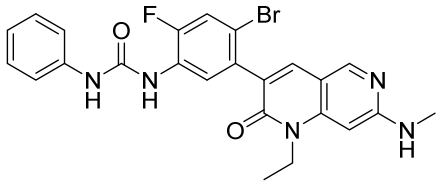
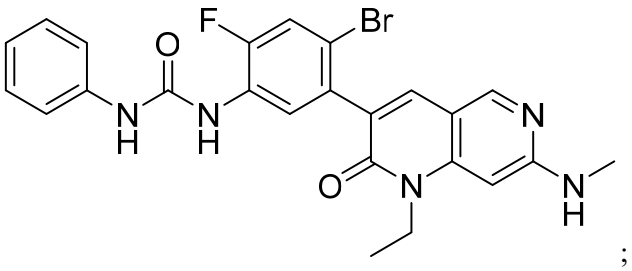
[0005b] In another aspect of the present disclosure, there is provided a pharmaceutically acceptable composition comprising a compound represented by Formula (I)



Formula (I)

and a pharmaceutically acceptable excipient, wherein greater than 96% by weight of the compound present in the pharmaceutically acceptable composition is in the amorphous form.

[0005c] In a further aspect of the present disclosure, there is provided a pharmaceutically acceptable composition for orally delivering to a patient 50 mg of a compound represented by Formula (I):



;

Formula (I)

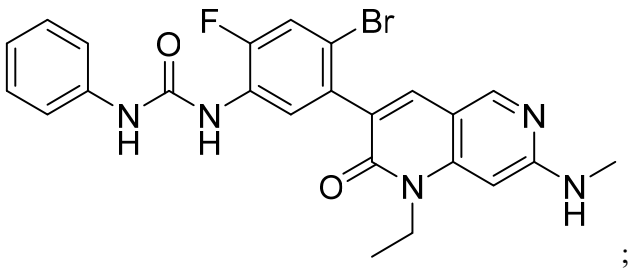
comprising:

an intragranular blend, wherein the intragranular blend comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, hydroxypropyl methyl cellulose acetate succinate; a bulking agent and/or filler; and a lubricant and/or a glidant; and

an extragranular blend comprising a glidant and/or a lubricant.

[0005d] In another aspect of the present disclosure, there is provided a pharmaceutically acceptable composition for orally delivering to a patient 50 mg of a compound represented by Formula (I):



;

Formula (I)

comprising:

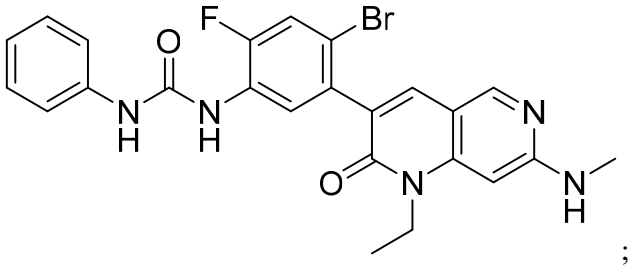
a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form and hydroxypropyl methyl cellulose acetate succinate;

a bulking agent,

a filler, and

a lubricant and/or a glidant.

[0005e] In a further aspect of the present disclosure, there is provided a pharmaceutically acceptable tablet having 50 mg of a compound represented by Formula (I):



;

Formula (I)

comprising:

an intragranular blend, wherein the intragranular blend comprises:

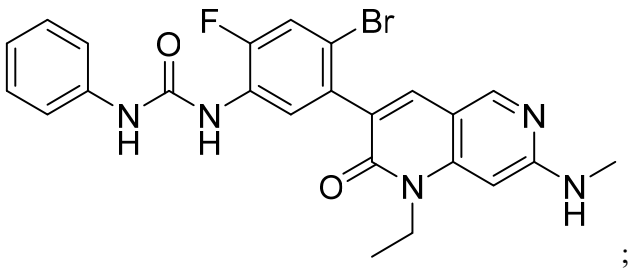
a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, and hydroxypropyl methyl cellulose acetate succinate;

25-35% by weight of a bulking agent based on the total amount of the pharmaceutical composition;

25-35% by weight of a filler based on the total amount of the pharmaceutical composition; and

an extragranular blend comprising a glidant and/or a lubricant.

