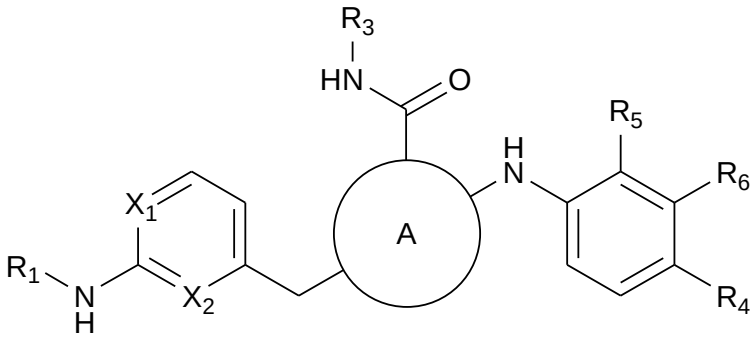
CLAIMS

1. A composition comprising a compound represented by general formula (1) below or a pharmaceutically acceptable salt thereof, or a pharmaceutically acceptable solvate of said compound or salt, and a dispersant:

[Chemical Formula 1]

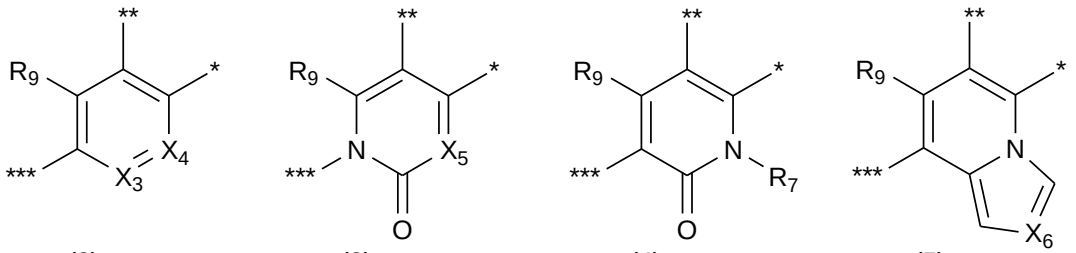


(1)

wherein:

ring A is a group represented by general formula (2), (3), (4) or (5) below (where the bonds denoted by *, ** and *** are bonded to −NH−, −CONH− and $-CH_2-$, respectively):

[Chemical Formula 2]



(2) (3) (4) (5)

X_1, X_2, X_3, X_4, X_5 and X_6 are each independently $-CR_2=$ or −N=;

R_2 is a hydrogen atom, a halogen atom, or a C1-6 alkyl group;

R_1 is $-S(=O)_2-NH-R_8$ or $-S(=O)_2-R_8$;

R_8 is a hydrogen atom, a C1-6 alkyl group (the C1-6 alkyl group being optionally substituted with a halogen atom, a hydroxy group, a C1-6 alkoxy group, a C3-6 cycloalkyl group or a C3-6 heterocycloalkyl group), a monocyclic or bicyclic C3-6 cycloalkyl group (the C3-6 cycloalkyl group being optionally substituted with a C1-6 alkyl group or a C1-6 alkoxy group), or a monocyclic or bicyclic C3-6 heterocycloalkyl group;

R_3 is a hydrogen atom, a C1-6 alkyl group (the C1-6 alkyl group being optionally substituted with a halogen atom, a hydroxy group or a C1-6 alkoxy group), a C3-6 cycloalkyl group (the C3-6 cycloalkyl group being optionally substituted with a halogen atom or a C1-6 alkyl group), or a C1-6 alkoxy group (the C1-6 alkoxy group being optionally substituted with a halogen atom, a hydroxy group or a C1-6 alkoxy group);

R_5 is a halogen atom or a C1-6 alkyl group;

R_6 is a hydrogen atom, a halogen atom or a C1-6 alkyl group and R_4 is a hydrogen atom, a halogen atom, a C1-6 alkyl group, a C2-7 alkenyl group, a C2-7 alkynyl group, a C3-6 cycloalkyl group or a C1-6 alkylthio group, or R_6 and R_4 form an unsaturated hetero 5-membered ring together with the carbon atoms to which they are bonded;

R_7 is a hydrogen atom or a C1-6 alkyl group; and

R_9 is a hydrogen atom, a halogen atom, or a C1-6 alkyl group.

