CLAIMS

1. A modified-release pharmaceutical composition comprising:

tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof; and

a release modifying agent.

2. The modified-release pharmaceutical composition of claim 1, wherein the release modifying agent comprises at least one selected from the group consisting of a sustained-release agent and an enteric agent.

3. The modified-release pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises particle comprising, tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient.

4. The modified-release pharmaceutical composition of claim 3, wherein the release modifying agent is contained in the particle.

5. The modified-release pharmaceutical composition of claim 4, wherein the release modifying agent comprises at least one selected from the group consisting of a sustained-release agent and an enteric agent.

6. The modified-release pharmaceutical composition of claim 3, wherein the pharmaceutical composition comprises a release modifying agent-containing layer, which comprises the release modifying agent, formed on the particle.

7. The modified-release pharmaceutical composition of claim 6, wherein the release modifying agent comprises at least one selected from the group consisting of a sustained-release agent and an enteric agent.

8. A modified-release pharmaceutical composition comprising:

a core comprising tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient; and

a release modifying agent-containing layer formed on the core.

9. The modified-release pharmaceutical composition of claim 8, wherein the core comprises:

an inert particle; and

an active ingredient layer, which comprises the active ingredient, positioned on the inert particle.

10. The modified-release pharmaceutical composition of claim 9, wherein the inert particle comprises at least one selected from the group consisting of white sugar, lactose, starch, mannitol, sucrose, dextrin, and microcrystalline cellulose.

11. The modified-release pharmaceutical composition of claim 8, wherein the pharmaceutical composition comprises an organic acid.

12. The modified-release pharmaceutical composition of claim 11, wherein the organic acid is at least one selected from the group consisting of tartaric acid, fumaric acid, succinic acid, citric acid, malic acid, glutamic acid and aspartic acid.

13. The modified-release pharmaceutical composition of claim 9, wherein the inert particle and the active ingredient are comprised in the core at a weight ratio of 5:1 to 1:5.

14. The modified-release pharmaceutical composition of claim 8, wherein the core is a core tablet prepared by tableting a mixture of a granule comprising the active ingredient and a pharmaceutically acceptable additive.

15. The modified-release pharmaceutical composition of claim 8, wherein the core is a granule comprising a mixture comprising the active ingredient and a pharmaceutically acceptable additive.

16. The modified-release pharmaceutical composition of claim 8, wherein the release modifying agent comprises at least one selected from the group consisting of a sustained-release agent and an enteric agent.

17. The modified-release pharmaceutical composition of claim 16, wherein the enteric agent is any one or more selected from the group consisting of ethyl cellulose, cellulose acetate, polyvinyl acetate, cellulose butyrate phthalate, cellulose hydrogen phthalate, cellulose propionate phthalate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methyl cellulose phthalate, polyvinyl acetate, hydroxypropyl methyl acetate, dioxypropyl methyl cellulose succinate, carboxymethyl ethyl cellulose, hydroxypropyl methyl cellulose acetate succinate, and polymers thereof; Shellac; and acrylic acid, methacrylic acid or esters thereof or copolymer formed from thereof.

18. The modified-release pharmaceutical composition of claim 17, wherein the enteric agent is any one or more selected

from the group consisting of methacrylic acid-ethyl acrylate copolymer, methacrylic acid copolymer L, and methacrylic acid copolymer S.

19. The modified-release pharmaceutical composition of claim 18, wherein the enteric agent comprises methacrylic acid copolymer L and methacrylic acid copolymer S at a weight ratio of 1:3 to 1:0.2.

20. The modified-release pharmaceutical composition of claim 18, wherein the enteric agent comprises methacrylic acid-ethyl acrylate copolymer and methacrylic acid copolymer S at a weight ratio of 0.3:1 to 3:1.

21. The modified-release pharmaceutical composition of claim 16, wherein the sustained-release agent comprises one or more selected from the group consisting of polyvinyl alcohol, polyethylene oxide, methacrylic acid copolymer, hydroxypropyl methyl cellulose, ethyl cellulose, povidone, and talc.

22. The modified-release pharmaceutical composition of claim 8, wherein the release modifying agent-containing layer is pH-dependent soluble at pH 5.5 or higher.

23. The modified-release pharmaceutical composition of claim 8, wherein the release modifying agent-containing layer is comprised in an amount of 10 to 70 wt% based on the weight of the pharmaceutical composition.

24. The modified-release pharmaceutical composition of claim 8, wherein the pharmaceutical composition further comprises at least one additional coating layer.

25. The modified-release pharmaceutical composition of claim 8, wherein the core comprises the release modifying agent.

26. The modified-release pharmaceutical composition of claim 25, wherein the pharmaceutical composition comprises:

a core comprising, tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient, and a first release modifying agent; and

a release modifying agent-containing layer, which comprises a second release modifying agent, formed on the core, and

wherein the first release modifying agent and the second release modifying agent each independently comprises at least one selected from the group consisting of a sustained-release agent and an enteric agent.

