CLAIMS

1. A pharmaceutical formulation comprising Polymorph E of *N*-(3-{[(2*Z*)-3-[(2-chloro-5-methoxyphenyl)amino]quinoxalin-2(1*H*)-ylidene]sulfamoyl}phenyl)-2-methylalaninamide, a hydrogel polymer and a diluent.

2. The pharmaceutical formulation of claim 1, wherein the hydrogel is selected from the group consisting of microcrystalline cellulose, methyl cellulose, hydroxymethyl cellulose, polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene oxides, gums, acrylate polymers and methacrylate polymers.

3. The pharmaceutical formulation of claim 1, wherein the hydrogel is microcrystalline cellulose.

4. The pharmaceutical formulation of claim 1, wherein the diluent is selected from the group consisting of sugars, starches, vegetable oils, lactose monohydrate, calcium phosphate, dextrin, dextrose, maltitol, maltose, starch, sucrose and talc.

5. The pharmaceutical formulation of claim 1, wherein the diluent is a starch, and the starch is pregelatinized starch or sodium starch glycolate.

6. The pharmaceutical formulation of claim 1 comprising, by weight, 40-60% Polymorph E; 15-35% microcrystalline cellulose; 5-15% pregelatinized starch and between 0.1-10.0% each of hypromellose, silicon dioxide and sodium starch glycolate.

7. The pharmaceutical formulation of claim 1 comprising, by weight, about 50% Polymorph E; about 27% microcrystalline cellulose; about 10% pregelatinized starch, about 3% hypromellose, about 1% silicon dioxide and about 4% sodium starch glycolate.

8. The pharmaceutical formulation of any one of claims 1-7, wherein the pharmaceutical formulation is in tablet form.

9. The pharmaceutical formulation of claim 8, wherein the pharmaceutical formulation is in caplet form.

10. The pharmaceutical formulation of any one of claims 1-9, wherein the pharmaceutical formulation is an immediate-release tablet form.

11. The pharmaceutical formulation of any one of claims 1-10, wherein the formulation comprises about 50 mg, 100 mg, 150 mg, or 200 mg of Polymorph E.

12. The pharmaceutical formulation of any one of claims 1-11, wherein the formulation provides a therapeutic effect.

13. A compressed solid dosage form comprising Polymorph E of *N*-(3-{[(2*Z*)-3-[(2-chloro-5-methoxyphenyl)amino]quinoxalin-2(1*H*)-ylidene]sulfamoyl}phenyl)-2-methylalaninamide, a hydrogel polymer and a diluent.

14. The dosage form of claim 13, comprising, by weight, 40-60% Polymorph E; 15-35% microcrystalline cellulose; 5-15% pregelatinized starch and between 0.1-10.0% each of hypromellose, silicon dioxide and sodium starch glycolate.

15. The dosage form of claim 13 comprising, by weight, about 50% Polymorph E; about 27% microcrystalline cellulose; about 10% pregelatinized starch, about 3% hypromellose, about 1% silicon dioxide and about 4% sodium starch glycolate.

16. The dosage form of claim 13, wherein the dosage form comprises about 40 to 250 mg of Polymorph E.

17. The dosage form of claim 13, wherein the dosage form comprises about 50 mg, 100 mg, 150 mg or 200 mg of Polymorph E.

18. The dosage form of any one of claims 13 to 17, wherein the dosage form is a tablet.

19. The dosage form of any one of claims 13 to 18, wherein the dosage form is a caplet.

20. A compressed solid dosage form comprising

A) an active agent containing an effective amount of Polymorph E of *N*-(3-{[(2*Z*)-3-[(2-chloro-5-methoxyphenyl)amino]quinoxalin-2(1*H*)-ylidene]sulfamoyl}phenyl)-2-methylalaninamide, and

B) at least one pharmaceutically acceptable additive,

wherein the active agent is present in an amount of more than about 40% by weight based upon the total weight of the compressed solid dosage form.

21. The dosage form of claim 20, comprising, by weight, 40-60% Polymorph E; 15-35% microcrystalline cellulose; 5-15% pregelatinized starch and between 0.1-10.0% each of hypromellose, silicon dioxide and sodium starch glycolate.

22. The dosage form of claim 20 comprising, by weight, about 50% Polymorph E; about 27% microcrystalline cellulose; about 10% pregelatinized starch, about 3% hypromellose, about 1% silicon dioxide and about 4% sodium starch glycolate.

23. The dosage form of any one of claims 20 to 22, wherein the active agent comprises at least 95% Polymorph E.

24. The dosage form of any one of claims 20 to 22, wherein the active agent comprises at least 97% Polymorph E.

25. The dosage form of any one of claims 20 to 22, wherein the active agent comprises at least 99% Polymorph E.

26. A method of treating cancer in a subject, comprising administering to the subject the pharmaceutical formulation of any one of claims 1-12.

27. A method of treating cancer in a subject, comprising administering to the subject the dosage form of any one of claims 13-25.

