CLAIMS

[Claim 1]

An injectable preparation comprising a composition comprising a poorly soluble drug, a dispersion medium, and a suspending agent, the suspending agent comprising polyethylene glycol and carboxymethyl cellulose or a salt thereof,

the composition having a viscosity of 40 Pa·s or more in at least one point in the shear rate range of 0.01 to 0.02 s^{-1} and having a viscosity of 0.2 Pa·s or less in at least one point in the shear rate range of 900 to 1,000 s^{-1}, as measured by a rheometer, wherein the poorly soluble drug is aripiprazole or a salt thereof, or 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof.

[Claim 2]

An injectable preparation comprising a composition comprising a poorly soluble drug, a dispersion medium, and a suspending agent, the suspending agent comprising polyethylene glycol and carboxymethyl cellulose or a salt thereof,

the composition having a viscosity of 40 Pa·s or more in at least one point in the shear rate range of 0.01 to 0.02 s^{-1} and having a viscosity of 0.2 Pa·s or less in at least one point in the shear rate range of 900 to 1,000 s^{-1}, as measured by a rheometer at 25°C, wherein the poorly soluble drug is aripiprazole or a salt thereof, or 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof.

[Claim 3]

The injectable preparation according to claim 1 or 2 comprising a composition comprising at least water as a dispersion medium.

[Claim 4]

The injectable preparation according to any one of claims 1 to 3 wherein the suspending agent is contained at a concentration of 0.05 to 150 mg/mL.

[Claim 5]

The injectable preparation according to any one of claims 1 to 4 wherein the poorly soluble drug is a monohydrate of aripiprazole or a salt thereof, or a hydrate of 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof.

[Claim 6]

The injectable preparation according to any one of claims 1 to 5 wherein the suspending agent further comprises polyvinylpyrrolidone.

[Claim 7]

A gel composition comprising

a poorly soluble drug which is aripiprazole or a salt thereof, or 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof,

water, and

a suspending agent,

wherein the suspending agent comprises polyethylene glycol and carboxymethyl cellulose or a salt thereof, and wherein the poorly soluble drug has a mean primary particle diameter of 0.5 to 30 μm and is contained in a concentration of 200 to 600 mg/mL.

[Claim 8]

The composition according to claim 7 wherein the suspending agent is contained at a concentration of 0.05 to 150 mg/mL.

[Claim 9]

The composition according to claim 7 or 8 wherein the concentration of polyethylene glycol is 0.05 to 2 mg/mL, and the concentration of carboxymethyl cellulose or a salt thereof is 0.5 to 50 mg/mL.

[Claim 10]

The composition according to any one of claims 7 to 9 wherein the poorly soluble drug has a mean secondary particle diameter that is up to but not exceeding three times the mean primary particle diameter thereof.

[Claim 11]

The composition according to any one of claims 7 to 10 wherein the suspending agent further comprises polyvinylpyrrolidone.

[Claim 12]

The composition according to any one of claims 7 to 11 which has a viscosity of 40 Pa·s or more in at least one point in the shear rate range of 0.01 to 0.02 s^{-1} and which has a viscosity of 0.2 Pa·s or less in at least one point in the shear rate range of 900 to 1,000 s^{-1}, as measured by a rheometer.

[Claim 13]

The composition according to any one of claims 7 to 11

which has a viscosity of 40 Pa·s or more in at least one point in the shear rate range of 0.01 to 0.02 s^{-1} and which has a viscosity of 0.2 Pa·s or less in at least one point in the shear rate range of 900 to 1,000 s^{-1}, as measured by a rheometer at 25°C.

[Claim 14]

An injectable preparation comprising the composition according to any one of claims 7 to 13.

[Claim 15]

A prefilled syringe that is prefilled with the composition according to any one of claims 7 to 13.

[Claim 16]

A kit comprising the prefilled syringe according to claim 15.

[Claim 17]

A method for producing a gel composition comprising aripiprazole or a salt thereof, or 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof, the method comprising

allowing a liquid mixture to stand at 5 to 70°C for 5 minutes or more, the liquid mixture comprising aripiprazole or a salt thereof, or 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof in a concentration of 200 to 600 mg/mL, water, and a suspending agent, the suspending agent comprising polyethylene glycol and carboxymethyl cellulose or a salt thereof, and

the aripiprazole or a salt thereof, or the 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-

one or a salt thereof having a mean primary particle diameter of 0.5 to 30 μm.

[Claim 18]

A method for producing a prefilled syringe that is prefilled with a gel composition comprising aripiprazole or a salt thereof, or 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof,

the method comprising:

filling into a syringe a liquid mixture comprising aripiprazole or a salt thereof, or 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof in a concentration of 200 to 600 mg/mL, water, and a suspending agent,

wherein the suspending agent comprises polyethylene glycol and carboxymethyl cellulose or a salt thereof, and

wherein the aripiprazole or a salt thereof, or the 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof has a mean primary particle diameter of 0.5 to 30 μm; and

allowing the liquid mixture to stand at 5 to 70°C for 5 minutes or more.

[Claim 19]

A sustained release injectable preparation comprising the gel composition according to any one of claims 7 to 13,

wherein the mean primary particle diameter of the poorly soluble drug is 1 to 10 μm and the concentration of the poorly soluble drug is 200 to 400 mg/mL,

wherein the gel composition is in the form of a gel when allowed to stand, and changes to a sol when subjected to an impact, and

wherein the preparation is to be administered once per

month.

[Claim 20]

The injectable preparation according to claim 19 wherein the mean primary particle diameter of the poorly soluble drug is 2 to 7 μm.

[Claim 21]

A sustained release injectable preparation comprising the gel composition according to any one of claims 7 to 13,

wherein the mean primary particle diameter of the poorly soluble drug is 4 to 30 μm and the concentration of the poorly soluble drug is 300 to 600 mg/mL,

wherein the gel composition is in the form of a gel when allowed to stand, and changes to a sol when subjected to an impact, and

wherein the preparation is to be administered once every two to three months.

[Claim 22]

The injectable preparation according to claim 21 wherein the mean primary particle diameter of the poorly soluble drug is 5 to 20 μm.

[Claim 23]

The injectable preparation according to any one of claims 1 to 6, 14, and 19 to 22 for use in treating or preventing a recurrence of schizophrenia, bipolar disorder, or depression.

[Claim 24]

The injectable preparation according to claim 23 wherein the injectable preparation is to be administered

intramuscularly or subcutaneously.