[25] The orally disintegrating tablet of the present invention may be used in the treatment of diseases mediated by an acid pump antagonistic activity due to its properties in that the tablet includes the compound represented by formula 1 above, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof.

[26] The diseases mediated by an acid pump antagonistic activity may be at least one selected from the group consisting of gastrointestinal disease, gastroesophageal disease, gastroesophageal reflux disease (GERD), peptic ulcer, gastric ulcer, duodenal ulcer, NSAID-induced ulcer, gastritis, Helicobacter pylori infection, dyspepsia, functional dyspepsia, Zollinger-Ellison syndrome, nonerosive reflux disease (NERD), visceral referred pain, pyrosis, nausea, esophagitis, dysphagia, salivation, airway lesion and asthma, and specifically may be gastroesophageal reflux disease (GERD), but are not limited thereto.

[27] The "gastroesophageal reflux disease (GERD)" may refer to a case in which gastric contents reflux into the esophagus, causing symptoms that interfere with daily life or causing complications, and may be divided into erosive esophagitis (EE) and non-erosive reflux disease (NERD).

[28] The orally disintegrating tablet of the present invention may include a therapeutically effective amount of tegoprazan.

[29] In the present invention, the "therapeutically effective amount" may refer to an amount effective in preventing or treating the diseases mediated by an acid pump antagonistic activity.

[30] The orally disintegrating tablet of the present invention may include wet granules, and the wet granules may include a sweetening agent.

[31] In the present invention, the wet granules may include the compound represented by formula 1, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof, and a sweetening agent at a weight ratio of 1:0.001 to 1:0.4.

[32] The compound represented by formula 1, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof and a sweetening agent may be included specifically at a weight ratio of 1:0.001 to 1:0.4, 1:0.005 to 1:0.35, and 1:0.01 to 1:0.3, more specifically 1:0.05 to 1:0.2, but is not limited thereto.

[33] In this regard, in one specific embodiment of the present invention, it was confirmed that a less total amount of related substances is generated, thereby exhibiting excellent stability, if the orally disintegrating tablet of the present invention includes the compound represented by formula 1, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof and a sweetening agent at a weight ratio of 1:0.05 to 1:0.2 (Table 8).

[34] In the present invention, the sweetening agent may be any one selected from the group consisting of sucralose, aspartame, saccharin, acesulfame potassium, stevioside,

[44] In the present invention, the diluent may be any one selected from the group consisting of mannitol, lactose, starch, microcrystalline cellulose, ludipress (BASF), pearlitol flash (Roqutte), calcium dihydrogen phosphate, dextrose, maltose, erythritol, sucrose, maltitol, trehalose, glucose, xylitol, F-melt (Fujichemical), sorbitol, pre-gelatinized starch, anhydrous calcium hydrogen phosphate, dicalcium phosphate, and mixtures thereof, and specifically may be mannitol, xylitol, pearlitol flash or mixtures thereof, but is not limited thereto.

[45] In the present invention, the diluent may be included in an amount of 1 to 99 wt%, specifically 1 to 99 wt%, 5 to 97 wt%, 10 to 95 wt%, 15 to 92 wt%, and more specifically 20 to 90 wt% based on the total weight of the tablet, but is not limited thereto.

[46] In the present invention, the flavoring agent may be any one selected from the group consisting of peppermint flavor, yogurt flavor, fruit flavor, and mixtures thereof, and specifically may be peppermint flavor, but is not limited thereto. The fruit flavor may be specifically apple flavor, grape flavor, strawberry flavor, or lemon flavor, but is not limited thereto.

[47] In the present invention, the flavoring agent may be included in an amount of 0.01 to 10 wt%, specifically 0.05 to 8 wt%, 0.1 to 6 wt%, 0.2 to 4 wt%, and more specifically 0.3 to 3 wt% based on the total weight of the tablet, but is not limited thereto.

