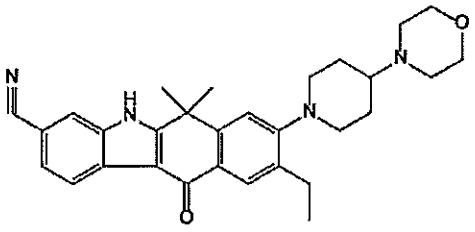
Claims

[Claim 1]

A pharmaceutical formulation comprising (i) a granule containing a compound represented by formula (I) or a salt thereof and (ii) a disintegrating agent, wherein the compound represented by formula (I) or a salt thereof is contained in an amount of 60 mg to 240 mg in terms of the free form per unit formulation.



(I)

[Claim 2]

The formulation according to Claim 1, wherein the disintegrating agent (ii) is contained in an amount of 7.5 wt% or more and 30 wt% or less based on the total amount of the formulation.

[Claim 3]

The formulation according to any of Claims 1 or 2, wherein the disintegrating agent (ii) is selected from sodium starch glycolate, lowsubstituted hydroxypropylcellulose, carmellose calcium, sodium hydrogen carbonate, pregelatinized starch,

sodium chloride, corn starch, croscarmellose sodium, crystalline cellulose, silicic anhydride and carmellose.

[Claim 4]

The formulation according to any of Claims 1 to 3, wherein the disintegrating agent (ii) is selected from low-substituted hydroxypropylcellulose, carmellose calcium, sodium hydrogen carbonate and pregelatinized starch.

[Claim 5]

The formulation according to any of Claims 1 to 4, wherein the granule contains a disintegrating agent therein.

[Claim 6]

The formulation according to Claim 5, wherein the disintegrating agent contained in the granule is selected from sodium starch glycolate, lowsubstituted hydroxypropylcellulose, carmellose calcium, sodium hydrogen carbonate, pregelatinized starch, sodium chloride, corn starch, croscarmellose sodium, crystalline cellulose, silicic anhydride and carmellose.

[Claim 7]

The formulation according to Claim 6, wherein the disintegrating agent contained in the granule is selected from carmellose calcium, low-substituted hydroxypropylcellulose and sodium starch glycolate.

[Claim 8]

The formulation according to any of Claims 1 to 7, wherein the granule contains a solubilizing agent therein.

[Claim 9]

The formalation according to Claim 8, wherein the solubilizing agent is sodium lauryl sulfate.

[Claim 10]

The formulation according to Claim 9, wherein sodium lauryl sulfate is obtained by crystallization.

[Claim 11]

The formulation according to any of Claim 8 or 10, wherein the weight ratio of the compound represented by formula (I) to the solubilizing agent is 100:2 to 100:60.

[Claim 12]

The formulation according to any of Claims 1 to 11, wherein the granule contains a binder therein.

[Claim 13]

The formulation according to Claim 12, wherein the binder is hydroxypropylcellulose.

[Claim 14]

The formulation according to any of Claims 1 to 13, wherein the granule has a mean particle diameter of 150 μm or more and 300 μm or less.

[Claim 15]

The formulation according to any of Claims 1 to 14, wherein the granule has a mean particle diameter of 200 μm or more and 300 μm or less.

[Claim 16]

The formulation according to any of Claims 8 to 11, wherein a compound represented by formula (I) or a salt thereof is contained in an amount of 20 to 70 wt% in terms of the free form based on the total amount of the composition.

[Claim 17]

The formulation according to any of Claims 8 to 11, wherein the compound represented by formula (I) or a salt thereof is contained in an amount of 35 to 60 wt% based on the total amount of the composition.

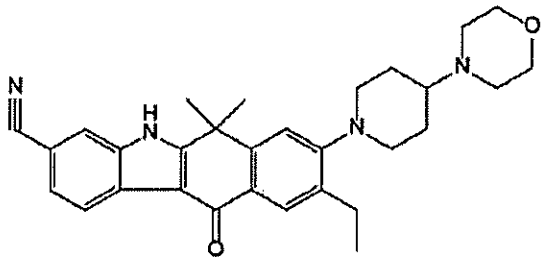
[Claim 18]

The formulation according to Claim 1 to 17, wherein the compound represented by formula (I) or a salt thereof is contained in an amount of 140 mg to 190 mg per unit formulation.

[Claim 19]

A method for producing a formulation improved in solubility of a compound represented by formula (I) or a salt thereof, comprising (i) granulating a granule containing a compound represented by formula (I) or a salt thereof and (ii) blending a disintegrating agent and optionally other additives as

external additives, wherein the compound represented by formula (I) or a salt thereof is contained in an amount of 60 mg to 240 mg in terms of the free form per unit formulation.



(I)

[Claim 20]

The method according to Claim 19, wherein the disintegrating agent (ii) is selected from sodium starch glycolate, low-substituted hydroxypropylcellulose, carmellose calcium, sodium hydrogen carbonate, pregelatinized starch, sodium chloride, corn starch, croscarmellose sodium, crystalline cellulose, silicic anhydride and carmellose.

[Claim 21]

The method according to Claim 19 or 20, wherein the disintegrating agent (ii) is contained in an amount of 7.5 wt% or more and 30 wt% or less based on the total amount of the formulation.

[Claim 22]

The method according to any of Claims 19 to 21, wherein the granule has a mean particle diameter of 150 μm or more and 1 mm or less.

[Claim 23]

The method according to any of Claims 19 to 22, wherein the granule has a mean particle diameter of 180 μm or more and 1 mm or less.

[Claim 24]

The method according to any of Claims 19 to 23, wherein the granule (i) has a disintegrating agent therein.

[Claim 25]

The method according to Claim 24, wherein the disintegrating agent contained in the granule is selected from sodium starch glycolate, low-substituted hydroxypropylcellulose, carmellose calcium, sodium hydrogen carbonate, pregelatinized starch, sodium chloride, corn starch, croscarmellose sodium, crystalline cellulose, silicic anhydride and carmellose.

[Claim 26]

The method according to any of Claims 19 to 25, wherein the granule contains a solubilizing agent therein.

[Claim 27]

The method according to Claim 26, wherein the solubilizing agent is sodium lauryl sulfate obtained by crystallization.

[Claim 28]

The method according to claim 26 or 27, wherein the dissolution aid is sodium lauryl sulfate.

[Claim 29]

The method according to any of Claims 26 to 28, wherein a weight ratio of the compound represented by formula (I) to the solubilizing agent is 100:2 to 100:60

[Claim 30]

The method according to any of Claims 19 to 29, wherein the granule contains a binder therein.

[Claim 31]

The method according to Claim 30, wherein the binder is hydroxypropylcellulose.

[Claim 32]

The method according to any of Claims 19 to 31, wherein the compound represented by formula (I) or a salt thereof is contained in an amount of 140 mg to 190 mg in terms of the free form per unit formulation.