ±0.1°2θ;

b) characterized by peaks at 4.22, 8.51, and 16.95 °2θ±0.1°2θ, and further characterized by a peak at 12.80 °2θ±0.1°2θ;

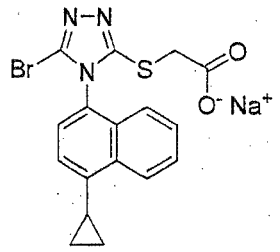
c) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 5;

d) characterized by an endothermic point onset, as determined by differential scanning calorimetry at about 173°C;

e) characterized by a differential scanning calorimetry pattern substantially the same as the differential scanning calorimetry pattern shown in FIGURE 6; or

f) characterized as crystalline polymorph Form B of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate.

3. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:

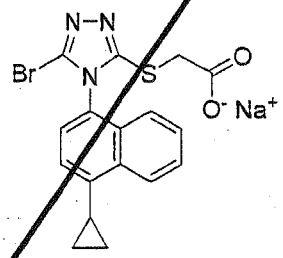


a) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 7;

b) characterized by a differential scanning calorimetry pattern substantially the same as the differential scanning calorimetry pattern shown in FIGURE 8; or

c) characterized as crystalline polymorph Form B' of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate.

4. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



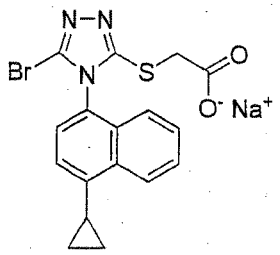
a) characterized by peaks at 6.9, 10.1 and 22.6 °2θ±0.1°2θ;

b) characterized by peaks at 6.9, 10.1 and 22.6 °2θ±0.1°2θ, and further characterized by at least two further peaks at 23.3, 23.9, 25.2, 28.3 or 29.0 °2θ±0.1°2θ;

c) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 9; or

d) characterized as crystalline polymorph Form C of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate.

5. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:

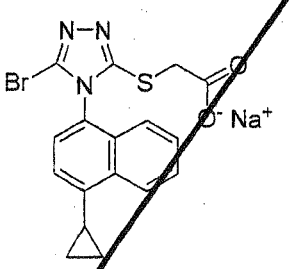


a) characterized by peaks at 10.3, 17.8 and 25.2 °2θ±0.1°2θ;

b) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 10; or

c) characterized as crystalline polymorph Form D of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate.

6. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:

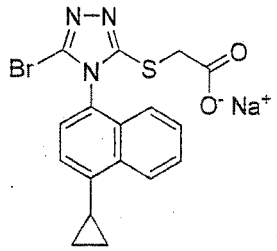


a) characterized by at least three peaks at 10.5, 22.9, 23.2 or 24.6 °2θ±0.1°2θ;

b) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 11; or

c) characterized as crystalline polymorph Form E of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate.

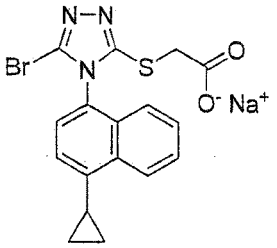
7. A solid mesophase form of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



a) exhibiting an x-ray powder diffraction substantially the same as the x-ray powder diffraction pattern shown in FIGURE 12; or

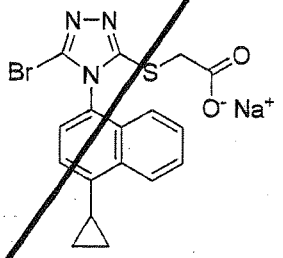
b) exhibiting a differential scanning calorimetry pattern substantially the same as the differential scanning calorimetry pattern shown in FIGURE 13.

8. A solid mesophase form of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 14.

9. A solid mesophase form of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate selected from:



a mesophase exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 15.

10. A solid pharmaceutical composition comprising:
an effective amount of the crystalline polymorph of claim 1 as an active ingredient; and
at least one excipient or carrier.

11. A solid pharmaceutical composition comprising an effective amount of at least two forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate selected from the group consisting of:
the crystalline polymorph of claim 1 as an active ingredient;
the crystalline polymorph of claim 2 as an active ingredient;
the crystalline polymorph of claim 3 as an active ingredient;
the crystalline form of claim 4 as an active ingredient;
the crystalline form of claim 5 as an active ingredient;
the crystalline form of claim 6 as an active ingredient;
the solid mesophase of claim 7 as an active ingredient;
the solid mesophase of claim 8 as an active ingredient; and
the solid mesophase of claim 9 as an active ingredient;
and at least one excipient or carrier.

12. Use of the crystalline polymorph of claim 1 in the manufacture of a medicament for treating or preventing hyperuricemia, or a disease caused by elevated uric acid levels.