27. The modified-release pharmaceutical composition of claim 26, wherein the pharmaceutical composition further comprises an additional coating layer comprising a third release modifying agent, between the core and the release modifying agent-containing layer comprising the second release modifying agent.

28. The modified-release pharmaceutical composition of claim 27, wherein the first release modifying agent and the third release modifying agent comprise a sustained-release agent, and the second release modifying agent comprises an enteric agent.

29. The modified-release pharmaceutical composition of any one of claims 1 to 28, wherein the pharmaceutical composition comprises tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient, and

wherein the pharmaceutical composition is for co-administration with an immediate-release pharmaceutical composition which releases the active ingredient immediately.

30. The modified-release pharmaceutical composition of any one of claims 1 to 29, wherein the modified-release pharmaceutical composition is for prevention or treatment of diseases mediated by acid pump antagonistic activity.

31. The modified-release pharmaceutical composition of any one of claims 1 to 30, wherein the pharmaceutical composition is a tablet, a pellet or a granule.

32. A capsule filled with the pharmaceutical composition according to any one of claims 1 to 31.

33. A tablet comprising the pharmaceutical composition according to any one of claims 1 to 31.

34. The tablet of claim 33, wherein the tablet comprises a granule comprising, tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient, and

wherein the granule comprises a core comprising the active ingredient and a sustained-release agent.

35. The tablet of claim 33, wherein the tablet comprises a granule comprising tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient, and

wherein the granule comprises:

a core comprising the active ingredient, or a core comprising the active ingredient and a sustained-release agent; and

an enteric agent-containing layer positioned on the core.

36. A formulation comprising:

a modified-release first pharmaceutical composition according to any one of claims 1 to 31, which comprises, tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient; and

a second pharmaceutical composition which comprises, tegoprazan, an optical isomer thereof, a pharmaceutically acceptable salt thereof, a hydrate or solvate thereof, or a mixture thereof as an active ingredient, and releases the active ingredient immediately.

37. The formulation of claim 36, wherein a weight ratio between the active ingredients comprised in the first pharmaceutical composition and the second pharmaceutical compositionis 5:1 to 1:5 (w:w).

38. The formulation of claim 36, wherein the first pharmaceutical composition and the second pharmaceutical composition exist as separate particles.

39. The formulation of claim 36, wherein the second pharmaceutical composition comprises an inert particle and an

active ingredient layer, which comprises the active ingredient, formed on the inert particle.

40. The formulation of claim 36, wherein the formulation is a capsule or tablet comprising a particle comprising the first pharmaceutical composition and a particle comprising the second pharmaceutical composition.

41. The formulation of claim 40, wherein the formulation is a capsule, and

wherein the first pharmaceutical composition and the second pharmaceutical composition are each independently a powder, a pellet, a granule or a tablet.

42. The formulation of claim 40, wherein the formulation is a tablet, and

wherein the first pharmaceutical composition and the second pharmaceutical composition are each independently a powder, a pellet or a granule.

43. The formulation of claim 42, wherein the formulation is a multilayered-tablet comprising:

a first layer comprising the first pharmaceutical composition; and

a second layer formed on the first layer and comprising the second pharmaceutical composition.

44. The formulation of claim 36, wherein the active ingredient of the first pharmaceutical composition and the active ingredient of the second pharmaceutical composition are comprised in a single particle,

wherein the first pharmaceutical composition comprises:

a core comprising the active ingredient or a core comprising the active ingredient and a sustained-release agent; and

an enteric agent-containing layer formed on the core and surrounding the core, and

wherein the second pharmaceutical composition is positioned on the enteric agent-containing layer and surrounds the enteric agent-containing layer.

45. The formulation of claim 36, wherein the active ingredient of the first pharmaceutical composition and the active ingredient of the second pharmaceutical composition are comprised in a single particle,

wherein the first pharmaceutical composition comprises a core comprising: the active ingredient; and a release modifying agent comprising at least one selected from the group consisting of a sustained-release agent and an enteric agent, and

wherein the second pharmaceutical composition is positioned on the core and surrounds the core.

46. The formulation of claim 44 or 45, wherein the particle is a pellet, a granule or a tablet.

47. The formulation of claim 46, wherein the formulation is a capsule filled with at least one selected from the group consisting of a pellet, a granule and a tablet.

48. The formulation of claim 46, wherein the formulation is a tablet prepared by tableting at least one selected from the group consisting of the pellet and the granule.

49. The formulation of any one of claims 36 to 48, wherein the formulation is for the prevention or treatment of diseases mediated by acid pump antagonistic activity.

50. Use of the modified-release pharmaceutical composition of any one of claims 1 to 31 or the formulation of any one of claims 36 to 49 in the manufacture of a medicament for the prevention or treatment of diseases mediated by acid pump antagonistic activity.