CLAIMS

1. A pharmaceutical composition for oral administration comprising:

4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof, as an active pharmaceutical ingredient; and

at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-aspartic acid, and L-glutamic acid.

2. The pharmaceutical composition for oral administration according to claim 1, wherein the acid additive is contained in an amount of 0.25 to 5 parts by mass per part by mass of the 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide.

3. The pharmaceutical composition for oral administration according to claim 1, wherein the acid additive is contained in an amount of 0.5 to 2 parts by mass per part by mass of the 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide.

4. The pharmaceutical composition for oral administration according to claim 1, wherein the composition further comprises a diluting agent, and the acid additive is contained in an amount of 0.15 to 6 parts by mass per part by mass of the diluent.

5. The pharmaceutical composition for oral administration according to any one of claims 1 to 4, wherein the acid additive is fumaric acid.

6. The pharmaceutical composition according to any one of claims 1 to 5, wherein a difference in dissolution rate between

an active pharmaceutical ingredient of a pharmaceutical preparation containing an acid additive and an active pharmaceutical ingredient of a pharmaceutical preparation containing no acid additive is above 10%, the pharmaceutical preparations being obtained 15 minutes after a dissolution test according to a dissolution test method described in the Japanese Pharmacopoeia, Sixteenth Edition.

7. The pharmaceutical composition for oral administration according to any one of claims 1 to 5, wherein the AUC and Cmax of the active pharmaceutical ingredient obtained after oral administration of the pharmaceutical composition are 1.5 or more times larger than the AUC and Cmax of the pharmaceutical composition containing no acid additive.

8. A method for stabilizing 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition, the method comprising

adding at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-aspartic acid, and L-glutamic acid to the pharmaceutical composition.

9. A method for improving dissolution of 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition, the method comprising

adding at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-aspartic acid, and L-glutamic acid to the pharmaceutical composition.

10. A method for improving absorption of 4-((1-methylpyrrol-2-

yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition, the method comprising

adding at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-aspartic acid, and L-glutamic acid to the pharmaceutical composition.

11. Use of at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-aspartic acid, and L-glutamic acid for stabilizing 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition.

12. Use of at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-aspartic acid, and L-glutamic acid for improving dissolution of 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition.

13. Use of at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-aspartic acid, and L-glutamic acid for improving absorption of 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition.

14. Use of at least one acid additive selected from the group consisting of adipic acid, succinic acid, fumaric acid, L-

aspartic acid, and L-glutamic acid for producing a pharmaceutical composition for oral administration comprising 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof.

CLAIMS

1. A pharmaceutical composition for oral administration comprising:

4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof, as an active pharmaceutical ingredient; and

at least one acid additive, the acid additive including fumaric acid.

2. The pharmaceutical composition for oral administration according to claim 1, wherein the acid additive is contained in an amount of 0.25 to 5 parts by mass per part by mass of the 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide.

3. The pharmaceutical composition for oral administration according to claim 1, wherein the acid additive is contained in an amount of 0.5 to 2 parts by mass per part by mass of the 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide.

4. The pharmaceutical composition for oral administration according to claim 1, wherein the composition further comprises a diluting agent, and the acid additive is contained in an amount of 0.15 to 6 parts by mass per part by mass of the diluent.

5. The pharmaceutical composition according to any one of claims 1 to 4, wherein a difference in dissolution rate between an active pharmaceutical ingredient of a pharmaceutical preparation containing an acid additive and an active pharmaceutical ingredient of a pharmaceutical

preparation containing no acid additive is above 10%, the pharmaceutical preparations being obtained 15 minutes after a dissolution test according to a dissolution test method described in the Japanese Pharmacopoeia, Sixteenth Edition.

6. The pharmaceutical composition for oral administration according to any one of claims 1 to 4, wherein the AUC and Cmax of the active pharmaceutical ingredient obtained after oral administration of the pharmaceutical composition are 1.5 or more times larger than the AUC and Cmax of the pharmaceutical composition containing no acid additive.

7. A method for stabilizing 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition, the method comprising

adding at least one acid additive to the pharmaceutical composition, the acid additive including fumaric acid.

8. A method for improving dissolution of 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition, the method comprising

adding at least one acid additive to the pharmaceutical composition, the acid additive including fumaric acid.

9. A method for improving absorption of 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition, the method comprising

adding at least one acid additive to the

pharmaceutical composition, the acid additive including fumaric acid.

10. Use of at least one acid additive including fumaric acid for stabilizing 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition.

11. Use of at least one acid additive including fumaric acid for improving dissolution of 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition.

12. Use of at least one acid additive including fumaric acid for improving absorption of 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof contained in a pharmaceutical composition.

13. Use of at least one acid additive including fumaric acid for producing a pharmaceutical composition for oral administration comprising 4-((1-methylpyrrol-2-yl)-carbonyl)-N-(4-(4-morpholin-1-yl-carbonylpiperidin-1-yl)-phenyl)-1-piperazinecarboxamide, a salt thereof, or a solvate thereof.