13. Use of at least two forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate in the manufacture of a medicament for treating or preventing hyperuricemia or a disease caused by elevated uric acid levels, wherein the at least two forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate are selected from the group consisting of:
the crystalline polymorph of claim 1 as an active ingredient;
the crystalline polymorph of claim 2 as an active ingredient;
the crystalline polymorph of claim 3 as an active ingredient;
the crystalline form of claim 4 as an active ingredient;
the crystalline form of claim 5 as an active ingredient;
the crystalline form of claim 6 as an active ingredient;
the solid mesophase of claim 7 as an active ingredient;

the solid mesophase of claim 8 as an active ingredient; and

the solid mesophase of claim 9 as an active ingredient.

14. Use of the crystalline polymorph of claim 1 in the manufacture of a medicament for treating or preventing gout.

15. Use of at least two forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate in the manufacture of a medicament for treating or preventing gout, wherein the at least two forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate are selected from the group consisting of:

the crystalline polymorph of claim 1 as an active ingredient;

the crystalline polymorph of claim 2 as an active ingredient;

the crystalline polymorph of claim 3 as an active ingredient;

the crystalline form of claim 4 as an active ingredient;

the crystalline form of claim 5 as an active ingredient;

the crystalline form of claim 6 as an active ingredient;

the solid mesophase of claim 7 as an active ingredient;

the solid mesophase of claim 8 as an active ingredient; and

the solid mesophase of claim 9 as an active ingredient.

16. A method for preparing a crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-trizaol-3-ylthio)acetate, comprising:

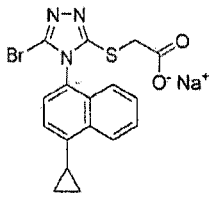
a) contacting amorphous sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-trizaol-3-ylthio)acetate with water and an aprotic solvent; and

b) isolating the solids from the mixture prepared in step a).

17. The method of claim 16, wherein the aprotic solvent is ethyl acetate.

CLAIMS

1. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



a) characterized by peaks at 4.90, 9.83, and 25.29 °2θ±0.1°2θ;

b) characterized by peaks at 4.90, 9.83, and 25.29 °2θ±0.1°2θ, further characterized by at least two further peaks at 6.86, 8.41,10.13,17.92, and 23.10 °2θ±0.1°2θ;

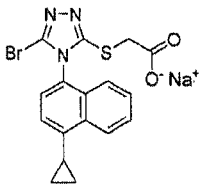
c) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 1;

d) characterized by an endothermic point onset, as determined by differential scanning calorimetry at about 62°C;

e) characterized by a differential scanning calorimetry pattern substantially the same as the differential scanning calorimetry pattern shown in FIGURE 2; or

f) characterized as crystalline polymorph Form A of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-l-yl)-4*H*-l,2,4-triazol-3-ylthio)acetate.

2. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



a) characterized by peaks at 4.22, 8.51, and 16.95 °2θ±0.1°2θ;

b) characterized by peaks at 4.22, 8.51, and 16.95 °2θ±0.1 °2θ, and further characterized by a peak at 12.80 °2θ±0.1°2θ;

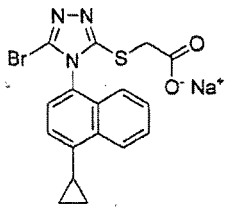
c) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 5;

d) characterized by an endothermic point onset, as determined by differential scanning calorimetry at about 173°C;

e) characterized by a differential scanning calorimetry pattern substantially the same as the differential calorimetry pattern shown in FIGURE 6; or

f) characterized as crystalline polymorph Form B of sodium 2-(5-bromo-4(-4-cyclopropylnapthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate.

3. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnapthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:

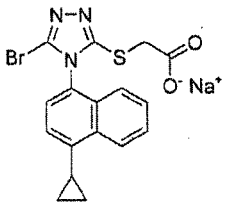


a) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 7;

b) characterized by a differential scanning calorimetry pattern substantially the same as the differential scanning calorimetry pattern shown in FIGURE 8; or

c) characterized as crystalline polymorph Form B' of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1 ,2,4-triazol-3-ylthio)acetate.

4. A crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-l-yl)-4*H*-1,2,44riazol-3-ylthio)acetate:



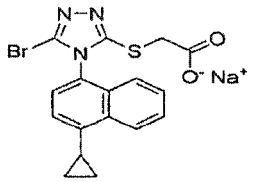
a) characterized by peaks at 6.9, 10.1, and 22.6 °2θ±0.1°2θ;

b) characterized by peaks at 6.9, 10.1, and 22.6 °2θ±0.1°2θ;, and further characterized by at least two further peaks at 23.3, 23.9, 25.2, 28.3 or 29.0 °2θ±0.1°2θ;

c) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 9; or

d) characterized polymorph of sodium2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate.

5. A crystalline polymorph of sodium 2-5-bromo-4-(4-cycloproplynaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:

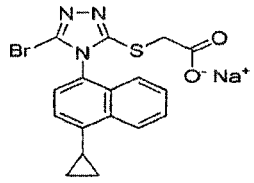


a) characterized by peaks at 10.3,17.8 and 25.2 °2θ±0.1°2θ;

b) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 10; or

c) characterized as crystalline polymorph Form D of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-l-yl)-4*H*-l,2$_s$4-triazol-3-ylthio)acetate.