[48] The orally disintegrating tablet of the present invention may further include a sweetening agent in addition to the sweetening agent included in the wet granules, and the sweetening agent to be further included may be any one selected from the group consisting of sucralose, aspartame, saccharin, acesulfame potassium, stevioside, enzymatically modified stevia, sucrose, isomalt, maltitol, mannitol, sorbitol, steviol glycoside, erythritol, xylose, xylitol, lactitol, neotame, ribose, tomatine, polyglycitol, advantam, tagatose, trehalose, glucose, maltose, dextrose, white sugar, fructose, honey, glycyrrhizin, monellin, rubusoside, curculin, corn syrup, lactose, oligosaccharides, and mixtures thereof, and specifically may be maltitol, sucralose, enzymatically modified stevia or mixtures thereof, but is not limited thereto.

[49] The sweetening agent included in the wet granules and the sweetening agent further included therein may be of the same type or different types.

[50] In the present invention, the sweetening agent included in the wet granules may be referred to as a first sweetening agent, and the sweetening agent further included therein may be referred to as a second sweetening agent. In this case, "first," "second," etc. are only used to distinguish a plurality of components, and do not indicate priority thereof.

[51] The orally disintegrating tablet of the present invention may include the sweetening agent in an amount of 0.01 to 10 wt%, specifically 0.01 to 5 wt%, and more

preparation of a drug for preventing or treating diseases mediated by an acid pump antagonistic activity.

[95] The diseases mediated by an acid pump antagonistic activity may be at least one selected from the group consisting of gastrointestinal disease, gastroesophageal disease, gastroesophageal reflux disease (GERD), peptic ulcer, gastric ulcer, duodenal ulcer, NSAID-induced ulcer, gastritis, Helicobacter pylori infection, dyspepsia, functional dyspepsia, Zollinger-Ellison syndrome, nonerosive reflux disease (NERD), visceral referred pain, pyrosis, nausea, esophagitis, dysphagia, salivation, airway lesion and asthma, and specifically may be gastroesophageal reflux disease (GERD), but are not limited thereto.

[96] In the medicinal use of the orally disintegrating tablet of the present invention, the contents described in the foregoing item of the orally disintegrating tablet may be equally applied as long as there is no contradiction. Thus, the wet granules, the components included therein, the content of respective components, the weight ratio of respective components, uses, effects, etc. of the foregoing orally disintegrating tablet may be directly applied to the medicinal use of the orally disintegrating tablet as long as there is no contradiction.

Advantageous Effects of Invention

[97] The orally disintegrating tablet of the present invention may disintegrate in the oral cavity within a short time and exhibit excellent sensory properties such as a masked bitter taste, etc., thereby greatly improving a patient's compliance with medication.

[98] In addition, compared to the existing method for masking a bitter taste in which drug particles are coated with a polymeric substance or a lipid component or coated by using an enteric or gastric-soluble base, this preparation process is simple and economical, as well as exhibits a fast disintegration rate and an excellent release rate (speed) without any delay in drug disintegration and release, and produces a uniform tablet and small granular particles, thereby improving a patient's compliance with medication.

[99] In addition, compared to the existing method for masking a bitter taste by simply adding various patterns of high sweetening agents and flavoring agents, this process show no change in appearance caused by moisture and heat (for example, occurrence of dark brown spots) on a surface of the tablet, thereby exhibiting excellent stability of appearance and produce a less total amount of related substances, thereby exhibiting excellent stability.

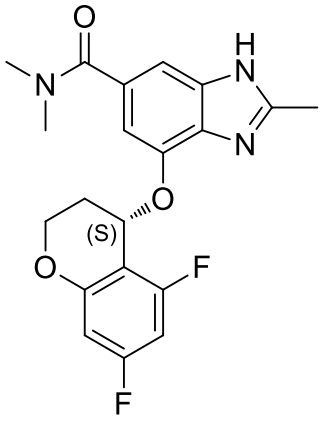
Brief Description of Drawings

[100] FIG. 1 is a view showing a drug dissolution rate at pH 1.2 with respect to the tablet prepared according to Example 1 and the K-CAP tablet.