[0005f] In another aspect of the present disclosure, there is provided a pharmaceutically acceptable tablet having 50 mg of a compound represented by Formula (I):



;

Formula (I)

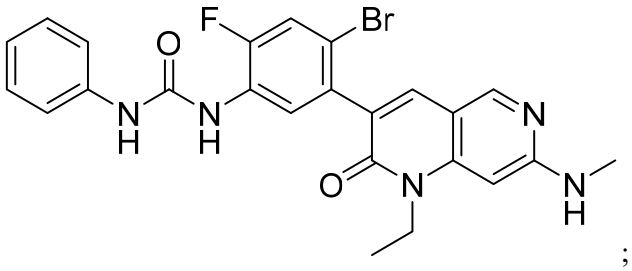
wherein the tablet comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, and hydroxypropyl methyl cellulose acetate succinate;

25-35% by weight microcrystalline cellulose based on the total weight of the tablet; and

25-35% by weight of lactose or a hydrate thereof based on the total amount of the pharmaceutical composition.

[0005g] In a further aspect of the present disclosure, there is provided a pharmaceutically acceptable composition for orally delivering 50 mg of a compound represented by Formula (I):



;

Formula (I)

comprising:

an intragranular blend, wherein the intragranular blend comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form and hydroxypropyl methyl cellulose acetate succinate;

25-35% by weight microcrystalline cellulose based on the total amount of the pharmaceutical composition;

25-35%% by weight of lactose or a hydrate thereof based on the total amount of the pharmaceutical composition;

5% by weight of crospovidone based on the total amount of the pharmaceutical composition;

0.5% by weight of silicon dioxide based on the total amount of the pharmaceutical composition; and

0.5% by weight of magnesium stearate based on the total amount of the pharmaceutical composition; and

an extragranular blend comprising (i) 0.5% by weight of silicon dioxide based on the total amount of the pharmaceutical composition; and (ii) 0.5% by weight of magnesium stearate based on the total amount of the pharmaceutical composition.

[0005h] In another aspect of the present disclosure, there is provided a use of the composition or one or more of the tablets disclosed herein, in the manufacture of a medicament for treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, or non-small cell lung cancer.

[0005i] In a further aspect of the present disclosure, there is provided a use of the composition or one or more of the tablets disclosed herein, in the manufacture of a medicament for treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, lung cancer, glioblastoma, a glioma, malignant peripheral nerve sheath sarcoma, or hypereosinophilic syndrome.

[0005j] In another aspect of the present disclosure, there is provided a use of the composition or one or more of the tablets disclosed herein, in the manufacture of a medicament for treating a disease selected from the group consisting of KIT driven germ cell tumor (e.g., testicular germ cell), KIT driven skin cancer, or KIT driven renal cell carcinoma.

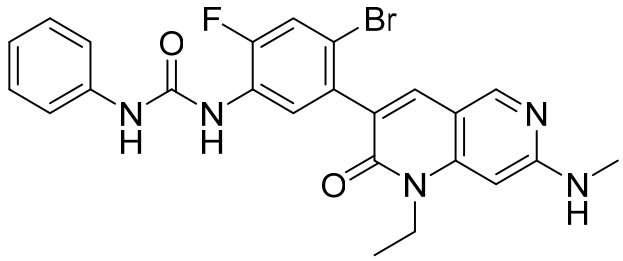
[0005k] In a further aspect of the present disclosure, there is provided a use of the composition or one or more of the tablets disclosed herein, in the manufacture of a medicament for treating a disease selected from the group consisting of penile cancer,

PDGFRA driven penile cancer, prostate cancer, PDGFRA driven prostate cancer, PDGFRA driven non-melanoma skin cancer, PDGFRA driven glioma, PDGFRA driven sarcoma, PDGFRA driven glioblastoma, or PDGFRA driven pancreatic cancer.

[0005l] In another aspect of the present disclosure, there is provided a use of the composition or one or more of the tablets disclosed herein, in the manufacture of a medicament for treating a disease selected from the group consisting of vaginal cancer, prostate cancer, penile cancer, non-melanoma skin cancer, melanoma, or breast sarcoma, wherein the disease comprises a PDGFRAB mutation.

