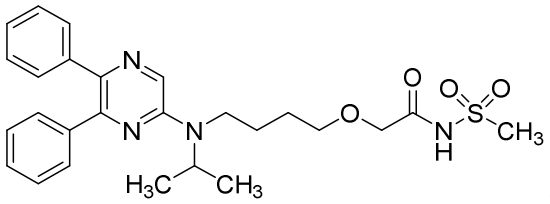
Claims

1. A pharmaceutical composition comprising the compound of formula (I) in the amount of 80 to 170 mcg



(I).

or a pharmaceutically acceptable salt, solvate, hydrate or morphological form thereof.

2. The pharmaceutical composition according to claim 1, further comprising one or more selected from the group consisting of:
   a) a filler;
   b) a disintegrant;
   c) a binder; and
   d) a lubricant.

3. The pharmaceutical composition according to claim 2, wherein
   - the filler, if present, is one or more selected from the group consisting of: D-mannitol, maize starch, lactose, pregelatinized starch, dibasic calcium phosphate dihydrate (CaHPO4•2H2O), microcrystalline cellulose, and maltodextrin;
   - the disintegrant, if present, is one or more selected from the group consisting of: low substituted hydroxypropyl cellulose, croscarmellose sodium, sodium starch glycolate, and cross-linked polyvinylpyrrolidone;
   - the binder, if present, is one or more selected from the group consisting of: hydroxypropyl cellulose, sucrose, gelatine, starch, pregelatinized starch, alginic acid, sodium alginate, methyl cellulose, ethyl cellulose, hydroxy propyl methyl cellulose, polyvinyl pyrrolidinone, calcium carboxymethylcellulose, sodium carboxymethylcellulose, guar gum, clays, ion exchange resins and calcium silicate;
   - the lubricant, if present, is one or more selected from the group consisting of: magnesium stearate, aluminium stearate, calcium stearate, stearic acid,

sodium stearyl fumarate, talc, sodium benzoate, glyceryl mono fatty acid, polyethylene glycol, hydrogenated cotton seed oil, castor seed oil, sucrose esters, calcium silicate and silicon dioxide.

4. The pharmaceutical composition according to any one of claims 1 to 3, wherein
   (i) the filler is comprised in an amount from 11.5 to 145.0 mg;
   (ii) the disintegrant is comprised in an amount from 0.6 to 8.5 mg;
   (iii) the binder is comprised in an amount from 0.5 to 6.5 mg; and
   (iv) the lubricant is comprised in an amount from 0.2 to 2.5 mg.

5. The pharmaceutical composition according to any one of claims 1 to 4, wherein
   (i) the filler is comprised in an amount from 12.0 to 45.0 mg;
   (ii) the disintegrant is comprised in an amount from 0.6 to 2.5 mg;
   (iii) the binder is comprised in an amount from 0.5 to 2.0 mg; and
   (iv) the lubricant is comprised in an amount from 0.2 to 0.7 mg.

6. The pharmaceutical composition according to any one of claims 1 to 3, which comprises
   - D-mannitol and maize starch;
   - low substituted hydroxypropyl cellulose;
   - hydroxypropyl cellulose; and
   - magnesium stearate.

7. The pharmaceutical composition according to claim 6, which comprises
   - D-mannitol in an amount from 7.0 to 90.0 mg;
   - maize starch in an amount from 4.5 to 60.0 mg;
   - low substituted hydroxypropyl cellulose in an amount from 0.6 to 9.0 mg;
   - hydroxypropyl cellulose in an amount from 0.5 to 6.5 mg; and
   - magnesium stearate is comprised in an amount from 0.2 to 2.5 mg.

8. The pharmaceutical composition according to claim 6 or 7, which comprises
   - D-mannitol in an amount from 7.0 to 25.0 mg;
   - maize starch in an amount from 4.5 to 20.0 mg;
   - low substituted hydroxypropyl cellulose in an amount from 0.6 to 3.0 mg;
   - hydroxypropyl cellulose in an amount from 0.5 to 2.0 mg; and
   - magnesium stearate is comprised in an amount from 0.2 to 0.7 mg.

9. The pharmaceutical composition according to any one of claims 1 to 8, which is in the form of a tablet.

10. The pharmaceutical composition according to claim 9, wherein the tablet is coated, the coating material comprising one or more selected from the group consisting of a plasticizer, a film former and a pigment.

11. The pharmaceutical composition according to claim 9, wherein the tablet is coated, the coating material comprising one or more selected from the group consisting of a plasticizer, a film former, a glidant and a pigment.

12. The pharmaceutical composition according to claim 9 to11, wherein the tablet has a diameter of 1.5 to 4 mm.

13. The pharmaceutical composition according to any one of claims 1 to 12 for use as a medicament.

14. The pharmaceutical composition according to any one of claim 1 to 12 for use as a pediatric medicament.

15. The pharmaceutical composition according to any one of claim 1 to 12 for use in patients with hepatic impairment or patients experiencing drug drug interaction with CYP 2C8 inhibitors.

16. The pharmaceutical composition according to any one of claims 1 to 15 for the use in the prevention or treatment of ulcer, digital ulcer, diabetic gangrene, diabetic foot ulcer, pulmonary hypertension, pulmonary arterial hypertension, Fontan disease and pulmonary hypertension associated with Fontan disease, sarcoidosis and pulmonary hypertension associated with sarcoidosis, peripheral circulatory disturbance, connective tissue disease, chronic kidney diseases including glomerulonephritis and diabetic nephropathy at any stage, diseases in which fibrosis of organs or tissues is involved, or respiratory diseases.

17. The pharmaceutical composition according to any one of claims 1 to 16 for the use in the prevention or treatment of pulmonary arterial hypertension (PAH).

18. ~~Method~~ Use of a pharmaceutical composition according to any one of claims 1 to 9 in the manufacture of a medicament for preventing and/or treating ulcer, digital ulcer, diabetic gangrene, diabetic foot ulcer, pulmonary hypertension, pulmonary arterial hypertension, Fontan disease and pulmonary hypertension associated with Fontan disease, sarcoidosis and pulmonary hypertension associated with sarcoidosis, peripheral circulatory disturbance, connective tissue disease, chronic kidney diseases including glomerulonephritis and diabetic nephropathy at any stage, diseases in which fibrosis of organs or tissues is involved, or respiratory diseases~~, comprising administering the pharmaceutical composition according to any one of claims 1 to 9 to~~ in a human subject in need thereof.

19. ~~Method~~ Use according to claim 18, wherein the human subject is from ≥ 2 years to < 18 years old.

20. ~~Method~~ Use according to claim 18, wherein the human subject is a patient with hepatic impairment or a patient experiencing drug drug interaction with CYP 2C8 inhibitors.

21. A process for manufacturing the pharmaceutical composition according to any one of claims 1 to 12, comprising the steps of

a) mixing the compound of formula (I) or a pharmaceutically acceptable salt, solvate, hydrate or morphological form thereof with a filler;
b) adding a filler and a disintegrant to the blend of step a) and mixing it;
c) wet-granulating the blend received from step (b) with a solution comprising the binder;
d) drying and milling the granulate of step (c);
e) lubricating the granulate with a lubricant in a suitable blender;
f) compressing the granulate into core tablets.