Claims

1. An orally disintegrating tablet comprising wet granules including a compound represented by formula 1 below, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof; and a sweetening agent:

[Formula 1]



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2. The orally disintegrating tablet of claim 1, wherein the wet granules comprise the compound represented by formula 1, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof, and the sweetening agent at a weight ratio of 1:0.001 to 1:0.4.

3. The orally disintegrating tablet of claim 2, wherein the wet granules comprise the compound represented by formula 1, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof, and the sweetening agent at a weight ratio of 1:0.05 to 1:0.2.

4. The orally disintegrating tablet of claim 1, wherein the sweetening agent is one selected from the group consisting of sucralose, aspartame, saccharin, acesulfame potassium, stevioside, enzymatically modified stevia, sucrose, isomalt, maltitol, mannitol, sorbitol, steviol glycoside, erythritol, xylose, xylitol, lactitol, neotame, ribose, tomatine, polyglycitol, advantam, tagatose, trehalose, glucose, maltose, dextrose, white sugar, fructose, honey, glycyrrhizin, monellin, rubusoside, curculin, corn syrup, lactose, oligosaccharides, and mixtures thereof.

5. The orally disintegrating tablet of claim 1, wherein the sweetening agent is

comprised in an amount of 0.01 to 10 wt% based on the total weight of the tablet.

6. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet further comprises a disintegrant.

7. The orally disintegrating tablet of claim 6, wherein the disintegrant is one selected from the group consisting of crospovidone, croscarmellose sodium, sodium starch glycolate, alginic acid, sodium alginate, low-substituted hydroxypropyl cellulose, carboxymethyl cellulose, corn starch, pregelatinized starch, microcrystalline cellulose, hydroxypropyl cellulose, sodium bicarbonate, and mixtures thereof.

8. The orally disintegrating tablet of claim 6, wherein the disintegrant is comprised in an amount of 1 to 50 wt% based on the total weight of the tablet.

9. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet further comprises diluents, flavoring agents, sweetening agents, lubricants, or mixtures thereof.

10. The orally disintegrating tablet of claim 9, wherein the diluent is one selected from the group consisting of mannitol, lactose, starch, microcrystalline cellulose, ludipress, pearlitol flash, calcium dihydrogen phosphate, dextrose, maltose, erythritol, sucrose, maltitol, trehalose, glucose, xylitol, F-melt, sorbitol, pregelatinized starch, anhydrous calcium hydrogen phosphate, dicalcium phosphate, and mixtures thereof.

11. The orally disintegrating tablet of claim 9, wherein the diluent is comprised in an amount of 1 to 99 wt% based on the total weight of the tablet.

12. The orally disintegrating tablet of claim 9, wherein the flavoring agent is one selected from the group consisting of peppermint flavor, yogurt flavor, fruit flavor, and mixtures thereof.

13. The orally disintegrating tablet of claim 9, wherein the flavoring agent is comprised in an amount of 0.01 to 10 wt% based on the total weight of the tablet.

14. The orally disintegrating tablet of claim 9, wherein the lubricant is one selected from the group consisting of stearic acid, stearic acid metal salts, talc, colloidal silica, sucrose fatty acid ester, hydrogenated vegetable oil, wax, glycerin fatty acid ester, glycerol dibehenate, and mixtures thereof.

15. The orally disintegrating tablet of claim 9, wherein the lubricant is comprised in an amount of 0.1 to 10 wt% based on the total weight of the tablet.

16. The orally disintegrating tablet of claim 1, wherein the wet granules are prepared with a binder solution including one selected from the group consisting of alcohol, water, and a mixture thereof and a sweetening agent.

17. The orally disintegrating tablet of claim 16, wherein the binder solution further comprises a binder or an additive capable of giving binding force.