[0005m] In a further aspect of the present disclosure, there is provided a use of the composition or tablets disclosed herein in the preparation of a medicament for the treatment of a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, or non-small cell lung cancer.

[0005n] In another aspect of the present disclosure, there is provided a process for the preparation of the solid dispersion comprising an amorphous form of a compound of Formula (I)



Formula (I)

disclosed herein, the process comprising:

(a) mixing the compound of Formula (I), a solvent, the polymer and water to obtain a suspension;

(b) optionally agitating and/or mixing the suspension while maintaining a temperature of 10 to 25 ºC;

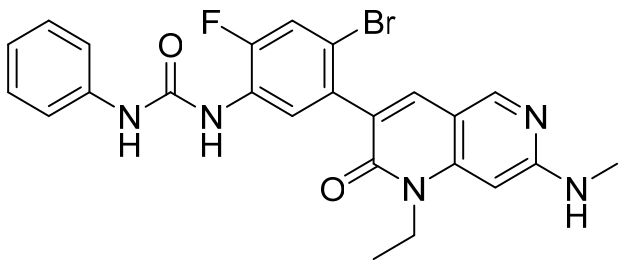
CLAIMS

What is claimed is:

1. A pharmaceutically acceptable composition for oral administration, the composition comprising:

(i) a solid dispersion, wherein the solid dispersion comprises:

the amorphous form of a compound represented by Formula (I):



and

Formula (I)

a pharmaceutically acceptable polymer; and

(ii) one or more pharmaceutically acceptable excipients.

2. The pharmaceutically acceptable composition of claim 1, wherein the solid dispersion has no more than 5% w/w of any crystalline form of the compound.

3. The pharmaceutically acceptable composition of claim 1 or 2, wherein the solid dispersion has substantially no detectable amount of any crystalline form of the compound.

4. The pharmaceutically acceptable composition of any one of claims 1-3, wherein the solid dispersion has a powder X-ray diffraction pattern substantially as shown in Figure 1.

5. The pharmaceutically acceptable composition of any one of claims 1-4, wherein the composition contains not more than 5% (w/w) of any crystalline form of the compound in the aggregate when exposed to 60% relative humidity at 25 ºC for 1 month, 3 months or 6 months.

6. The pharmaceutically acceptable composition of any one of claims 1-4, wherein the composition contains not more than 5% (w/w) of any crystalline form of the compound in the

aggregate when exposed to 75% relative humidity at 40 ºC for 1 month, 3 months or 6 months.

7. The pharmaceutically acceptable composition of any one of claims 1-6 comprising 10% to 30% by weight of the compound based on the total weight of the solid dispersion.

8. The pharmaceutically acceptable composition of any one of claims 1-7, comprising 20% to 30% by weight of the compound based on the total weight of the solid dispersion.

9. The pharmaceutically acceptable composition of any one of claims 1-8, comprising 25% by weight of the compound based on the total weight of the solid dispersion.

10. The pharmaceutically acceptable composition of any one of claims 1-9, wherein the pharmaceutically acceptable polymer is selected from the group consisting of: polyvinyl pyrrolidone, polyethyleneoxide, polyethylene glycol, poly(vinyl pyrrolidone-co-vinyl acetate), polyoxyethylene-polyoxypropylene block copolymers, graft copolymers comprised of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, polymethacrylates, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polycaprolactam, polylactic acid, polyglycolic acid, poly(lactic-glycolic)acid, lipids, cellulose, pullulan, dextran, maltodextrin, hyaluronic acid, polysialic acid, chondroitin sulfate, heparin, fucoidan, pentosan polysulfate, spirulan, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose propionate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, cellulose acetate terephthalate, cellulose acetate isophthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate phthalate, hydroxypropyl methylcellulose propionate phthalate, hydroxypropyl methylcellulose acetate trimellitate, hydroxypropyl methylcellulose propionate trimellitate, cellulose acetate succinate, methyl cellulose acetate succinate, dextran, dextran acetate, dextran propionate, dextran succinate, dextran acetate propionate, dextran acetate succinate, dextran propionate succinate, dextran acetate propionate succinate, poly(methacrylic acid-co-methyl methacrylate) 1:1, poly(methacrylic acid-co-methyl methacrylate) 1:2, poly(methacrylic acid-co-ethyl acrylate) 1:1, hydroxyethyl cellulose, methyl cellulose and hydroxy propyl cellulose, poly methacrylic acid-ethyl acrylate, poly methacrylic acid-methyl methacrylate, poly methyl methacrylate-ethyl acrylate, poly trimethylammonioethyl methacrylate chloride-methyl methacrylate-ethyl acrylate and

poly(butylmethacrylate-co-(2-dimethylaminoethyl)methacrylate-co-methyl methacrylate), and mixtures thereof.

