[Document Name] Claims

[Claim 1]

An oral pharmaceutical composition comprising α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl)methyl-2,4(1H,3H)-pyrimidine dione hydrochloride as an active ingredient; and being substantially free of an additive comprising a metal salt.

[Claim 2]

The oral pharmaceutical composition according to claim 1, wherein the metal salt is selected from alkali metal salts and alkaline earth metal salts.

[Claim 3]

The oral pharmaceutical composition according to claim 1 or 2, wherein the metal salt is selected from sodium salts, potassium salts, calcium salts, and magnesium salts.

[Claim 4]

The oral pharmaceutical composition according to any of claims 1 to 3, wherein the content of the metal salt is 0 to 0.1 parts by mass based on 1 part by mass of α,α,α-trifluorothymidine.

[Claim 5]

The oral pharmaceutical composition according to any of claims 1 to 4, wherein the oral pharmaceutical composition is substantially free of an additive

comprising a metal salt; and comprises a sugar alcohol or a disaccharide as an excipient.

[Claim 6]

The oral pharmaceutical composition according to claim 5, wherein the sugar alcohol or disaccharide comprised as the excipient are one or more selected from lactose, sucrose, erythritol, and mannitol.

[Claim 7]

The oral pharmaceutical composition according to claim 6, wherein the content of the sugar alcohol or disaccharide is 3.6 parts by mass or more based on 1 part by mass of α,α,α-trifluorothymidine.

[Claim 8]

The oral pharmaceutical composition according to any of claims 1 to 7, further comprising one or more selected from low-substituted hydroxypropyl cellulose, corn starch, partly pregelatinized starch, carmellose, and crospovidone as a disintegrating agent.

[Claim 9]

The oral pharmaceutical composition according to claim 8, wherein the content of the disintegrating agent is from 2 to 16% by mass in the total amount of the composition.

[Claim 10]

The oral pharmaceutical composition according to any of claims 1 to 9, further comprising one or more selected

from hydrogenated oils, stearic acid, and sucrose fatty acid esters as a lubricant.

[Claim 11]

The oral pharmaceutical composition according to claim 10, wherein the content of the lubricant is from 0.001 to 3% by mass in the total composition.

[Claim 12]

The oral pharmaceutical composition according to any of claims 1 to 11, 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 13]

The oral pharmaceutical composition according to any of claims 1 to 12, wherein the oral pharmaceutical composition comprises α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl)methyl-2,4(1H,3H)-pyrimidine dione hydrochloride as the active ingredients in a molar ratio of 1:0.5; is substantially free of an additive comprising a metal salt; comprises one or more selected from lactose, sucrose, or mannitol as the excipient; one or more selected from low-substituted hydroxypropyl cellulose, corn starch, partly pregelatinized starch, and carmellose as the disintegrating agent; and one or two hydrogenated oils and stearic acid as the lubricant.

[Claim 14]

The oral pharmaceutical composition according to any of claims 1 to 13, wherein the pharmaceutical composition is in a formulation form of a granulated product, a compression-molded product, or a mixture.

[Claim 15]

An oral pharmaceutical formulation comprising the oral composition according to any of claims 1 to 14, wherein the composition is coated.

[Document Name] Claims

[Claim 1]

A uncoated tablet comprising α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl)methyl-2,4(1H,3H)-pyrimidine dione hydrochloride as an active ingredient, comprising a sugar alcohol or a disaccharide as an excipient, and comprising one or more selected from hydrogenated oils, stearic acid, and sucrose fatty acid esters as a lubricant; and being free of an additive comprising a metal salt

[Claim 2]

The tablet according to claim 1, wherein the metal salt is selected from alkali metal salts and alkaline earth metal salts.

[Claim 3]

The tablet according to claim 1 or 2, wherein the metal salt is selected from sodium salts, potassium salts, calcium salts, and magnesium salts.

[Claim 4]

The tablet according to any of claims 1 to 3, wherein the sugar alcohol or disaccharide comprised as the excipient are one or more selected from lactose, sucrose, erythritol, and mannitol.

[Claim 5]

The tablet according to any of claims 1 to 4, wherein the content of the sugar alcohol or disaccharide is 3.6 parts by mass or more based on 1 part by mass of α,α,α-trifluorothymidine.

[Claim 6]

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

[Claim 7]

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

[Claim 8]

The tablet according to any of claims 1 to 7, wherein the content of the lubricant is from 0.001 to 3% by mass in the total composition.

[Claim 9]

The tablet according to any of claims 1 to 8, 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 10]

The tablet according to any of claims 1 to 9, wherein the oral pharmaceutical composition comprises α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl)methyl-2,4(1H,3H)-pyrimidine dione hydrochloride as the active ingredients in a molar ratio of 1:0.5; is free of an additive comprising a metal salt; comprises one or more selected from lactose, sucrose, or mannitol as the excipient; one or more selected from low-substituted hydroxypropyl cellulose, corn starch, partly pregelatinized starch, and carmellose as the disintegrating agent; and one or two hydrogenated oils and stearic acid as the lubricant.

[Claim 11]

A coated tablet comprising the tablet according to any of claims 1 to 10, wherein the tablet is coated.

[Claim 12]

A coated tablet according to claim 11, comprising magnesium stearate on the surface.

[Claim 13]

A stabilization method comprising a sugar alcohol or a disaccharide as an excipient, and comprising one or more selected from hydrogenated oils, stearic acid, and sucrose fatty acid esters as a lubricant; and being free of an additive

comprising a metal salt; in uncoated tablet comprising α,α,α-trifluorothymidine and 5-chloro-6-(2-iminopyrrolidine-1-yl)methyl-2,4(1H,3H)-pyrimidine dione hydrochloride as an active ingredient.