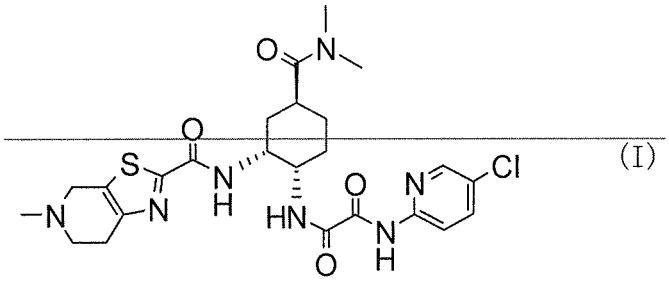
Claims

~~1. A solid pharmaceutical composition containing N^1-(5-chloropyridin-2-yl)-N^2-((1S,2R,4S)-4-[(dimethylamino)carbonyl]-2-{[(5-methyl-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridin-2-yl)carbonyl]amino}cyclohexyl)ethanediamide represented by the following formula (I):~~

~~[Formula 1]~~



(I)

~~or a pharmacologically acceptable salt thereof, or a solvate thereof, wherein the content of the compound represented by formula (I) is 5% by weight or more and 10% by weight or less with respect to the total weight of the pharmaceutical composition, and wherein the dosage form is a tablet.~~

~~2. The pharmaceutical composition according to claim 1, wherein the tablet has a density of 1.2 mg/mm^3 to 1.4 mg/mm^3.~~

~~3. The pharmaceutical composition according to claim 1 or 2, wherein the pharmaceutical composition further~~

~~contains a sugar alcohol and a water-swelling additive as excipients.~~

~~4. The pharmaceutical composition according to claim 3, wherein the sugar alcohol is D-mannitol or erythritol, and the water-swelling additive is pregelatinized starch or crystalline cellulose.~~

~~5. The pharmaceutical composition according to claim 4, wherein the sugar alcohol is D-mannitol, and the water-swelling additive is pregelatinized starch.~~

~~6. The pharmaceutical composition according to claim 5, wherein when the composition is subjected to a dissolution test by the paddle method at a rotation rate of 50 rpm, the composition exhibits an average percentage dissolution of the compound represented by formula (I), in a dissolution test medium having a pH of 6.8, of 60% or higher in 30 minutes after the start of the dissolution test and 80% or higher in 60 minutes after the start.~~

~~7. The pharmaceutical composition according to claim 6, wherein when the composition is subjected to a dissolution test by the paddle method at a rotation rate of 50 rpm, the composition exhibits an average percentage dissolution of the compound represented by formula (I), in a dissolution test medium having a pH of 6.8, of 70%~~

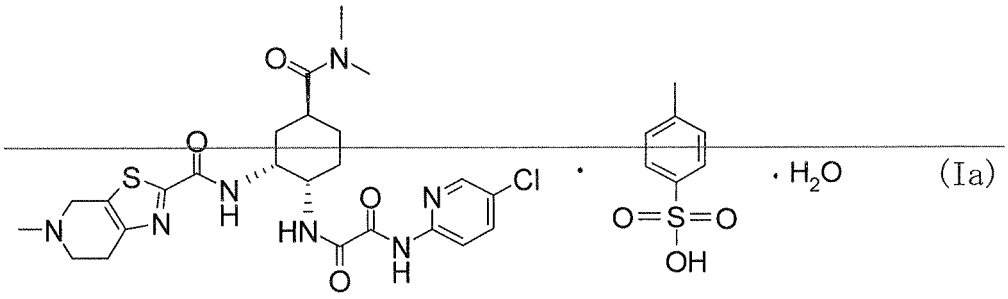
~~or higher in 30 minutes after the start of the dissolution test and 80% or higher in 60 minutes after the start.~~

~~8. The pharmaceutical composition according to any one of claims 1 to 7, which is coated with one or more coating agents selected from a cellulose derivative, a polyvinyl compound, an acrylate derivative, or a saccharide.~~

~~9. The pharmaceutical composition according to claim 8, wherein the coating agents are one or more species selected from the group comprising hypromellose, methylcellulose, ethylcellulose, hydroxypropyl cellulose, polyvinyl alcohol, povidone, vinyl acetate resin, polyvinyl acetal diethylaminoacetate, aminoalkyl methacrylate copolymer RS, ethyl acrylate-methyl methacrylate copolymer dispersion, sucrose, and mannitol.~~

