Claims

[Claim 1]

A method for sorting a pharmaceutical raw material for a formulation consisting essentially of sodium lauryl sulfate, the method comprising detecting an impurity after pretreating the pharmaceutical raw material for a formulation,

wherein pretreating the pharmaceutical raw material for a formulation comprises allowing the pharmaceutical raw material for a formulation to stand still under an accelerated condition,

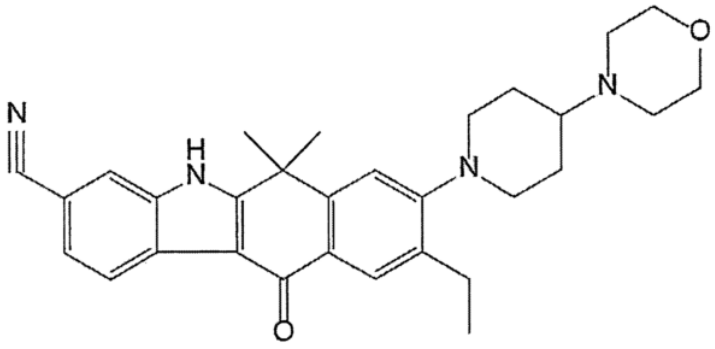
wherein the accelerated condition comprises:

(i) a temperature condition of 65 to 75°C; and/or

(ii) a humidity condition of less than 79%RH.

[Claim 2]

A method for evaluating the quality of a pharmaceutical formulation containing a compound represented by formula (I)



(I)

or a salt thereof and a pharmaceutical raw material for a formulation consisting essentially of sodium lauryl sulfate, the method comprising:

a) selecting a pharmaceutical formulation containing a sorted pharmaceutical raw material for a formulation, wherein the sorted

pharmaceutical raw material for a formulation is the pharmaceutical raw material for a formulation which was sorted out by detecting an impurity after pretreating the pharmaceutical raw material for a formulation; and

b) skipping impurity measurement in the pharmaceutical formulation selected in step a,

wherein pretreating the pharmaceutical raw material for a formulation comprises allowing the pharmaceutical raw material for a formulation to stand still under an accelerated condition,

wherein the accelerated condition comprises:

(i) a temperature condition of 65 to 75°C; and/or

(ii) a humidity condition of less than 79%RH.

[Claim 3]

The method according to any one of claims 1 to 2, wherein the accelerated condition is a humidity condition of about 10%RH or less.

[Claim 4]

The method according to any one of claims 1 to 3, wherein the accelerated condition includes a temperature condition of about 70°C and a humidity condition of about 10%RH or less.

[Claim 5]

The method according to any one of claims 1 to 4, wherein the impurity is a sulfate ion, dodecanol or a sodium lauryl sulfate-dodecanol complex.

[Claim 6]

The method according to any one of claims 1 to 5, wherein the impurity is detected by X-ray powder diffraction, ion exchange chromatography, gas chromatography or quantitative NMR.

[Claim 7]

The method according to any one of claims 1 to 6, wherein the impurity is a sulfate ion, and the impurity is detected by ion exchange chromatography.

[Claim 8]

The method according to any one of claims 1 to 7, wherein the pretreatment is performed under the accelerated condition for 2 days or more.

[Claim 9]

The method according to any one of claims 1 to 8, wherein the pretreatment is performed under the accelerated condition for 4 days.

[Claim 10]

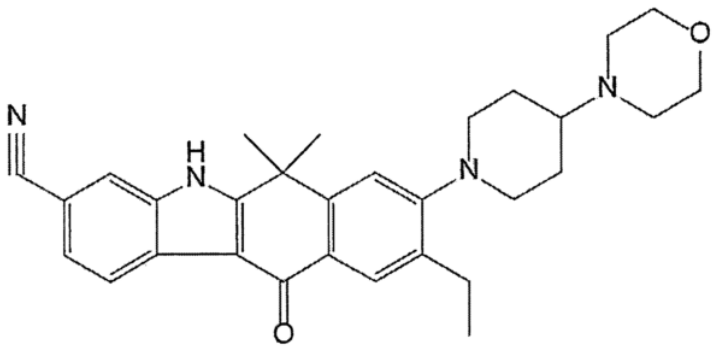
A method for evaluating the quality of a pharmaceutical formulation containing sodium lauryl sulfate, the method comprising detecting an impurity after pretreating the pharmaceutical formulation containing sodium lauryl sulfate,

wherein pretreating the pharmaceutical formulation comprises allowing the pharmaceutical formulation to stand still under an accelerated condition,

wherein the accelerated condition is a temperature condition of 55 to 65°C.