11. The pharmaceutically acceptable composition of any one of claims 1-10, wherein the pharmaceutically acceptable polymer is selected from the group consisting of: polyvinyl pyrrolidone, polyethyleneoxide, polyethylene glycol, poly(vinyl pyrrolidone-co-vinyl acetate), polyoxyethylene-polyoxypropylene block copolymers, graft copolymers comprised of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, polymethacrylates, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polycaprolactam, polylactic acid, polyglycolic acid, poly(lactic-glycolic)acid, lipids, cellulose, pullulan, dextran, maltodextrin, hyaluronic acid, polysialic acid, chondroitin sulfate, heparin, fucoidan, pentosan polysulfate, spirulan, hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose propionate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, methyl cellulose acetate phthalate, hydroxypropyl cellulose acetate phthalate, cellulose acetate terephthalate, cellulose acetate isophthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate phthalate, hydroxypropyl methylcellulose propionate phthalate, hydroxypropyl methylcellulose acetate trimellitate, hydroxypropyl methylcellulose propionate trimellitate, cellulose acetate succinate, methyl cellulose acetate succinate, dextran, dextran acetate, dextran propionate, dextran succinate, dextran acetate propionate, dextran acetate succinate, dextran propionate succinate, dextran acetate propionate succinate, poly(methacrylic acid-co-methyl methacrylate) 1:1, poly(methacrylic acid-co-methyl methacrylate) 1:2, poly(methacrylic acid-co-ethyl acrylate) 1:1, and mixtures thereof.

12. The pharmaceutically acceptable composition of any one of claims 1-11, wherein the pharmaceutically acceptable polymer is hydroxypropyl methyl cellulose acetate succinate.

13. The pharmaceutically acceptable composition of any one of claims 1-12, wherein the compound and the pharmaceutically acceptable polymer are present in a ratio of compound:polymer from 40:60 to 10:90.

14. The pharmaceutically acceptable composition of any one of claims 1-13, wherein the compound and the pharmaceutically acceptable polymer are present in a ratio of compound:polymer from 30:70 to 20:80.

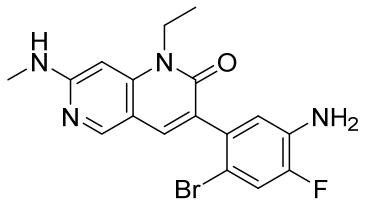
15. The pharmaceutically acceptable composition of any one of claims 1-14, wherein the compound and the pharmaceutically acceptable polymer are present in a ratio of compound:polymer of 25:75.

16. The pharmaceutically acceptable composition of anyone of claims 1-15, wherein the solid dispersion is a solid spray-dried dispersion.

17. The pharmaceutically acceptable composition of any one of claims 1-16, wherein the solid dispersion has a solubility in water at pH 6.5 of 120 µg/mL at 25 °C.

18. The pharmaceutically acceptable composition of any one of claims 1-17, wherein the solid dispersion has a solubility in water at pH 2 of 178 µg/mL at 25 °C.

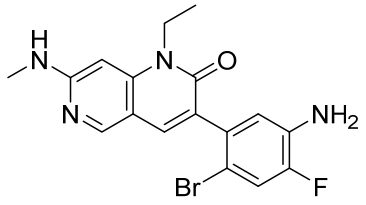
19. The pharmaceutically acceptable composition of any one of claims 1-18, comprising less than 10 % by weight of a compound represented by Formula (II):



Formula (II)

based on the weight of the compound of Formula (I).

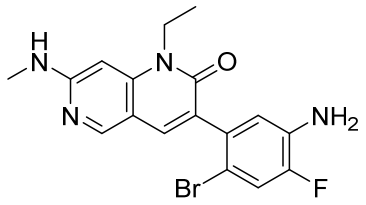
20. The pharmaceutically acceptable composition of any one of claims 1-19, comprising less than 3 % by weight of a compound represented by Formula (II):



Formula (II)

based on the weight of the compound of Formula (I).

