CLAIMS

[Claim 1] An oral solid formulation comprising

(1) 5-fluoro-2-[(4-{7-[(1S,3S,4R)-5-methylidene-2-azabicyclo[2.2.2]octane-3-carbonyl]-2,7-diazaspiro[3.5]nonan-2-yl}pyrimidin-5-yl)oxy]-N,N-di(propan-2-yl)benzamide or a pharmaceutically acceptable salt thereof, or a hydrate or solvate thereof,

(2) a binder in 4.0 - 6.0% (w/w) per 100% (w/w) of the formulation, and

(3) sodium stearyl fumarate in 2.0 - 10.0% (w/w) per 100% (w/w) of the formulation,

wherein the binder is hydroxypropyl cellulose or polyvinyl alcohol.

[Claim 2] The oral solid formulation of claim 1, wherein the content of the binder is 5.0 - 6.0% (w/w) per 100% (w/w) of the formulation.

[Claim 3] The oral solid formulation of claim 1, wherein the binder is hydroxypropyl cellulose.

[Claim 4] The oral solid formulation of claim 3, wherein the content of the hydroxypropyl cellulose is 5.0 - 6.0% (w/w) per 100% (w/w) of the formulation.

[Claim 5] The oral solid formulation of claim 1, wherein the content of the sodium stearyl fumarate is 2.0 – 6.0% (w/w) per 100% (w/w) of the formulation.

[Claim 6] The oral solid formulation of claim 1, wherein the content of the sodium stearyl fumarate is 4.0 – 6.0% (w/w) per 100% (w/w) of the formulation.

[Claim 7] The oral solid formulation of claim 1, which further comprises an excipient.

[Claim 8] The oral solid formulation of claim 7, wherein the excipient is a hydrophilic excipient.

[Claim 9] The oral solid formulation of claim 8, wherein the hydrophilic excipient is any one selected from sugar alcohol, pregelatinized starch, lactose hydrate, and microcrystalline cellulose, or a combination of two or more thereof.

[Claim 10] The oral solid formulation of claim 8, wherein the hydrophilic excipient is any one selected from sugar alcohol and pregelatinized starch, or a combination of two or more thereof.

[Claim 11] The oral solid formulation of claim 8, wherein the hydrophilic excipient is a combination of sugar alcohol and pregelatinized starch.

[Claim 12] The oral solid formulation of claim 11, wherein the pregelatinized starch is partially pregelatinized starch.

[Claim 13] The oral solid formulation of claim 11, wherein the sugar alcohol is D-mannitol.

[Claim 14] The oral solid formulation of claim 1, which further comprises a disintegrant.

[Claim 15] The oral solid formulation of claim 14, wherein the content of the disintegrant is 0.5 - 50.0% (w/w) per 100% (w/w) of the formulation.

[Claim 16] The oral solid formulation of claim 14, wherein the content of the disintegrant is 1.0 - 10.0% (w/w) per 100% (w/w) of the formulation.

[Claim 17] The oral solid formulation of claim 14, wherein the content of the disintegrant is 2.0 - 5.0% (w/w) per 100% (w/w) of the formulation.

[Claim 18] The oral solid formulation of claim 14, wherein the disintegrant is any one selected from croscarmellose sodium, sodium starch glycolate, and crospovidone, or a combination of two or more thereof.

[Claim 19] The oral solid formulation of claim 14, wherein the disintegrant is croscarmellose sodium.

[Claim 20] The oral solid formulation of claim 19, wherein the content of the croscarmellose sodium is 1.0 – 10.0% (w/w) per 100% (w/w) of the formulation.

[Claim 21] The oral solid formulation of any one of claims 1 to 20, wherein the content of the 5-fluoro-2-[(4-{7-[(1S,3S,4R)-5-methylidene-2-azabicyclo[2.2.2]octane-3-carbonyl]-2,7-diazaspiro[3.5]nonan-2-yl}pyrimidin-5-yl)oxy]-N,N-di(propan-2-yl)benzamide or a pharmaceutically acceptable salt thereof, or a hydrate or solvate thereof is 0.5 – 70% (w/w) per 100% (w/w) of the formulation.

