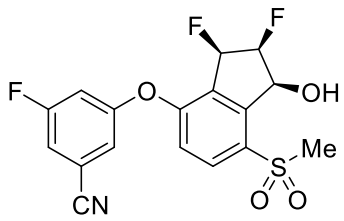
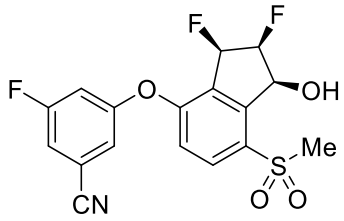


Formula (I),

wherein the solid dosage form comprises (a) a solid dispersion comprising a compound of Formula (I); and (b) one or more pharmaceutically acceptable excipients. In one aspect, the present disclosure provides a pharmaceutical solid dosage form for oral delivery of a compound of Formula (I),



Formula (I),

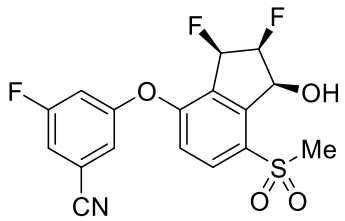
wherein the solid dosage form comprises a solid dispersion comprising the compound of Formula (I) and one or more pharmaceutically acceptable excipients, wherein the solid dispersion comprises a pharmaceutically acceptable polymer which is hypromellose acetate succinate (HPMCAS); and the solid dosage form is a capsule or a tablet. In some examples, the solid dosage form is a capsule or a tablet. In some examples, the solid dosage form is a tablet. In some examples, the one or more pharmaceutically acceptable excipients comprise a binder, a filler, a disintegrant and a lubricant. In some examples, the solid dispersion is present in an amount from 15% to 50% by weight of the solid dosage form. In some examples, the solid dispersion comprises a pharmaceutically acceptable polymer. In some examples, the pharmaceutically acceptable polymer is HPMCAS. In some examples, the polymer is present in an amount from 15% to 35% by weight of the solid dosage form. In some examples, the compound of Formula (I) is present in an amount from 1% to 15% by weight of the solid dosage form. The solid dosage form may comprise 5 mg to 100 mg of the compound of Formula (I), such as about 10 mg of the compound of Formula (I) or about 40 mg of the compound of Formula (I).

[0015] A solid dosage form of the present disclosure may comprise a binder in an amount from 20% to 50% by weight of the solid dosage form, optionally wherein the binder is microcrystalline cellulose. The solid dosage form may comprise a filler in an amount from 20% to 40% by weight of the solid dosage form. In some examples, the solid dosage form comprises an intragranular filler and an extragranular filler, wherein the intragranular filler is present in an amount from 12% to 22% by weight of the solid dosage form, and wherein the extragranular filler is present in an amount from 8% to 18% of the solid dosage form. In some examples, the filler is mannitol. The solid dosage form may comprise a disintegrant in an amount from 1.0% to 5.0% by weight of the solid dosage form. In some examples, the solid dosage form comprises an intragranular disintegrant and an extragranular disintegrant, wherein the intragranular disintegrant is present in an amount from 0.9% to 3.0% by weight of the solid dosage form, and wherein the extragranular disintegrant is present in an amount from 0.1% to

CLAIMS

WHAT IS CLAIMED IS:

1. A pharmaceutical solid dosage form for oral delivery of a compound of Formula (I),



Formula (I),

wherein the solid dosage form comprises a solid dispersion comprising the compound of Formula (I) and one or more pharmaceutically acceptable excipients,

wherein the solid dispersion comprises a pharmaceutically acceptable polymer which is hypromellose acetate succinate (HPMCAS);

and the solid dosage form is a capsule or a tablet.

2. The solid dosage form of claim 1, wherein the solid dosage form is a tablet.

3. The solid dosage form of claim 1 or 2, wherein the one or more pharmaceutically acceptable excipients comprise a binder, a filler, a disintegrant and a lubricant.

4. The solid dosage form of claim 3, wherein the one or more pharmaceutically acceptable excipients further comprise a glidant.

5. The solid dosage form of any one of claims 1 to 4, wherein the solid dispersion is present in an amount from 15% to 50% by weight of the solid dosage form.

6. The solid dosage form of any one of claims 1 to 5, wherein the pharmaceutically acceptable polymer is present in an amount from 15% to 35% by weight of the solid dosage form.

7. The solid dosage form of any one of claims 1 to 6, wherein the compound of Formula (I) is present in an amount from 1% to 15% by weight of the solid dosage form.

8. The solid dosage form of any one of claims 1 to 6, comprising 5 mg to 100 mg of the compound of Formula (I).

9. The solid dosage form of any one of claims 1 to 8, comprising about 10 mg of the compound of Formula (I).

10. The solid dosage form of any one of claims 1 to 8, comprising about 40 mg of the compound of Formula (I).

11. A solid dosage form of any one of claims 1 to 10 for use in treating von Hippel-Lindau (VHL) disease in a subject.

12. Use of a solid dosage form of any one of claims 1 to 10 in the manufacture of a medicament for the treatment of von Hippel-Lindau (VHL) disease in a subject.

13. The solid dosage form for use of claim 11 or the use of claim 12, wherein the subject also suffers from a hemangioblastoma, a pheochromocytoma, a pancreatic neuroendocrine tumor or renal cell carcinoma.

14. The solid dosage form for use of claim 11 or the use of claim 12, wherein the subject suffers from renal cell carcinoma.

15. A solid dosage form of any one of claims 1 to 10 for use in treating renal cell carcinoma in a subject.

16. Use of a solid dosage form of any one of claims 1 to 10 in the manufacture of a medicament for the treatment of renal cell carcinoma.

17. The solid dosage form for use of claim 14 or 15 or the use of claim 14 or 15, wherein the renal cell carcinoma is clear cell renal cell carcinoma.