~~10. The pharmaceutical composition according to any one of claims 1 to 9, wherein the compound represented by formula (I) or a pharmacologically acceptable salt thereof, or a solvate thereof is N^1-(5-chloropyridin-2-yl)-N^2-((1S,2R,4S)-4-[(dimethylamino)carbonyl]-2-{[(5-methyl-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridin-2-yl)carbonyl]amino}cyclohexyl)ethanediamide p-toluenesulfonate monohydrate represented by the following formula (Ia):~~

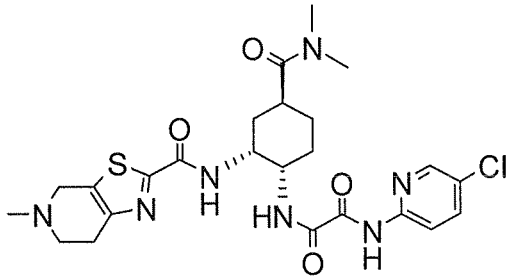
~~[Formula 2]~~



(Ia)

Claims

1. A solid pharmaceutical composition containing N^1-(5-chloropyridin-2-yl)-N^2-((1S,2R,4S)-4-[(dimethylamino)carbonyl]-2-{[(5-methyl-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridin-2-yl)carbonyl]amino}cyclohexyl)ethanediamide of the following formula (I):



(I)

or a pharmacologically acceptable salt thereof, or a hydrate thereof, wherein the content of the compound of formula (I) is 0.5% by weight or more and less than 10% by weight with respect to the total weight of the pharmaceutical composition.

2. The pharmaceutical composition according to claim 1, wherein the dosage form is a tablet.

3. The pharmaceutical composition according to claim 2, wherein the tablet has a density of 1.2 mg/mm^3 to 1.4 mg/mm^3.

4. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition further contains a sugar alcohol and a water-swelling additive as excipients.

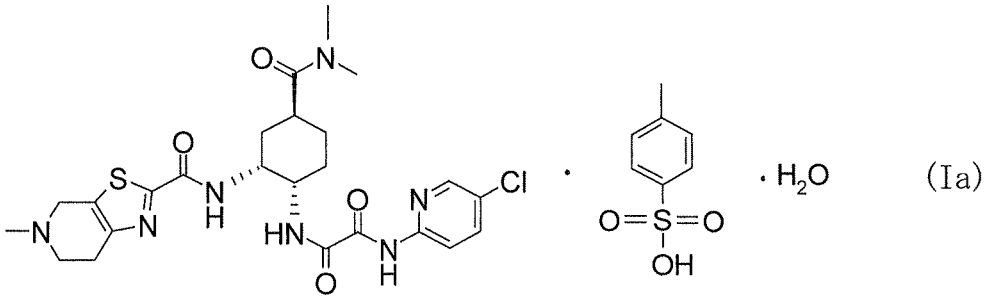
5. The pharmaceutical composition according to claim 4, wherein the sugar alcohol is D-mannitol or erythritol, and the water-swelling additive is pregelatinized starch or crystalline cellulose.

6. The pharmaceutical composition according to claim 5, wherein the sugar alcohol is D-mannitol, and the water-swelling additive is pregelatinized starch.

7. The pharmaceutical composition according to claim 1, wherein, when the pharmaceutical composition is coated with one or more coating agents, the coating agents are one or more species selected from the group consisting of a saccharide, hypromellose, methylcellulose, ethylcellulose, hydroxypropyl cellulose, polyvinyl alcohol, povidone, vinyl acetate resin, polyvinyl acetal diethylaminoacetate, aminoalkyl methacrylate copolymer RS, and ethyl acrylate-methyl methacrylate copolymer dispersion.

8. The pharmaceutical composition according to claim 7, wherein the saccharide is selected from the group consisting of sucrose and mannitol.

9. The pharmaceutical composition according to claim 1, wherein the compound of formula (I) or a pharmacologically acceptable salt thereof, or a hydrate thereof is N^1-(5-chloropyridin-2-yl)-N^2-((1S,2R,4S)-4-[(dimethylamino)carbonyl]-2-{[(5-methyl-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridin-2-yl)carbonyl]amino}cyclohexyl)ethanediamide p-toluenesulfonate monohydrate represented by the following formula (Ia):



(Ia)