6. A crystalline polymorph of sodium 2-5-bromo-4-(4-cycloproplynaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:

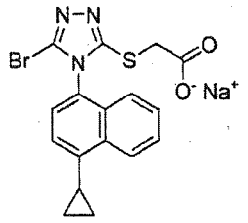


a) characterized by at least three peaks at 10.5,22.9.8, 23.2 or 24.6 °2θ±0.1°2θ;

b) exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 11; or

c) characterized as crystalline polymorph Form E of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl-4*H*-1,2,4-triazol-3-ylthio)acetate.

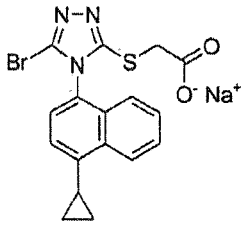
7. A solid mesophase form of sodium 2-5-bromo-4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



a) exhibiting an x-ray powder diffraction substantially the same as the x-ray powder diffraction pattern shown in FIGURE 12; or

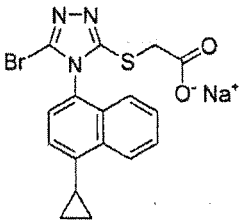
b) exhibiting a differential scanning calorimetry pattern substantially the same as the differential scanning calorimetry pattern shown in FIGURE 13.

8. A solid mesophase form of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate:



exhibiting an x-ray powder diffraction substantially the same as the x-ray powder diffraction pattern shown in FIGURE 14; or

9. A solid mesophase form of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate selected from:



a mesophase exhibiting an x-ray powder diffraction pattern substantially the same as the x-ray powder diffraction pattern shown in FIGURE 15.

10. A solid pharmaceutical composition comprising:
an effective amount of the crystalline polymorph of claim 1 as an active ingredient; and
at least one excipient or carrier.

11. A solid pharmaceutical composition comprising an effective amount of at least two of the forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate selected from the group consisting of:

the crystalline polymorph of claim 1 as an active ingredient;
the crystalline polymorph of claim 2 as an active ingredient;
the crystalline polymorph of claim 3 as an active ingredient;
the crystalline form of claim 4 as an active ingredient;
the crystalline form of claim 5 as an active ingredient;
the crystalline form of claim 6 as an active ingredient;
the solid mesophase of claim 7 as an active ingredient;
the solid mesophase of claim 8 as an active ingredient; and
the solid mesophase of claim 9 as an active ingredient;

and at least one excipient or carrier.

12. Use of an effective amount of the crystalline polymorph of claim 1, in the manufacture of a medicament for treating or preventing hyperuricemia, or a disease caused by elevated uric acid levels.

13. Use of an effective amount of at least two of the forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate selected from the group consisting of:

the crystalline polymorph of claim 1 as an active ingredient;
the crystalline polymorph of claim 2 as an active ingredient;
the crystalline polymorph of claim 3 as an active ingredient;
the crystalline form of claim 4 as an active ingredient;
the crystalline form of claim 5 as an active ingredient;
the crystalline form of claim 6 as an active ingredient;
the solid mesophase of claim 7 as an active ingredient;
the solid mesophase of claim 8 as an active ingredient; and
the solid mesophase of claim 9 as an active ingredient;

and at least one excipient or carrier, in the manufacture of a medicament for treating or preventing hyperuricemia, or a disease caused by elevated uric acid levels.

14. Use of an effective amount of the crystalline polymorph of claim 1, in the manufacture of a medicament for treating or preventing gout.

15. Use of an effective amount of at least two of the forms of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-l-yl)-4*H*-l,2,4-triazol-3-ylthio)acetate selected from the group consisting of:

the crystalline polymorph of claim 1 as an active ingredient;
the crystalline polymorph of claim 2 as an active ingredient;
the crystalline polymorph of claim 3 as an active ingredient;
the crystalline form of claim 4 as an active ingredient;
the crystalline form of claim 5 as an active ingredient;
the crystalline form of claim 6 as an active ingredient;
the solid mesophase of claim 7 as an active ingredient;
the solid mesophase of claim 8 as an active ingredient; and
the solid mesophase of claim 9 as an active ingredient;

and at least one excipient or carrier , in the manufacture of a medicament for treating or preventing gout.

16. A method for preparing a crystalline polymorph of sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-l-yl)-4*H*-l,2,4-triazol-3-ylthio)acetate comprising:

a) contacting amorphous sodium 2-(5-bromo-4-(4-cyclopropylnaphthalen-1-yl)-4*H*-1,2,4-triazol-3-ylthio)acetate with water and an aprotic solvent; and

b) isolating the solids from the mixture prepared in a step a).

17. The method of claim 16, wherein the aprotic solvent is ethyl acetate.