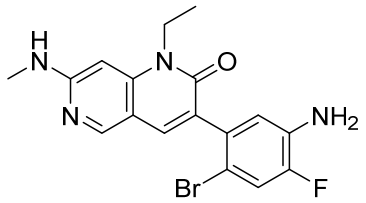
21. The pharmaceutically acceptable composition of any one of claims 1-20, comprising less than 1 % by weight of a compound represented by Formula (II):



Formula (II)

based on the weight of the compound of Formula (I).

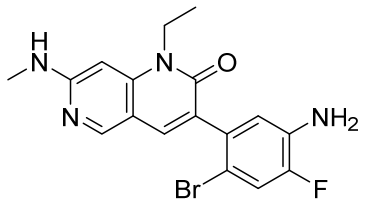
22. The pharmaceutically acceptable composition of any one of claims 1-21, comprising 0.1 % by weight to 0.5% by weight of a compound represented by Formula (II):



Formula (II)

based on the weight of the compound of Formula (I).

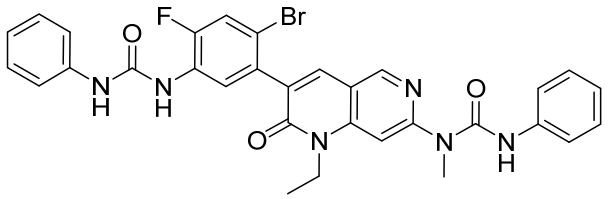
23. The pharmaceutically acceptable composition of any one of claims 1-22, comprising 0.01 % by weight to 0.1% by weight of a compound represented by Formula (II):



Formula (II)

based on the weight of the compound of Formula (I).

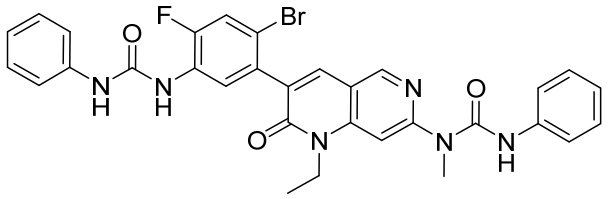
24. The pharmaceutically acceptable composition of any one of claims 1-23, comprising less than 10 % by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

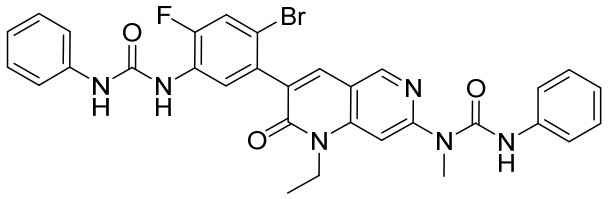
25. The pharmaceutically acceptable composition of any one of claims 1-24, comprising less than 3 % by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

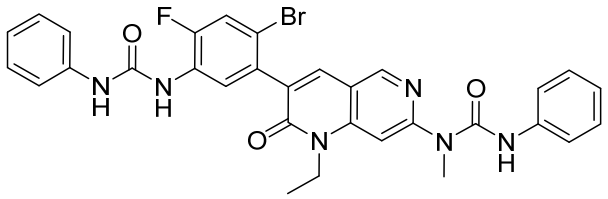
26. The pharmaceutically acceptable composition of any one of claims 1-25, comprising less than 1 % by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

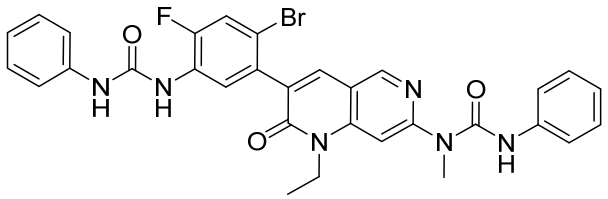
27. The pharmaceutically acceptable composition of any one of claims 1-26, comprising 0.1 % by weight to 0.5% by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

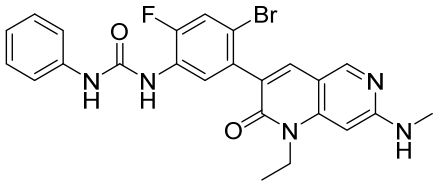
28. The pharmaceutically acceptable composition of any one of claims 1-28, comprising 0.01 % by weight to 0.1% by weight of a compound represented by Formula (III):



Formula (III)

based on the weight of the compound of Formula (I).

