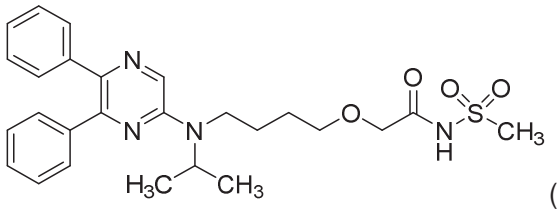
SUMMARY

In one aspect, there is provided 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.

In another aspect, there is provided a pharmaceutical composition as described herein for use as a medicament

In yet another aspect, the present disclosure provides a pharmaceutical composition as described herein for use as a pediatric medicament.

In a further aspect, there is provided a pharmaceutical composition as described herein for use in patients with hepatic impairment or patients experiencing drug drug interaction with CYP 2C8 inhibitors.

In another aspect, the present disclosure provides a 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 in a human subject in need thereof.

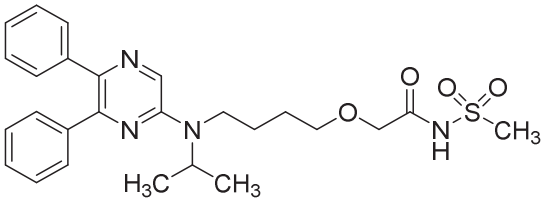
In yet another aspect, there is provided a process for manufacturing the pharmaceutical composition described herein, comprising the steps of a) mixing the compound of formula (I) or a pharmaceutically acceptable salt, solvate, hydrate or morphological form thereof with a filler; b) adding a filler and 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; and f) compressing the granulate into core tablets.

DETAILED DESCRIPTION

The present invention provides a means for treating pediatric patients with e.g. PAH, which is effective and safe for children with different age classes, such as ≥ 2 to < 6 years of age, ≥ 6 to < 12 years of age and ≥ 12 to < 18 years of age.

Moreover, the present invention provides a means for treating patients with e.g. PAH, suffering from hepatic impairment or experiencing drug drug interaction with CYP 2C8 inhibitors.

1) A first embodiment relates to 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.

Thereby, the abbreviation “mcg” stands for microgram, i.e. 1 x 10^{-6} of a gram.

In a preferred embodiment, the pharmaceutical composition comprises the compound of formula (I) in the amount of 80 to 160 mcg, more preferably in the amount of 90 to 110 ug mcg and 140 to 160 mcg, and most preferably in the amount of 93 to 107 mcg and 143 to 157 mcg, e.g. 100 mcg with a tolerance of ± 7% and 150 mcg with a tolerance of ± 7%. Thereby, the tolerance is applied to a group of 20 tablets.

Preferably, the compound of formula (I), namely 2-{4-[N-(5,6-diphenylpyrazin-2-yl)-N-isopropylamino]butyloxy}-N-(methylsulfonyl)acetamide, in crystalline form, especially in essentially pure crystalline form (preferably in essentially pure crystalline form I or essentially pure crystalline form II as disclosed in WO2010/150865 / EP2447254), is used for the preparation of said composition.

2) A further embodiment relates to the composition according to embodiment 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.