

Claims

1. An aqueous pharmaceutical composition comprising:
 - 4-((*R*)-2-[[6-((*S*)-3-methoxy-pyrrolidin-1-yl)-2-phenyl-pyrimidine-4-carbonyl]-amino]-3-phosphono-propionyl)-piperazine-1-carboxylic acid butyl ester;
- 5 • a pharmaceutically acceptable buffer; and
- water;
- wherein the aqueous pharmaceutical composition has a pH value between 8.2 and 12.0.
2. An aqueous pharmaceutical composition according to claim 1, wherein the sum of the
 10 amount of 4-((*R*)-2-[[6-((*S*)-3-methoxy-pyrrolidin-1-yl)-2-phenyl-pyrimidine-4-carbonyl]-amino]-3-phosphono-propionyl)-piperazine-1-carboxylic acid butyl ester, of the amount of the pharmaceutically acceptable buffer and of the amount of water is at least 95 ww% of the aqueous pharmaceutical composition.
3. An aqueous pharmaceutical composition according to claim 1, consisting essentially of:
 - 15 • 4-((*R*)-2-[[6-((*S*)-3-methoxy-pyrrolidin-1-yl)-2-phenyl-pyrimidine-4-carbonyl]-amino]-3-phosphono-propionyl)-piperazine-1-carboxylic acid butyl ester in an amount between 0.7 to 7.0 ww%;
 - a pharmaceutically acceptable buffer selected from a boric acid buffer or an arginine buffer;
 - 20 • water; and
 - optionally an inorganic salt of an alkali metal or an alkaline earth metal;
 - wherein the aqueous pharmaceutical composition has a pH value between 8.7 and 9.5.
 - 4. An aqueous pharmaceutical composition according to any one of claims 1 or 2,
 25 wherein the mass concentration of 4-((*R*)-2-[[6-((*S*)-3-methoxy-pyrrolidin-1-yl)-2-phenyl-pyrimidine-4-carbonyl]-amino]-3-phosphono-propionyl)-piperazine-1-carboxylic acid butyl ester in the aqueous pharmaceutical composition is between 6 mg/mL and 60 mg/mL.
 - 5. An aqueous pharmaceutical composition according to any one of claims 1 or 2, wherein the mass concentration of 4-((*R*)-2-[[6-((*S*)-3-methoxy-pyrrolidin-1-yl)-2-phenyl-pyrimidine-
 30 4-carbonyl]-amino]-3-phosphono-propionyl)-piperazine-1-carboxylic acid butyl ester in the aqueous pharmaceutical composition is 32 mg/mL $\pm$ 3.2 mg/mL.
 - 6. An aqueous pharmaceutical composition according to any one of claims 1, 2, 4 or 5, wherein the pharmaceutically acceptable buffer is selected from ammonium buffer, boric acid buffer, carbonate buffer, phosphate buffer, arginine buffer, glycine buffer, histidine
 35 buffer, meglumine buffer, or tris(hydroxymethyl)aminomethane buffer.

7. An aqueous pharmaceutical composition according to any one of claims 1 to 5, wherein the pharmaceutically acceptable buffer is boric acid buffer.
8. An aqueous pharmaceutical composition according to any one of claims 1 to 5, wherein the pharmaceutically acceptable buffer is arginine buffer.
- 5 9. An aqueous pharmaceutical composition according to any one of claims 1 to 8, wherein the molar concentration of the pharmaceutically acceptable buffer in the aqueous pharmaceutical composition is between 40 mmol/L and 100 mmol/L.
10. An aqueous pharmaceutical composition according to any one of claims 1 to 9, wherein the aqueous pharmaceutical composition has a pH value between 8.7 and 9.5.
- 10 11. An aqueous pharmaceutical composition according to any one of claims 1 to 10, wherein the aqueous pharmaceutical composition comprises sodium chloride.
12. An aqueous pharmaceutical composition according to any one of claims 1 to 11, wherein the osmolality of the aqueous pharmaceutical composition is between 230 mOsm/kg and 1000 mOsm/kg.
- 15 13. An aqueous pharmaceutical composition according to any one of claims 1 to 12, wherein the aqueous pharmaceutical composition is in a container and wherein the container is selected from a vial, an ampoule, a cartridge, or a syringe.
14. An aqueous pharmaceutical composition according to any one of claims 1 to 13, wherein the amount of 4-((*R*)-2-[[6-((*S*)-3-methoxy-pyrrolidin-1-yl)-2-phenyl-pyrimidine-
20 4-carbonyl]-amino]-3-phosphono-propionyl)-piperazine-1-carboxylic acid butyl ester in the aqueous pharmaceutical composition after storage for 1 year at 25°C is at least 80% of the amount of 4-((*R*)-2-[[6-((*S*)-3-methoxy-pyrrolidin-1-yl)-2-phenyl-pyrimidine-4-carbonyl]-
amino]-3-phosphono-propionyl)-piperazine-1-carboxylic acid butyl ester in the aqueous
25 pharmaceutical composition.
15. A container comprising an aqueous pharmaceutical composition according to any one of claims 1 to 14, wherein the container is selected from a vial, an ampoule, a cartridge, or a syringe.
16. A method for the preparation of a container according to claim 15, wherein the
30 aqueous pharmaceutical composition is filled in the container using aseptic processing.
17. Use of an aqueous pharmaceutical composition according to any one of claims 1 to 14 in the preparation of a medicament for the prevention or treatment of a disease or disorder, wherein the disease or disorder is selected from acute arterial thromboses or acute venous thromboses.

18. Use of an aqueous pharmaceutical composition according to any one of claims 1 to 14 in the preparation of a medicament for the prevention or treatment of acute myocardial infarction.
19. Use of an aqueous pharmaceutical composition according to any one of claims 1 to 5 14 in the preparation of a medicament for the emergency treatment of suspected acute myocardial infarction by patient self-administration prior to hospitalization.
20. Use of an aqueous pharmaceutical composition according to any one of claims 1 to 14 in the preparation of a medicament for use according to any one of claims 17 to 19, wherein the aqueous pharmaceutical composition is to be administered by subcutaneous 10 administration.