29. A pharmaceutically acceptable composition comprising a compound represented by Formula (I)



Formula (I)

and a pharmaceutically acceptable excipient, wherein greater than 96% by weight of the compound present in the pharmaceutically acceptable composition is in the amorphous form.

30. The pharmaceutically acceptable composition of claim 29, wherein the amorphous

form has a characteristic amorphous powder X-ray diffraction halo pattern.

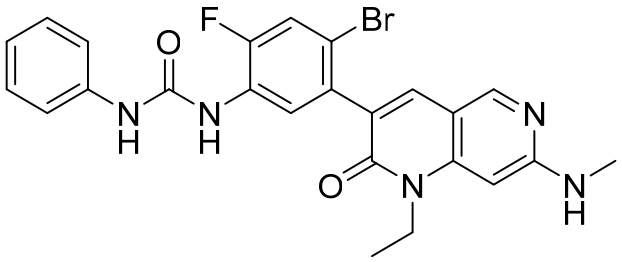
31. The pharmaceutically acceptable composition of claim 29 or 30 of any one of claims 1-3, where the amorphous form has a powder X-ray diffraction pattern substantially as shown in Figure 1.

32. The pharmaceutically acceptable composition of claim 29 or 30, wherein the powder X-ray diffraction spectrum is obtained using Cu Kα radiation.

33. The pharmaceutically acceptable composition of any one of claims 29-32, wherein the amorphous form of the compound has a glass transition temperature of 125 °C.

34. The pharmaceutically acceptable composition of any one of claims 29-33, wherein the composition has no detectable amounts of any crystalline form of the compound of Formula (I).

35. A pharmaceutically acceptable composition for orally delivering to a patient 50 mg of a compound represented by Formula (I):



;

Formula (I)

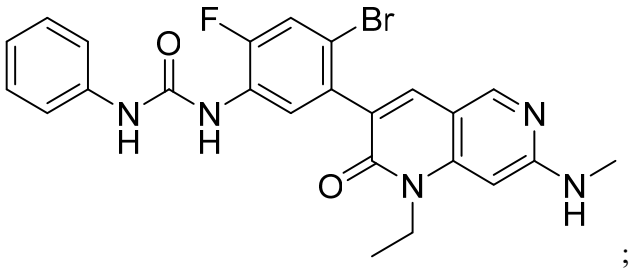
comprising:

an intragranular blend, wherein the intragranular blend comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, hydroxypropyl methyl cellulose acetate succinate; a bulking agent and/or filler; and a lubricant and/or a glidant; and

an extragranular blend comprising a glidant and/or a lubricant.

36. A pharmaceutically acceptable composition for orally delivering to a patient 50 mg of a compound represented by Formula (I):



;

Formula (I)

comprising:

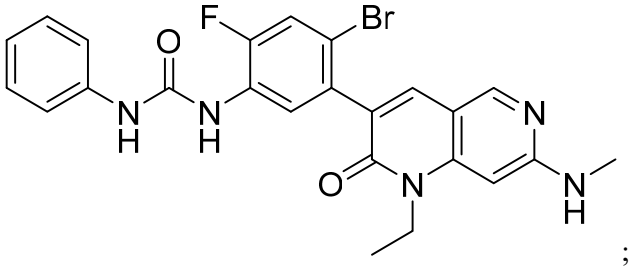
a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form and hydroxypropyl methyl cellulose acetate succinate;

a bulking agent,

a filler, and

a lubricant and/or a glidant.

