CLAIMS

[Claim 1]

An oral pharmaceutical composition in the form of a dry syrup comprising: ~~an active pharmaceutical ingredient having a pH-dependent dissolution profile~~ ART-001 (serabelisib); an inorganic or organic acid; and a hydrophilic polymer.

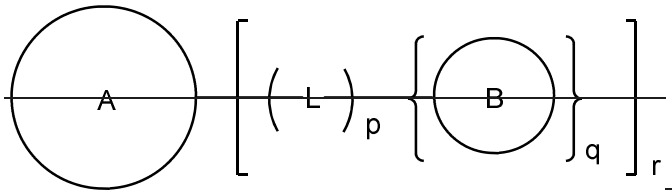
~~[Claim 2]~~

~~The oral pharmaceutical composition according to claim 1, wherein the active pharmaceutical ingredient is an aromatic compound having a π-conjugated system.~~

~~[Claim 3]~~

~~The oral pharmaceutical composition according to claim 1 or 2, wherein the active pharmaceutical ingredient is a compound having a structure represented by Formula I.~~

~~[Chem. 1]~~



~~Formula I~~

~~wherein~~

~~Ring A represents a 5- to 16-membered monocyclic or fused bicyclic or tricyclic aromatic hydrocarbon group or aromatic heterocyclic group that may have one or more substituents,~~

~~Ring B represents a 5- to 12-membered monocyclic or fused bicyclic aromatic hydrocarbon group or aromatic heterocyclic group that may have one or more substituents,~~

~~L represents a divalent or trivalent linking group that may have one or more substituents,~~

~~p represents an integer of 0 or 1,~~

~~q represents an integer of 1 or 2, and~~

~~r represents an integer of 1 or 2.~~

~~[Claim 4]~~

~~The oral pharmaceutical composition according to any one of claims 1 to 3, wherein the active pharmaceutical ingredient is one or more compounds selected from ART-001 (serabelisib), alpelisib, afatinib, gefitinib, bosutinib, alectinib, palbociclib, taselisib, and copanlisib.~~

~~[Claim 5]~~

~~The oral pharmaceutical composition according to any one of claims 1 to 4, wherein the ratio of the solubility at pH 6 to the solubility at pH 2.5 of the active pharmaceutical ingredient is 50% or less.~~

[Claim ~~6~~2]

The oral pharmaceutical composition according to ~~any one of claims 1 to 5~~claim 1, wherein the inorganic or organic acid is one or more acids selected from phosphoric acid, hydrochloric acid, citric acid, malic acid, tartaric acid, ascorbic acid, fumaric acid, succinic acid, aspartic acid, lactic acid, acetic acid, glutamic acid, and adipic acid.

[Claim 3]

The oral pharmaceutical composition according to claim 1 or 2, wherein the inorganic or organic acid is one or more acids selected from phosphoric acid, citric acid, tartaric acid, and glutamic acid.

[Claim ~~7~~4]

The oral pharmaceutical composition according to any one of claims 1 to ~~6~~3, wherein the hydrophilic polymer is one or more polymers selected from polyvinyl alcohol, povidone, hypromellose, copovidone, hydroxypropylcellulose, polyvinyl alcohol-polyethylene glycol-graft copolymer, hypromellose phthalate, and hypromellose acetate succinate.

[Claim ~~8~~5]

The oral pharmaceutical composition according to any one of claims 1 to ~~7~~4, wherein the content percentage of ART-001 (serabelisib) ~~the active pharmaceutical ingredient~~ is from 2 to 40 mass %

[Claim ~~9~~6]

The oral pharmaceutical composition according to any one of claims 1 to ~~8~~5, wherein the content ratio of the inorganic or organic acid to one mass part of ART-001 (serabelisib) ~~the active pharmaceutical ingredient~~ is from 0.1 to 10 mass parts.

[Claim ~~10~~7]

The oral pharmaceutical composition according to any one of claims 1 to ~~9~~6, wherein the content ratio of the hydrophilic polymer to one mass part of ART-001 (serabelisib) ~~the active pharmaceutical ingredient~~ is from 0.02 to 5 mass parts.

~~[Claim 11]~~

~~The oral pharmaceutical composition according to any one of claims 1 to 10, which is in the form of a dry syrup.~~

[Claim ~~12~~8]

A method of producing an oral pharmaceutical composition according to any one of claims 1 to ~~11~~7, comprising: wet-granulating a mixture containing ART-001 (serabelisib)~~the active pharmaceutical ingredient~~, the inorganic or organic acid, and the hydrophilic polymer, and drying the granulated product.

~~[Claim 13]~~

~~An oral pharmaceutical composition obtainable by the method according to claim 12.~~