18. The orally disintegrating tablet of claim 17, wherein the binder or the additive capable of giving binding force is one selected from the group consisting of hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), gelatin, pregelatinized starch, polyvinylpyrrolidone, polyvinyl alcohol, pullulan, polyethylene glycol, natural gum, synthetic gum, copovidone, ethyl cellulose, methacrylate copolymer, and mixtures thereof.

19. The orally disintegrating tablet of claim 1, wherein the wet granules are prepared by high-speed shear granulation or fluidized bed granulation.

20. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet disintegrates within 30 seconds.

21. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet has a masked bitter taste.

22. The orally disintegrating tablet of claim 1, wherein the orally disintegrating tablet is used for preventing or treating diseases mediated by an acid pump antagonistic activity.

23. The orally disintegrating tablet according to claim 22, wherein the diseases mediated by an acid pump antagonistic activity are at least one selected from the group consisting of gastrointestinal disease, gastroesophageal disease, gastroesophageal reflux disease (GERD), peptic ulcer, gastric ulcer, duodenal ulcer, NSAID-induced ulcer, gastritis, Helicobacter pylori infection, dyspepsia, functional dyspepsia, Zollinger-Ellison syndrome, nonerosive reflux disease (NERD), visceral referred pain, pyrosis, nausea, esophagitis, dysphagia, salivation, airway lesion and asthma.

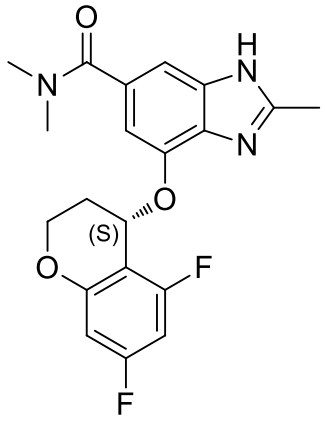
24. A method for preparing an orally disintegrating tablet, comprising:

(1) preparing wet granules including a compound represented by formula 1 below, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof, and a sweetening agent;

(2) preparing a mixture by adding one or more pharmaceutically acceptable additives to the wet granules; and

(3) compressing the mixture into tablets:

[Formula 1]



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25. The method of claim 24, wherein the sweetening agent is one selected from the group consisting of sucralose, aspartame, saccharin, acesulfame potassium, stevioside, enzymatically modified stevia, sucrose, isomalt, maltitol, mannitol, sorbitol, steviol glycoside, erythritol, xylose, xylitol, lactitol, neotame, ribose, tomatine, polyglycitol, advantam, tagatose, trehalose, glucose, maltose, dextrose, white sugar, fructose, honey, glycyrrhizin, monellin, rubusoside, curculin, corn syrup, lactose, oligosaccharides, and mixtures thereof.

26. The method of claim 24, wherein the preparing of wet granules is performed by a wet granulation with a binder solution including one selected from the group consisting of alcohol, water, and a mixture thereof and a sweetening agent.

27. The method of claim 26, wherein the binder solution further comprises a binder or an additive capable of giving binding force.

28. The method of claim 27, wherein the binder or the additive capable of giving binding force is one selected from the group consisting of hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), gelatin, pregelatinized starch, polyvinylpyrrolidone, polyvinyl alcohol, pullulan, polyethylene glycol, natural gum, synthetic gum, copovidone, ethyl cellulose, methacrylate copolymer, and mixtures thereof.

29. The method of claim 26, wherein the wet granulation is a high-speed shear granulation or a fluidized bed granulation.

30. The method of claim 24, wherein the pharmaceutically acceptable additives are disintegrants, diluents, flavoring agents, sweetening agents, lubricants, or mixtures thereof.

31. An orally disintegrating tablet prepared by the preparation method according to any one of claims 24 to 30.

32. Use of the orally disintegrating tablet according to any one of claims 1 to 23 in the manufacture of a medicament for preventing or treating diseases mediated by an acid pump antagonistic activity.