37. A pharmaceutically acceptable tablet having 50 mg of a compound represented by Formula (I):



;

Formula (I)

comprising:

an intragranular blend, wherein the intragranular blend comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, and hydroxypropyl methyl cellulose acetate succinate;

25-35% by weight of a bulking agent based on the total amount of the pharmaceutical composition;

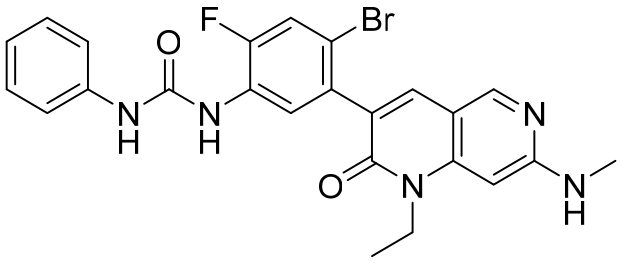
25-35% by weight of a filler based on the total amount of the pharmaceutical composition; and

an extragranular blend comprising a glidant and/or a lubricant.

38. The pharmaceutically acceptable tablet of claim 37, wherein the bulking agent is microcrystalline cellulose.

39. The pharmaceutically acceptable tablet of claim 37 or 38, wherein the filler is lactose or a hydrate thereof.

40. A pharmaceutically acceptable tablet having 50 mg of a compound represented by Formula (I):



;

Formula (I)

wherein the tablet comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form, and hydroxypropyl methyl cellulose acetate succinate;

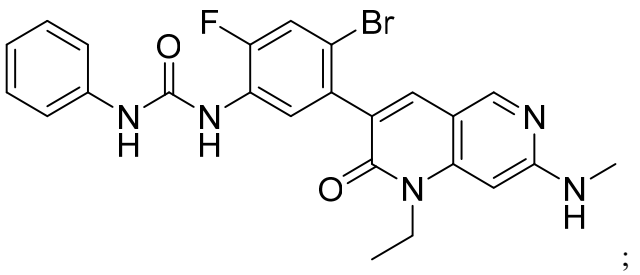
25-35% by weight microcrystalline cellulose based on the total weight of the tablet; and

25-35% by weight of lactose or a hydrate thereof based on the total amount of the pharmaceutical composition.

41. The pharmaceutically acceptable tablet of claim 40, further comprising at least one of: magnesium stearate, crospovidone and silicon dioxide.

42. The pharmaceutically acceptable tablet of any one of claims 40 or 41, wherein the tablet disintegrates in less than 1 minute as tested using USP <701> for uncoated tablets.

43. A pharmaceutically acceptable composition for orally delivering 50 mg of a compound represented by Formula (I):



;

Formula (I)

comprising:

an intragranular blend, wherein the intragranular blend comprises:

a solid dispersion having 50 mg of the compound wherein the compound is present in amorphous form and hydroxypropyl methyl cellulose acetate succinate;

25-35% by weight microcrystalline cellulose based on the total amount of the pharmaceutical composition;

25-35%% by weight of lactose or a hydrate thereof based on the total amount of the pharmaceutical composition;

5% by weight of crospovidone based on the total amount of the pharmaceutical composition;

0.5% by weight of silicon dioxide based on the total amount of the pharmaceutical composition; and

0.5% by weight of magnesium stearate based on the total amount of the pharmaceutical composition; and

an extragranular blend comprising (i) 0.5% by weight of silicon dioxide based on the total amount of the pharmaceutical composition; and (ii) 0.5% by weight of magnesium stearate based on the total amount of the pharmaceutical composition.

44. The pharmaceutically acceptable composition or tablet of any one of claims 1-43, wherein the composition or tablet releases at least 80% of the compound after 10 minutes to 40 minutes when the composition is tested in 900 mL sodium acetate buffer at pH 4.5 using a USP Apparatus II (Paddle Method) at 37 °C, with a paddle speed of 75 rpm.

45. The pharmaceutically acceptable composition or tablet of any one of claims 1-44, wherein the composition or tablet releases at least 80% of the compound after 20 minutes when the composition is tested in 900 mL sodium acetate buffer at pH 4.5 using a USP Apparatus II (Paddle Method) at 37 °C, with a paddle speed of 75 rpm.

46. Use of the composition or one or more of the tablets of claims 1-42, in the manufacture of a medicament for treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), NF-1-deficient gastrointestinal stromal tumors, succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors, KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, or non-small cell lung cancer.

47. Use of the composition or one or more of the tablets of claims 1-45, in the manufacture of a medicament for treating a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, lung cancer, glioblastoma, a glioma, malignant peripheral nerve sheath sarcoma, or hypereosinophilic syndrome.