[Claim 22] The oral solid formulation of any one of claims 1 to 20, wherein the content of the 5-fluoro-2-[(4-{7-[(1S,3S,4R)-5-methylidene-2-azabicyclo[2.2.2]octane-3-carbonyl]-2,7-diazaspiro[3.5]nonan-2-yl}pyrimidin-5-

yl)oxy]-N,N-di(propan-2-yl)benzamide or a pharmaceutically acceptable salt thereof, or a hydrate or solvate thereof is 15 - 38% (w/w) per 100% (w/w) of the formulation.

[Claim 23] The oral solid formulation of any one of claims 1 to 20, wherein the content of the 5-fluoro-2-[(4-{7-[(1S,3S,4R)-5-methylidene-2-azabicyclo[2.2.2]octane-3-carbonyl]-2,7-diazaspiro[3.5]nonan-2-yl}pyrimidin-5-yl)oxy]-N,N-di(propan-2-yl)benzamide or a pharmaceutically acceptable salt thereof, or a hydrate or solvate thereof is 20 - 38% (w/w) per 100% (w/w) of the formulation.

[Claim 24] The oral solid formulation of claim 1, comprising

(1) 5-fluoro-2-[(4-{7-[(1S,3S,4R)-5-methylidene-2-azabicyclo[2.2.2]octane-3-carbonyl]-2,7-diazaspiro[3.5]nonan-2-yl}pyrimidin-5-yl)oxy]-N,N-di(propan-2-yl)benzamide or a pharmaceutically acceptable salt thereof, or a hydrate or solvate thereof in 15 - 38% (w/w) per 100% (w/w) of the formulation,

(2) a binder in 4.0 - 6.0% (w/w) per 100% (w/w) of the formulation, and

(3) sodium stearyl fumarate in 2.0 - 6.0% (w/w) per 100% (w/w) of the formulation,

wherein the binder is hydroxypropyl cellulose or

polyvinyl alcohol.

[Claim 25] The oral solid formulation of claim 24, wherein the binder is hydroxypropyl cellulose.

[Claim 26] The oral solid formulation of claim 25, wherein the content of the sodium stearyl fumarate is 3.0 – 6.0% (w/w) per 100% (w/w) of the formulation.

[Claim 27] The oral solid formulation of claim 26, wherein the content of the hydroxypropyl cellulose is 4.5 – 5.5% (w/w) per 100% (w/w) of the formulation.

[Claim 28] The oral solid formulation of any one of claims 24 to 27, which further comprises croscarmellose sodium in 1.0 – 10.0% (w/w) per 100% (w/w) of the formulation.

[Claim 29] The oral solid formulation of claim 28, which further comprises D-mannitol and partially pregelatinized starch.

[Claim 30] The oral solid formulation of claim 1, comprising

(1) 5-fluoro-2-[(4-{7-[(1S,3S,4R)-5-methylidene-2-azabicyclo[2.2.2]octane-3-carbonyl]-2,7-

diazaspiro[3.5]nonan-2-yl}pyrimidin-5-yl)oxy]-N,N-di(propan-2-yl)benzamide or a pharmaceutically acceptable salt thereof, or a hydrate or solvate thereof in 20 - 30% (w/w) per 100% (w/w) of the formulation,

(2) a binder in 4.5 - 5.5% (w/w) per 100% (w/w) of the formulation,

(3) sodium stearyl fumarate in 3.0 - 6.0% (w/w) per 100% (w/w) of the formulation,

(4) croscarmellose sodium in 1.0 - 10.0% (w/w) per 100% (w/w) of the formulation, and

(5) D-mannitol and partially pregelatinized starch,

wherein the binder is hydroxypropyl cellulose.

[Claim 31] The oral solid formulation of claim 1, which is film-coated with a coating agent.

[Claim 32] The oral solid formulation of claim 1, for use in treating and/or preventing a tumor.