28. The method of claim 26 or 27, wherein the cancer is a solid tumor or lymphoma.

29. The method of claim 28, wherein the lymphoma is a relapsed or refractory lymphoma.

30. The method of claim 28, wherein the lymphoma is lymphocytic lymphoma (CLL) or small lymphocytic lymphoma (SLL).

31. The method of claim 26 or 27, wherein the cancer is breast cancer, colon cancer, rectal cancer, endometrial cancer, gastric carcinoma, glioblastoma, hepatocellular carcinoma, small cell lung cancer, non-small cell lung cancer, melanoma, ovarian cancer, cervical cancer, pancreatic cancer, prostate carcinoma, acute myelogenous leukemia (AML), chronic myelogenous leukemia (CML), or thyroid carcinoma.

32. The method of any one of claims 26 to 31, wherein the treatment comprises the administration of an additional anticancer agent.

33. The method of claim 32, wherein the anticancer agent is carboplatin, paclitaxel, erlotinib, or trastuzumab.

CLAIMS

1. A pharmaceutical formulation comprising Polymorph E of N-(3-{[(2Z)-3-[(2-chloro-5-methoxyphenyl)amino]quinoxalin-2(lH)-ylidene]sulfamoyl}phenyl)-2-methylalaninamide, a hydrogel polymer and a diluent.

2. The pharmaceutical formulation of claim 1 , wherein the hydrogel is selected from the group consisting of microcrystalline cellulose, methyl cellulose, hydroxymethyl cellulose, polyvinyl pyrrolidone, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene oxides, gums, acrylate polymers and methacrylate polymers.

3. The pharmaceutical formulation of claim 1 , wherein the hydrogel is microcrystalline cellulose.

4. The pharmaceutical formulation of claim 1 , wherein the diluent is selected from the group consisting of sugars, starches, vegetable oils, lactose monohydrate, calcium phosphate, dextrin, dextrose, maltitol, maltose, starch, sucrose and talc.

5. The pharmaceutical formulation of claim 1 , wherein the diluent is a starch, and the starch is pregelatinized starch or sodium starch glycolate.

6. The pharmaceutical formulation of claim 1 comprising, by weight, 40-60% Polymorph E; 15-35% microcrystalline cellulose; 5-15% pregelatinized starch and between 0.1 - 10.0% each of hypromellose, silicon dioxide and sodium starch glycolate.

7. The pharmaceutical formulation of claim 1 comprising, by weight, about 50% Polymorph E; about 27% microcrystalline cellulose; about 10% pregelatinized starch, about 3% hypromellose, about 1% silicon dioxide and about 4% sodium starch glycolate.

8. The pharmaceutical formulation of claim 1, wherein the pharmaceutical formulation is in tablet form.

9. The pharmaceutical formulation of claim 8, wherein the pharmaceutical formulation is in caplet form.

10. The pharmaceutical formulation of claim 8, wherein the pharmaceutical formulation is an immediate-release tablet form.

11. The pharmaceutical formulation of claim 1, wherein the formulation comprises about 50 mg, 100 mg, 150 mg, or 200 mg of Polymorph E.

12. A compressed solid dosage form comprising Polymorph E of N-(3-{[(2Z)-3-[(2-chloro-5-methoxyphenyl)amino]quinoxalin-2(lH)-ylidene]sulfamoyl}phenyl)-2-methylalaninamide, a hydrogel polymer and a diluent.

13. The dosage form of claim 12, comprising, by weight, 40-60% Polymorph E; 15-35% microcrystalline cellulose; 5-15% pregelatinized starch and between 0.1 -10.0% each of hypromellose, silicon dioxide and sodium starch glycolate.

14. The dosage form of claim 13 comprising, by weight, about 50% Polymorph E; about 27% microcrystalline cellulose; about 10% pregelatinized starch, about 3% hypromellose, about 1% silicon dioxide and about 4% sodium starch glycolate.

15. The dosage form of claim 12, wherein the dosage form comprises about 40 to 250 mg of Polymorph E.

16. The dosage form of claim 12, wherein the dosage form comprises about 50 mg, 100 mg, 150 mg or 200 mg of Polymorph E.

17. The dosage form of claim 12, wherein the dosage form is a tablet.

18. The dosage form of claim 17, wherein the dosage form is a caplet.

19. A compressed solid dosage form comprising:

A) an active agent containing an effective amount of Polymorph E ofN-(3-{[(2Z)-3-[(2-chloro-5-methoxyphenyl)amino]quinoxalin-2(lH)-ylidene]sulfamoyl}phenyl)-2-methylalaninamide, and
B) at least one pharmaceutically acceptable additive, wherein the active agent is present in an amount of more than about 40% by weight based upon the total weight of the compressed solid dosage form.

20. The dosage form of claim 19, comprising, by weight, 40-60% Polymorph E; 15-35% micro crystalline cellulose; 5-15% pregelatinized starch and between 0.1 -10.0% each of hypromellose, silicon dioxide and sodium starch glycolate.

21. The dosage form of claim 20 comprising, by weight, about 50% Polymorph E; about 27% micro crystalline cellulose; about 10% pregelatinized starch, about 3% hypromellose, about 1% silicon dioxide and about 4% sodium starch glycolate.

22. The dosage form of claim 19, wherein the active agent comprises at least 95% Polymorph E.

23. The dosage form of claim 22, wherein the active agent comprises at least 97% Polymorph E.

24. The dosage form of claim 23, wherein the active agent comprises at least 99% Polymorph E.