48. Use of the composition or one or more of the tablets of claims 1-45, in the manufacture of a medicament for treating a disease selected from the group consisting of KIT driven germ cell tumor (e.g., testicular germ cell), KIT driven skin cancer, or KIT driven renal cell carcinoma.

49. Use of the composition or one or more of the tablets of claims 1-45, in the manufacture of a medicament for treating a disease selected from the group consisting of penile cancer, PDGFRA driven penile cancer, prostate cancer, PDGFRA driven prostate cancer, PDGFRA driven non-melanoma skin cancer, PDGFRA driven glioma, PDGFRA driven sarcoma, PDGFRA driven glioblastoma, or PDGFRA driven pancreatic cancer.

50. Use of the composition or one or more of the tablets of claims 1-45, in the manufacture of a medicament for treating a disease selected from the group consisting of

vaginal cancer, prostate cancer, penile cancer, non-melanoma skin cancer, melanoma, or breast sarcoma, wherein the disease comprises a PDGFRAB mutation.

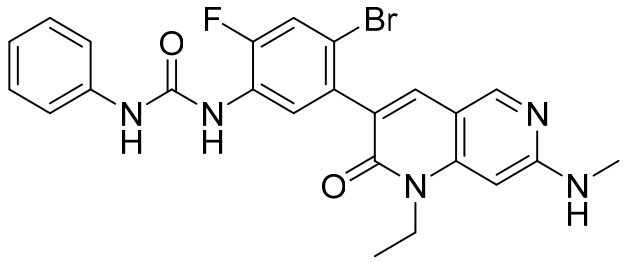
51. The use of claim 46, wherein the disease is gastrointestinal stromal tumors (GIST).

52. Use of the composition or tablets according to any one of claims 1-45 in the preparation of a medicament for the treatment of a disease selected from the group consisting of gastrointestinal stromal tumors (GIST), KIT driven gastrointestinal stromal tumors, PDGFRA driven gastrointestinal stromal tumors, melanoma, acute myeloid leukemia, germ cell tumors of the seminoma or dysgerminoma, mastocytosis, mast cell leukemia, lung adenocarcinoma, squamous cell lung cancer, glioblastoma, glioma, pediatric glioma, astrocytomas, sarcomas, malignant peripheral nerve sheath sarcoma, intimal sarcomas, hypereosinophilic syndrome, idiopathic hypereosinophilic syndrome, chronic eosinophilic leukemia, eosinophilia-associated acute myeloid leukemia, lymphoblastic T-cell lymphoma, or non-small cell lung cancer.

53. The use of claim 49, wherein the disease is gastrointestinal stromal tumors (GIST).

54. The use of any one of claims 46-53, wherein the disease is caused by the kinase activity of: c-KIT and/or PDGFRA, and/or oncogenic forms thereof.

55. A process for the preparation of the solid dispersion comprising an amorphous form of a compound of Formula (I)



Formula (I)

according to any one of claims 1-37, the process comprising:

(a) mixing the compound of Formula (I), a solvent, the polymer and water to obtain a suspension;

(b) optionally agitating and/or mixing the suspension while maintaining a temperature of 10 to 25 ºC;

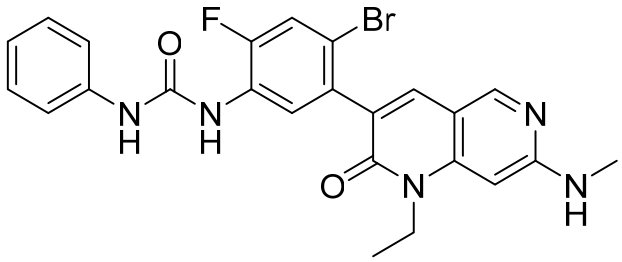
(c) heating the suspension to dissolve the suspended particles prior to introduction into a spray-dryer; and

(d) spray-drying the suspension to obtain a spray-dried dispersion;

(e) drying the spray-dried dispersion; thereby obtaining the solid dispersion.

56. The process of claim 55, wherein heating comprises passing the suspension through an in-line heat exchanger.

57. A solid dispersion comprising an amorphous form of a compound of Formula (I)



Formula (I)

produced by the process of claim 55 or 56.

58. The composition or one or more of the tablets of claims 1-45, for use in therapy.