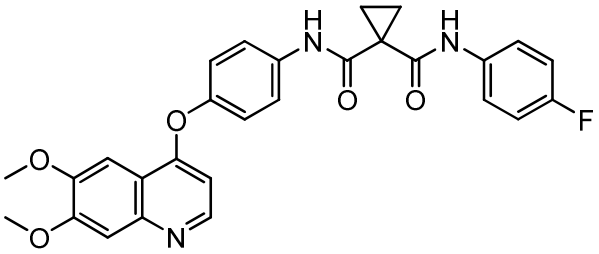
CLAIMS

1. A pharmaceutical composition comprising:

30-32 percent by weight of Compound I, L-malate Salt;
50-63.3 percent by weight of a filler;
2-4 percent by weight of a binder;
4-8 percent by weight of a disintegrant;
0.2-0.6 percent by weight of a glidant; and
0.5-1 percent by weight of a lubricant;

wherein Compound I is:



Compound I.

2. The pharmaceutical composition of claim 1, wherein the Compound I, L-malate salt is in amorphous, substantially amorphous, crystalline, or substantially crystalline form.

3. The pharmaceutical composition of claim 1 or 2, wherein the Compound I, L-malate salt is in crystalline or amorphous form.

4. The pharmaceutical composition of any one of claims 1 to 3, wherein the Compound I, L-malate salt is crystalline or in substantially crystalline form.

5. The pharmaceutical composition of any one of claims 1 to 4, wherein the Compound I, L-malate salt is in substantially pure N-2 form.

6. The pharmaceutical composition of any one of claims 1 to 5, wherein the filler is selected from the group consisting of sodium starch glycolate, corn starch, talc, sucrose, dextrose, glucose, lactose, xylitol, fructose, sorbitol, calcium phosphate, calcium sulfate, calcium carbonate, and microcrystalline cellulose, or mixtures thereof.

7. The pharmaceutical composition of any one of claims 1 to 6, wherein the filler comprises lactose and microcrystalline cellulose.

8. The pharmaceutical composition of any one of claims 1 to 7, wherein the binder is selected from the group consisting of acacia, alginic acid, carbomer, carboxymethylcellulose sodium, dextrin, ethylcellulose, gelatin, guar gum, hydrogenated vegetable oil (type I), hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, liquid glucose, magnesium aluminum silicate, maltodextrin, methylcellulose, polymethacrylates, povidone, pregelatinized starch, sodium alginate, starch, and zein, or mixtures thereof.

9. The pharmaceutical composition of any one of claims 1 to 8, wherein the binder is hydroxypropyl cellulose.

10. The pharmaceutical composition of any one of claims 1 to 9, wherein the disintegrant is selected from the group consisting of alginic acid, carboxymethylcellulose calcium, carboxymethylcellulose sodium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, guar gum, magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, polyacrilin potassium, powdered cellulose, pregelatinized starch, sodium alginate, and starch, or mixtures thereof.

11. The pharmaceutical composition of any one of claims 1 to 10, wherein the disintegrant is croscarmellose sodium.

12. The pharmaceutical composition of any one of claim 1 to 11, wherein the glidant is colloidal silicon dioxide.

13. The pharmaceutical composition of any one of claim 1 to 12, wherein the lubricant is selected from the group consisting of magnesium stearate, stearic acid, and talc, or mixtures thereof.

14. The pharmaceutical composition of any one of claims 1 to 13, wherein the lubricant is magnesium stearate.

15. The pharmaceutical composition of any one of claims claim 1 to 14, further comprising a film coating.

16. The pharmaceutical composition of claim 15, wherein the film coating comprises hypromellose, titanium dioxide, triacetin, and iron oxide yellow.

17. The pharmaceutical formulation of any one of claims 1 to 16, wherein the formulation is a tablet formulation.

18. The pharmaceutical composition of claim 17, wherein filler(s) are present in an amount of from about 57 to about 67 percent, by weight on a solids basis of a directly compressible formulation.

19. The pharmaceutical composition of claim 18, wherein the filler comprises lactose, and the lactose is in an amount of from about 18 to 22 percent by weight on a solids basis of the directly compressible formulation.

20. The pharmaceutical composition according to claim 18 or 19, wherein the filler comprises microcrystalline cellulose, and the microcrystalline cellulose is in an amount of from 38 to 40 percent by weight on a solids basis of the directly compressible formulation.

21. Use of the pharmaceutical composition of any one of claims 1 to 20, alone or in combination with another therapeutic agent, in manufacturing a medicament for treatment of cancer.

22. The pharmaceutical composition according to any one of claims 1 to 20, for use in the treatment of cancer, wherein the pharmaceutical composition is to be administered to a patent in need of such treatment, alone or in combination with another therapeutic agent.

23. The use of claim 21 or the composition of claim 22, wherein the cancer is selected from the group consisting of pancreatic c ancer, kidney cancer, liver cancer, prostate cancer, gastric cancer, gastroesophageal cancer, melanoma, lung cancer, breast cancer, thyroid cancer, and astrocytic tumors.

24. The use or the composition of claim 23, wherein the cancer is pancreatic cancer, hepatocellular carcinoma (HCC), renal cell carcinoma, castration-resistant prostate cancer (CRPC), gastric or gastroesophageal junction cancer, melanoma, small cell lung cancer (SCLC), ovarian cancer, primary peritoneal or fallopian tube carcinoma, estrogen receptor positive breast cancer, estrogen receptor/progesterone receptor/HER2-negative (triple-negative) breast cancer, inflammatory (regardless of receptor status) breast cancer, non-small cell lung cancer (NSCLC), or medullary thyroid cancer.