CLAIMS

1. A pharmaceutical composition comprising 6-ethyl-3-{3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]anilino}-5-[(oxan-4-yl)amino]pyrazine-2-carboxamide or a pharmaceutically acceptable salt thereof, sucralose, and two or more sugars and/or sugar alcohols,

wherein the two or more sugars and/or sugar alcohols comprise:

mannitol; and

one of the group consisting of isomalt hydrate, maltitol, sorbitol, sucrose, and trehalose; and

wherein the pharmaceutical composition is a tablet.

2. The pharmaceutical composition according to claim 1, wherein one of the two or more sugars and/or sugar alcohols is isomalt hydrate.

3. The pharmaceutical composition according to claim 1 or 2, wherein a content of the isomalt hydrate, maltitol, sorbitol, sucrose, or trehalose described in claim 1 or 2 with respect to a weight of the pharmaceutical composition is 1% by weight to 20% by weight.

4. The pharmaceutical composition according to claim 1 or 2, wherein the isomalt hydrate, maltitol, sorbitol, sucrose, or trehalose described in claim 1 or 2 is used as a binder.

5. The pharmaceutical composition according to any one of claims 1 to 4, wherein the pharmaceutically acceptable salt thereof is a hemifumarate.

6. The pharmaceutical composition according to any one of claims 1 to 5, further comprising a disintegrating agent.

7. The pharmaceutical composition according to any one of claims 1 to 6,
wherein, after storing the pharmaceutical composition according to any one of claims 1 to 6 at 40°C and 75% relative humidity for 1 month, a dissolution rate of 6-ethyl-3-{3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]anilino}-5-[(oxan-4-yl)amino]pyrazine-2-carboxamide after 15 minutes from the beginning of a Dissolution Test, a paddle method using 900 mL of 0.1 mol/L hydrochloric acid described in the Japanese Pharmacopoeia, Seventeenth Edition is 85% or more; or
wherein, after storing the pharmaceutical composition according to any one of claims 1 to 6 at 40°C and 75% relative humidity for 2 months and/or 3 months, a dissolution rate of 6-ethyl-3-{3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]anilino}-5-[(oxan-4-yl)amino]pyrazine-2-carboxamide after 15 minutes from the beginning of a Dissolution Test, a paddle method using 900 mL of 0.1 mol/L hydrochloric acid described in the Japanese Pharmacopoeia, Seventeenth Edition is 80% or more.

8. The pharmaceutical composition according to any one of claims 1 to 7, wherein the pharmaceutical composition is dissolved or dispersed in a suitable solvent, and is a solution, suspension, paste, or gel.

9. A pharmaceutical composition comprising 6-ethyl-3-{3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]anilino}-5-[(oxan-4-yl)amino]pyrazine-2-carboxamide hemifumarate, mannitol, sucralose, and isomalt hydrate.

10. A method of producing a pharmaceutical composition comprising 6-ethyl-3-{3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]anilino}-5-[(oxan-4-yl)amino]pyrazine-2-carboxamide or a pharmaceutically acceptable salt thereof, and two or more sugars and/or sugar alcohols, said method comprising:

(1) preparing a binder liquid by dispersing or dissolving at least one sugars and/or sugar alcohols in a solvent;

(2) obtaining a mixture by mixing 6-ethyl-3-{3-methoxy-4-[4-(4-methylpiperazin-1-yl)piperidin-1-yl]anilino}-5-[(oxan-4-yl)amino]pyrazine-2-carboxamide or a pharmaceutically acceptable salt thereof, sucralose, and at least one sugars and/or sugar alcohols; and

(3) spraying or adding the binder liquid obtained in step (1) to the mixture obtained in step (2) to form granules,

wherein the two or more sugars and/or sugar alcohols comprise:

mannitol; and

one of the group consisting of isomalt hydrate, maltitol, sorbitol, sucrose, and trehalose; and

wherein the pharmaceutical composition is a tablet.