2. The composition according to claim 1, wherein said dispersant is at least one selected from the group consisting of methylcellulose,

polyvinyl alcohol, hydroxypropylcellulose, copolyvidone, hydroxypropylmethylcellulose, methacrylic acid copolymer, polyvinylpyrrolidone, and hypromellose acetate succinate.

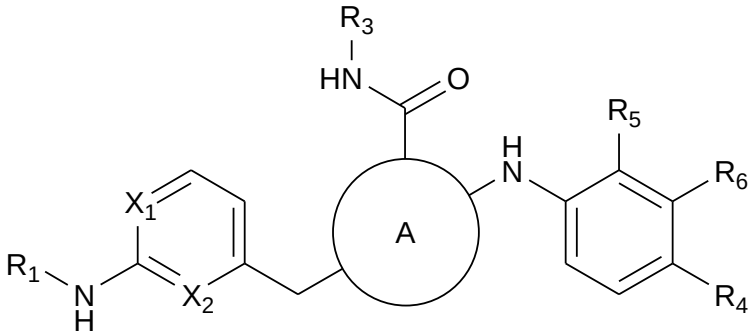
3. The composition according to claim 1 or 2, wherein said dispersant is methylcellulose.

4. The composition according to any one of claims 1 to 3, wherein the content of said dispersant is 0.1 to 20 parts by weight relative to 1 part by weight of said compound of general formula (1), said salt or said solvate.

5. The composition according to any one of claims 1 to 4, further comprising a basic compound.

6. A composition comprising a compound represented by general formula (1) below or a pharmaceutically acceptable salt thereof, or a pharmaceutically acceptable solvate of said compound or salt, and a basic compound:

[Chemical Formula 3]

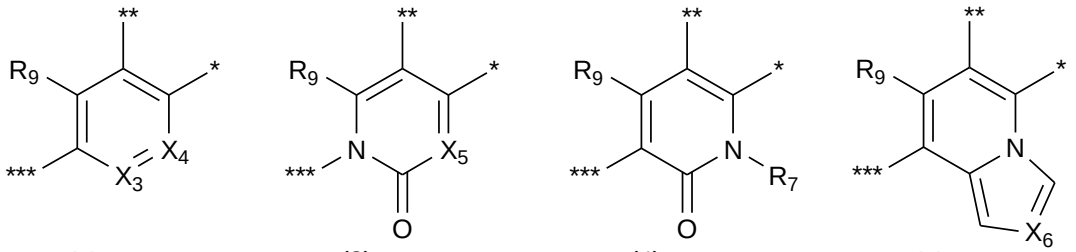


(1)

wherein:

ring A is a group represented by general formula (2), (3), (4) or (5) below (where the bonds denoted by *, ** and *** are bonded to −NH−, −CONH− and $-CH_2-$, respectively):

[Chemical Formula 4]



(2) (3) (4) (5)

X_1, X_2, X_3, X_4, X_5 and X_6 are each independently $-CR_2=$ or −N=;

R_2 is a hydrogen atom, a halogen atom, or a C1-6 alkyl group;

R_1 is $-S(=O)_2-NH-R_8$ or $-S(=O)_2-R_8$;

R_8 is a hydrogen atom, a C1-6 alkyl group (the C1-6 alkyl group being optionally substituted with a halogen atom, a hydroxy group, a C1-6 alkoxy group, a C3-6 cycloalkyl group or a C3-6 heterocycloalkyl group), a monocyclic or bicyclic C3-6 cycloalkyl group (the C3-6 cycloalkyl group being optionally substituted with a C1-6 alkyl group or a C1-6 alkoxy group), or a monocyclic or bicyclic C3-6 heterocycloalkyl group;

R_3 is a hydrogen atom, a C1-6 alkyl group (the C1-6 alkyl group being optionally substituted with a halogen atom, a hydroxy group or a C1-6 alkoxy group), a C3-6 cycloalkyl group (the C3-6 cycloalkyl group being optionally substituted with a halogen atom or a C1-6 alkyl group), or a C1-6 alkoxy group (the C1-6 alkoxy group being optionally

substituted with a halogen atom, a hydroxy group or a C1-6 alkoxy group);

R_5 is a halogen atom or a C1-6 alkyl group;

R_6 is a hydrogen atom, a halogen atom or a C1-6 alkyl group and R_4 is a hydrogen atom, a halogen atom, a C1-6 alkyl group, a C2-7 alkenyl group, a C2-7 alkynyl group, a C3-6 cycloalkyl group or a C1-6 alkylthio group, or R_6 and R_4 form an unsaturated hetero 5-membered ring together with the carbon atoms to which they are bonded;

R_7 is a hydrogen atom or a C1-6 alkyl group; and

R_9 is a hydrogen atom, a halogen atom, or a C1-6 alkyl group.

