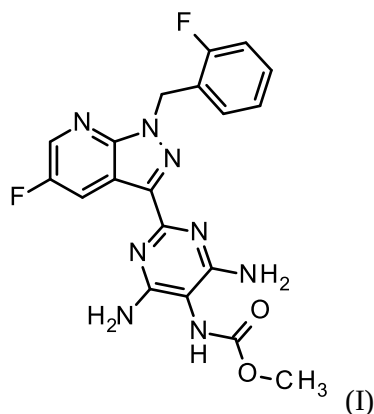


Claims

1. Process for producing an active compound product of the compound methyl {4,6-diamino-2-[5-fluoro-1-(2-fluorobenzyl)-1H-pyrazolo[3,4-b]pyridin-3-yl]pyrimidin-5-yl}carbamate of formula (I)



in the crystalline form of modification I, wherein the x-ray diffractogram of the compound of the formula (I) in modification I exhibits peak maxima of the 2 theta angle at 5.9, 6.9, 22.7,

wherein

- a) the compound of formula (I) in solid form is dissolved at a temperature of 30-100°C in one or more polar and/or aprotic solvents or in one or more polar and/or aprotic solvents in combination with at least one wetting agent selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, tetrahydrofuran, acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane and methyl-THF,
- b) the dissolved compound of formula (I) is subsequently crystallized out of the solution by addition of water as antisolvent or of water in combination with at least one wetting agent selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, tetrahydrofuran, acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane and methyl-THF, wherein the ratio of water to the at least one wetting agent added in step a) or b) is 1:0 - 20:1 w/w and the addition of water or of the combination of water with at least one wetting agent is carried out at a temperature of 30-100°C and over a duration of 0.1 min - 1200 min,

or

water as antisolvent or water in combination with at least one wetting agent is initially charged and the compound of formula (I) dissolved according to step a) is added, wherein the at least one wetting agent, the ratio of water to the at least one wetting agent added in step

a) and/or b), the temperature and the duration over which the addition of the dissolved compound is carried out are as specified above;

c) the suspension formed is subsequently cooled to a temperature of 5-50°C at a cooling rate of 1-60 K/h and

5 d) the crystals formed in step b) are subsequently agglomerated to afford active compound product by addition of an agglomeration liquid, wherein in the case where a wetting agent was added in step a) and/or b) the ratio of the mass of the agglomeration liquid to the sum of the mass of the compound of formula (I) plus the mass of the at least one wetting agent added in step a) and/or b) is 0.3 to 2.0.

10 2. Process according to Claim 1, wherein the at least one polar and/or aprotic solvent in step a) is selected from the group consisting of DMSO, N-methyl-2-pyrrolidone (NMP), dimethylacetamide (DMAc) and dimethylformamide (DMF) or combinations thereof with at least one wetting agent selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, tetrahydrofuran, acetonitrile, acetone, methyl ethyl ketone, 1,4-dioxane and
15 methyl-THF.

3. Process according to Claim 1 or 2, wherein step a) employs DMSO as solvent in combination with ethanol as wetting agent, wherein the ratio between DMSO and ethanol is 1:0 to 5:1 w/w.

4. Process according to any of Claims 1 to 3, wherein step a) is followed by a filtration.

20 5. Process according to any of Claims 1 to 4, wherein in step b) the dissolved compound of formula (I) is crystallized out of the solution by addition of water as antisolvent or water in combination with at least one wetting agent selected from the group consisting of methanol, ethanol, n-propanol and isopropanol, wherein the ratio of water to the at least one wetting agent added in step a) or b) is 1:0-12:1 w/w and the addition of water or of the combination
25 of water with at least one wetting agent is carried out at a temperature of 50-90°C and over a period of 0.1 min-360 min,

or

30 water as antisolvent or water in combination with at least one wetting agent is initially charged and the compound of formula (I) dissolved according to step a) is added, wherein the at least one wetting agent, the ratio of water to the at least one wetting agent added in step a) and/or b), the temperature and the duration over which the addition of the dissolved compound is carried out are as specified above.

6. Process according to any of Claims 1 to 5, wherein in step c) the suspension formed is cooled to a temperature of 10-30°C at a cooling rate of 5-45 K/h.
7. Process according to any of Claims 1 to 6, wherein the agglomeration liquid employed in step d) is selected from the group consisting of esters selected from methyl acetate, ethyl acetate, n-propyl acetate, isopropyl acetate, n-butyl acetate, isobutyl acetate, methyl propanoate, ethyl propanoate, n-propyl propanoate, isopropyl propanoate, n-butyl propanoate, isobutyl propanoate, methyl butanoate, ethyl butanoate, n-propyl butanoate, isopropyl butanoate, n-butyl butanoate and isobutyl butanoate; ethers selected from dimethyl ether, diethyl ether, ethyl methyl ether, di-n-propyl ether, ethyl n-propyl ether, methyl tert-butyl ether and tetrahydrofuran; ketones selected from methyl ethyl ketone and 2-pentanone; organochlorides selected from CCl₄, CHCl₃, CH₂Cl₂, CH₃Cl, and C₂H₄Cl₂; and toluene.
8. Process according to any of Claims 1 to 7, wherein the active compound product formed in step d) is isolated and dried in step e), wherein after isolation the active compound product is washed initially with a C₁-C₄ alcohol and subsequently with an acetate selected from methyl acetate, ethyl acetate, n-propyl acetate, isopropyl acetate, n-butyl acetate and isobutyl acetate and is subsequently dried under reduced pressure with a nitrogen stream at a temperature of 15-75°C.
9. Process according to Claim 8, wherein after isolation and drying the active compound product is comminuted in step f).