[Claim 11]

The quality evaluation method according to claim 10, wherein the pharmaceutical formulation contains a compound represented by formula (I)



(I)

or a salt thereof.

[Claim 12]

The quality evaluation method according to any one of claims 10 to 11, wherein the accelerated condition is a temperature condition of about 60°C.

[Claim 13]

The quality evaluation method according to any one of claims 10 to 12, wherein the impurity is a sulfate ion, dodecanol or a sodium lauryl sulfate-dodecanol complex.

[Claim 14]

The quality evaluation method according to any one of claims 10 to 13, wherein the impurity is detected by X-ray powder diffraction, ion exchange chromatography, gas chromatography or quantitative NMR.

[Claim 15]

The quality evaluation method according to any one of claims 10 to 14, wherein the impurity is dodecanol, and the impurity is detected by gas chromatography.

[Claim 16]

The quality evaluation method according to any one of claims 10 to 14, wherein the impurity is a sulfate ion, and the impurity is detected by ion exchange chromatography.

[Claim 17]

The quality evaluation method according to any one of claims 10 to 16, wherein the pretreatment is performed under the accelerated condition for 2 days or more.

[Claim 18]

The quality evaluation method according to any one of claims 10 to 17, wherein the pretreatment is performed under the accelerated condition for 7 days.

[Claim 19]

The quality evaluation method according to any one of claims 10 to 18, wherein a pharmaceutical formulation in which 2% or less of dodecanol/sodium lauryl sulfate (mol/mol%) or a sulfate ion/sodium lauryl sulfate (mol/mol%) as the impurity is present, is sorted out.

[Claim 20]

A method for manufacturing a pharmaceutical formulation containing sodium lauryl sulfate, the method comprising:

a) pretreating sodium lauryl sulfate of a pharmaceutical raw material for a formulation;

b) detecting an impurity after the pretreatment of step a to sort out a pharmaceutical raw material for a formulation in which the content of a sulfate ion as the impurity is 1 mg/L or less; and

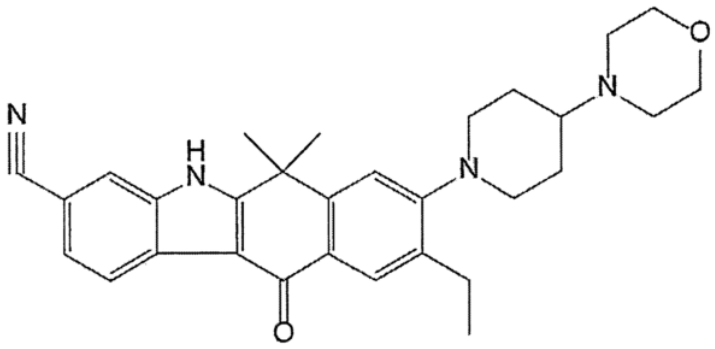
c) manufacturing a pharmaceutical formulation by using the pharmaceutical raw material for a formulation sorted out by step b,

wherein pretreating sodium lauryl sulfate comprises allowing the sodium lauryl sulfate to stand still under an accelerated condition,

wherein the accelerated condition is a temperature condition of 65 to 75°C.

[Claim 21]

The manufacturing method according to claim 20, wherein the pharmaceutical formulation contains a compound represented by formula (I)

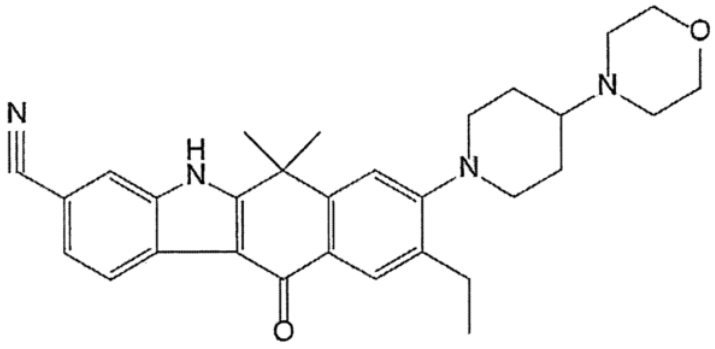


(I)

or a salt thereof.

