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 a 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 1 to 10 μm and is contained in a concentration of 200 to 400 mg/mL,

the composition being in the form of a gel when allowed to stand, and changing to a sol when subjected to an impact, and

the preparation being administered once per month.

[Claim 20]

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

[Claim 21]

A sustained release injectable preparation comprising a 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 4 to 30 μm and is contained in a concentration of 300 to 600 mg/mL,

the composition being in the form of a gel when allowed to stand, and changing to a sol when subjected to an impact, and

the preparation being administered once every two or three months.

[Claim 22]

The injectable preparation according to claim 21 wherein

the poorly soluble drug has a mean primary particle diameter of 5 to 20 μm.

[Claim 23]
The injectable preparation according to any one of claims 19 to 22 wherein the suspending agent is contained at a concentration of 0.05 to 150 mg/mL.

[Claim 24]
The injectable preparation according to any one of claims 19 to 23 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 25]
The injectable preparation according to any one of claims 19 to 24 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 26]
The injectable preparation according to any one of claims 19 to 25 wherein the suspending agent further comprises polyvinylpyrrolidone.

[Claim 27]
The injectable preparation according to any one of claims 1 to 6, 14, and 19 to 26, for use in a method for treating or preventing a recurrence of schizophrenia, bipolar disorder, or depression.

[Claim 28]
The injectable preparation according to claim 27 wherein

the injectable preparation is administered intramuscularly or subcutaneously.