[Document Name] Claims

[Claim 1]

An orally administrable pharmaceutical composition comprising α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl) methyl-2,4 (1H,3H)-pyrimidine dione hydrochloride as active ingredients and a sugar having a critical relative humidity of 85% or more at 25°C as an excipient.

[Claim 2]

The orally administrable pharmaceutical composition according to claim 1, wherein the content of the sugar having a critical relative humidity of 85% or more at 25°C is 3.6 pasts by mass or more based on 1 part by mass of α,α,α-trifluorothymidine.

[Claim 3]

The orally administrable pharmaceutical composition according to any of claims 1 to 2, wherein the sugar having a critical relative humidity of 85% or more at 25°C is a disaccharide or a sugar alcohol.

[Claim 4]

The orally administrable pharmaceutical composition according to any of claims 1 to 3, wherein the sugar having a critical relative humidity of 85% or more at 25°C is one or more selected from lactose, sucrose, mannitol, and erythritol.

[Claim 5]

The orally administrable pharmaceutical composition according to any of claims 1 to 4, comprising α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl)methyl-2,4(1H,3H)-pyrimidine dione hydrochloride at a molar ratio of 1:0.5.

[Claim 6]

The orally administrable pharmaceutical composition according to any of claims 1 to 5, comprising one or more selected from low-substituted hydroxypropyl cellulose, carmellose, corn starch, partly pregelatinized starch, and crospovidone as a disintegrating agent.

[Claim 7]

The oral pharmaceutical composition according to claim 6, wherein the content of the disintegrating agent is from 2 to 16% by mass in the total amount of the pharmaceutical composition.

[Claim 8]

The oral pharmaceutical composition according to any of claims 1 to 7, wherein the pharmaceutical composition is in a formulation form of a granule, a compression-molded product, or a mixture.

[Claim 9]

An orally administrable pharmaceutical formulation comprising the orally administrable composition according to any of claims 1 to 8, wherein the composition is coated.

[Document Name] Claims

[Claim 1]

An orally administrable pharmaceutical composition comprising α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl) methyl-2,4 (1H,3H)-pyrimidine dione hydrochloride as active ingredients and a sugar having a critical relative humidity of 85% or more at 25°C as an excipient, and comprising partly pregelatinized starch as disintegrating agent, wherein the content of the partly pregelatinized starch is from 2 to 16% by mass in the total amount of the pharmaceutical composition.

[Claim 2]

The orally administrable pharmaceutical composition according to claim 1, wherein the content of the sugar having a critical relative humidity of 85% or more at 25°C is 3.6 pasts by mass or more based on 1 part by mass of α,α,α-trifluorothymidine.

[Claim 3]

The orally administrable pharmaceutical composition according to claim 1 or 2, wherein the sugar having a critical relative humidity of 85% or more at 25°C is a disaccharide or a sugar alcohol.

[Claim 4]

The orally administrable pharmaceutical composition according to any of claims 1 to 3, wherein the sugar having a critical relative humidity of 85% or more at 25°C is one

or more selected from lactose, sucrose, mannitol, and erythritol.

[Claim 5]

The orally administrable pharmaceutical composition according to any of claims 1 to 4, comprising α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl)methyl-2,4(1H,3H)-pyrimidine dione hydrochloride at a molar ratio of 1:0.5.

[Claim 6]

The orally administrable pharmaceutical composition according to any of claims 1 to 5, wherein the sugar having a critical relative humidity of 85% or more at 25°C is lactose.

[Claim 7]

The oral pharmaceutical composition according to any of claims 1 to 6, wherein the sugar having a critical relative humidity of 85% or more at 25°C is 100% by mass in the total excipient.

[Claim 8]

The oral pharmaceutical composition according to any of claims 1 to 7, wherein the pharmaceutical composition is in a formulation form of a granule, a compression-molded product, or a mixture.

[Claim 9]

An orally administrable pharmaceutical formulation comprising the orally administrable composition according to any of claims 1 to 8, wherein the composition is coated.