[Claim 22]

A method for manufacturing a pharmaceutical formulation containing a compound represented by formula (I)



(I)

or a salt thereof and sodium lauryl sulfate, the method comprising:

a) manufacturing the pharmaceutical formulation by using a pharmaceutical raw material for a formulation consisting essentially of sodium lauryl sulfate;

b) pretreating the pharmaceutical formulation produced in step a; and

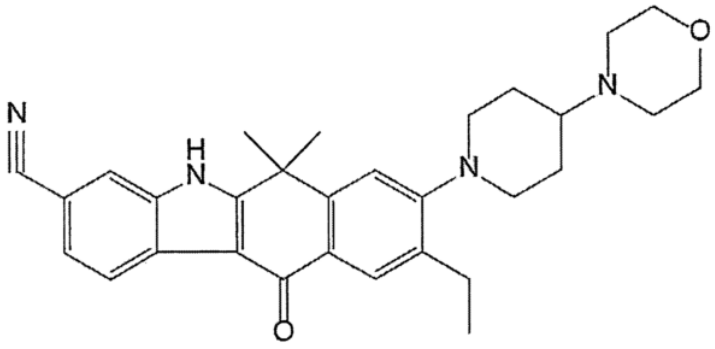
c) detecting an impurity after the pretreatment of step b to sort out a pharmaceutical formulation in which the content of dodecanol/sodium lauryl sulfate (mol/mol%) or sulfate ion/sodium lauryl sulfate (mol/mol%) as the impurity is 2% or less,

wherein pretreating the pharmaceutical formulation comprises allowing the the pharmaceutical formulation to stand still under an accelerated condition,

wherein the accelerated condition is a temperature condition of 55 to 65°C.

[Claim 23]

A pharmaceutical composition containing a compound represented by formula (I)



(I)

or a salt thereof and sodium lauryl sulfate, wherein dodecanol/sodium lauryl sulfate or sulfate ion/sodium lauryl sulfate is contained in a ratio such that it causes no effect on dissolution in a pharmaceutical formulation containing the composition when the formulation is measured after a pretreatment,

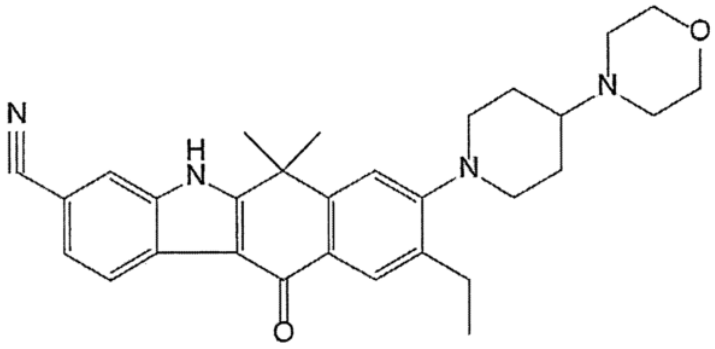
wherein the pretreatment comprises allowing the the pharmaceutical composition to stand still under an accelerated condition,

wherein the accelerated condition is a temperature condition of 55 to 65°C,

wherein the content of dodecanol/sodium lauryl sulfate (mol/mol%) or sulfate ion/sodium lauryl sulfate (mol/mol%) in the composition, as measured by X-ray powder diffraction, ion exchange chromatography, gas chromatography or quantitative NMR is 2% or less.

[Claim 24]

A pharmaceutical formulation containing a compound represented by formula (I)



(I)

or a salt thereof and sodium lauryl sulfate, wherein dodecanol/sodium lauryl sulfate or sulfate ion/sodium lauryl sulfate is contained in a ratio such that it causes no effect on dissolution behavior in the formulation when the formulation is measured after a pretreatment,

wherein the pretreatment comprises allowing the the pharmaceutical formulation to stand still under an accelerated condition,

wherein the accelerated condition is a temperature condition of 55 to 65°C,

wherein the ratio of dodecanol/sodium lauryl sulfate (mol/mol%) or sulfate ion/sodium lauryl sulfate (mol/mol%) in the formulation is 2% or less, as measured by X-ray powder diffraction, ion exchange chromatography, gas chromatography or quantitative NMR.

[Claim 25]

A pharmaceutical raw material for a formulation consisting essentially of sodium lauryl sulfate, wherein the content of the sulfate ion in the material is 1 mg/L or less when the pharmaceutical raw material for a formulation is pretreated and thereafter measured by ion exchange chromatography,

wherein the pretreatment comprises allowing the the pharmaceutical raw material to stand still under an accelerated condition,

wherein the accelerated condition is a temperature condition of 65 to 75°C.

[Claim 26]

A pharmaceutical formulation comprising the pharmaceutical raw material of claim 25, wherein the ratio of dodecanol/sodium lauryl sulfate or sulfate ion/sodium lauryl sulfate in the pharmaceutical formulation such that it causes no effect on dissolution behavior when the pharmaceutical formulation is measured after a pretreatment,

wherein the pretreatment comprises allowing the the pharmaceutical formulation to stand still under an accelerated condition,

wherein the accelerated condition is a temperature condition of 55 to 65°C.