7. The composition according to claim 5 or 6, wherein said basic compound is at least one selected from the group consisting of meglumine, arginine, histidine, magnesium oxide, calcium silicate, and magnesium stearate.

8. The composition according to any one of claims 5 to 7, wherein said basic compound is meglumine.

9. The composition according to any one of claims 5 to 8, wherein the content of said basic compound is 0.2 to 40 parts by weight relative to 1 part by weight of said compound of general formula (1), said salt or said solvate.

10. The composition according to any one of claims 1 to 9, wherein:

ring A is a group represented by general formula (2) or (4);

R_8 is a hydrogen atom, a C1-6 alkyl group (the C1-6 alkyl group being optionally substituted with a halogen atom, a hydroxy group or a C1-6 alkoxy group), or a monocyclic C3-6 cycloalkyl group (the C3-6 cycloalkyl group being optionally substituted with a C1-6 alkyl group);

R_3 is a hydrogen atom, a C1-6 alkyl group, a C3-6 cycloalkyl group, or a C1-6 alkoxy group (the C1-6 alkoxy group being optionally substituted with a hydroxy group);

R_6 is a hydrogen atom, a halogen atom or a C1-6 alkyl group and R_4 is a halogen atom or a cyclopropyl group; and

R_7 is a hydrogen atom or a methyl group.

11. The composition according to any one of claims 1 to 10, wherein said compound of general formula (1) is 2-(4-cyclopropyl-2-fluoroanilino)-3,4-difluoro-5-[[3-fluoro-2-(methylsulfamoylamino)pyridin-4-yl]methyl]benzamide.

12. A composition comprising a sodium salt of 2-(4-cyclopropyl-2-fluoroanilino)-3,4-difluoro-5-[[3-fluoro-2-(methylsulfamoylamino)pyridin-4-yl]methyl]benzamide and a dispersant, wherein said dispersant is methylcellulose.

13. A composition comprising a sodium salt of 2-(4-cyclopropyl-2-fluoroanilino)-3,4-difluoro-5-[[3-fluoro-2-(methylsulfamoylamino)pyridin-4-yl]methyl]benzamide and a basic compound, wherein said basic compound is meglumine.

14. A composition comprising a sodium salt of 2-(4-cyclopropyl-2-fluoroanilino)-3,4-difluoro-5-[[3-fluoro-2-(methylsulfamoylamino)pyridin-4-yl]methyl]benzamide, a dispersant, and a basic compound, wherein said dispersant is methylcellulose and said basic compound is meglumine.

~~12~~15. The composition according to any one of claims 1 to ~~11~~14, further comprising a pharmaceutically acceptable excipient.

~~13~~16. The composition according to any one of claims 1 to ~~12~~15, in the form of a capsule ~~or a tablet~~.

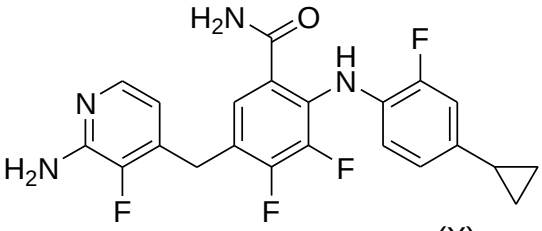
17. The composition according to any one of claims 1 to 15, in the form of a tablet.

~~14~~18. A method for producing the composition according to any one of claims 1 to ~~13~~17, the method comprising providing a mixture containing: said compound of general formula (1), said salt or said solvate; and said dispersant and/or said basic compound.

~~15~~19. A composition comprising 2-(4-cyclopropyl-2-fluoroanilino)-3,4-difluoro-5-[[3-fluoro-2-(methylsulfamoylamino)pyridin-4-yl]methyl]benzamide or a pharmaceutically acceptable salt thereof, or a pharmaceutically acceptable solvate of said compound or salt, together with a compound represented by formula (X) below, wherein the content of said compound of formula (X) is

3.0% by weight or less with respect to the content of said 2-(4-cyclopropyl-2-fluoroanilino)-3,4-difluoro-5-[[3-fluoro-2-(methylsulfamoylamino)pyridin-4-yl]methyl]benzamide, said salt or said solvate.

[Chemical Formula 5]



(X)