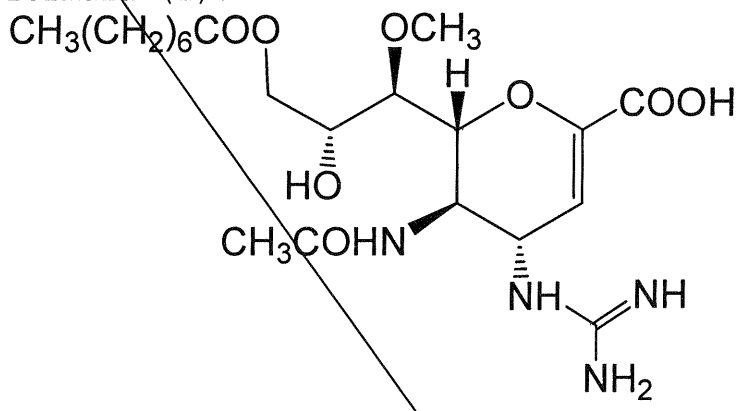
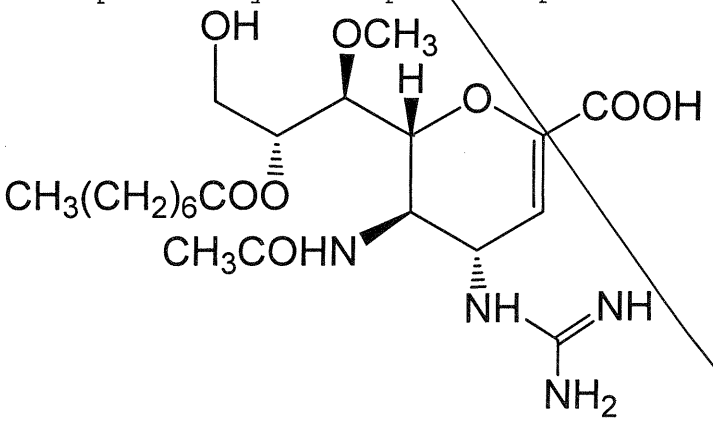
CLAIMS

1. A dry powder pharmaceutical composition for inhalation, comprising as a medicinal component a compound represented by formula (I):



(I)

and optionally a compound represented by formula (II):



(II)

, a pharmacologically acceptable salt thereof, or a hydrate thereof, and further comprising a diluting agent, wherein the diluting agent comprises:

a lactose hydrate having a particle size distribution satisfying one of

(Condition-1): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 5 μm to 60 μm,

a 50% by weight particle size of 50 μm to 110 μm, and

a 90% by weight particle size of 75 μm to 160 μm or

(Condition-2): in the particle size distribution measured by an air entrainment method,
the fraction with a particle size of less than 32 μm,
the fraction with a particle size of less than 63 μm, and
the fraction with a particle size of less than 100 μm
make up 5 to 10% by weight, 70 to 100% by weight, and 100% by weight, respectively; and

another lactose hydrate having a particle size distribution satisfying one of
(Condition-3): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has
a 10% by weight particle size of 3 μm or less,
a 50% by weight particle size of 20 μm or less, and
a 90% by weight particle size of 54 μm or less or
(Condition-4): in the particle size distribution measured by an air entrainment method,
the fraction with a particle size of less than 45 μm,
the fraction with a particle size of less than 63 μm, and
the fraction with a particle size of less than 150 μm
make up 90 to 100% by weight, 98 to 100% by weight, and 100% by weight, respectively.

2. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-5): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 19 μm to 43 μm,

a 50% by weight particle size of 53 μm to 66 μm, and

a 90% by weight particle size of 75 μm to 106 μm.

3. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-6): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 5 μm to 15 μm,

a 50% by weight particle size of 50 μm to 100 μm, and

a 90% by weight particle size of 120 μm to 160 μm.

4. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-7): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 30 μm to 60 μm,

a 50% by weight particle size of 70 μm to 110 μm, and

a 90% by weight particle size of 110 μm to 150 μm.

5. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-3) further satisfies

(Condition-8): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 1 μm to 3 μm,

a 50% by weight particle size of 11 μm to 20 μm, and

a 90% by weight particle size of 37 μm to 54 μm.

6. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-3) further satisfies

(Condition-9): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 50% by weight particle size of 5 μm or less and

a 90% by weight particle size of 10 μm or less.

7. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-3) further satisfies

(Condition-8): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 1 μm to 3 μm,

a 50% by weight particle size of 11 μm to 20 μm, and

a 90% by weight particle size of 37 μm to 54 μm.

8. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-4).

9. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-4), and the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-5): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 19 μm to 43 μm,

a 50% by weight particle size of 53 μm to 66 μm, and

a 90% by weight particle size of 75 μm to 106 μm.

10. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-5): the particle size distribution of the lactose

hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 19 μm to 43 μm,

a 50% by weight particle size of 53 μm to 66 μm, and

a 90% by weight particle size of 75 μm to 106 μm,

and the lactose hydrate satisfying (Condition-3) further satisfies

(Condition-8): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 1 μm to 3 μm,

a 50% by weight particle size of 11 μm to 20 μm, and

a 90% by weight particle size of 37 μm to 54 μm.

11. The dry powder pharmaceutical composition for inhalation according to claim 7, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-8), and the weight ratio between the lactose hydrate satisfying (Condition-2) and the lactose hydrate satisfying (Condition-8) is from 50:50 to 100:0.

12. The dry powder pharmaceutical composition for inhalation according to claim 8, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-4), and the weight ratio between the lactose hydrate satisfying (Condition-2) and the lactose hydrate satisfying (Condition-4) is from 50:50 to 100:0.

13. The dry powder pharmaceutical composition for inhalation according to claim 9, wherein the diluting agent comprises a

lactose hydrate satisfying (Condition-5) and a lactose hydrate satisfying (Condition-4), and the weight ratio between the lactose hydrate satisfying (Condition-5) and the lactose hydrate satisfying (Condition-4) is from 50:50 to 100:0.

14. The dry powder pharmaceutical composition for inhalation according to claim 10, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-5) and a lactose hydrate satisfying (Condition-8), and the weight ratio between the lactose hydrate satisfying (Condition-5) and the lactose hydrate satisfying (Condition-8) is from 50:50 to 100:0.

15. The dry powder pharmaceutical composition for inhalation according to claim 7 or 11, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-8), and the lactose hydrate satisfying (Condition-2) has a particle size controlled by sieving, and the lactose hydrate satisfying (Condition-8) has a particle size controlled by pulverization.

16. The dry powder pharmaceutical composition for inhalation according to claim 8 or 12, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-4), the lactose hydrate satisfying (Condition-2) has a particle size controlled by sieving, and the lactose hydrate satisfying (Condition-4) has a particle size controlled by pulverization.

17. The dry powder pharmaceutical composition for inhalation according to claim 9 or 13, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-5) and a lactose

hydrate satisfying (Condition-4), the lactose hydrate satisfying (Condition-5) has a particle size controlled by sieving, and the lactose hydrate satisfying (Condition-4) has a particle size controlled by pulverization.

18. The dry powder pharmaceutical composition for inhalation according to claim 10 or 14, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-5) and a lactose hydrate satisfying (Condition-8), the lactose hydrate satisfying (Condition-5) has a particle size controlled by sieving, and the lactose hydrate satisfying (Condition-8) has a particle size controlled by pulverization.

19. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 18, wherein the medicinal component has a 50% by weight particle size of 3.2 μm or less and a 90% by weight particle size of 8.0 μm or less as measured by particle size analysis-laser diffraction methods.

20. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 19, comprising 4% by weight to 30% by weight, on an anhydrous basis, of the medicinal component.

21. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 19, comprising 15% by weight to 25% by weight, on an anhydrous basis, of the medicinal component.

22. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 19, comprising 20% by weight, on an anhydrous basis, of the medicinal component.

23. The use of a dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 22 in the manufacture of a medicament for preventing influenza by inhalation to a respiratory system of a human subject before onset of an influenza virus infection, wherein the dose of the medicinal component to be administered is from 5 to 120 mg on an anhydrous basis.

24. The use of a dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 22 in the manufacture of a medicament for treating influenza by inhalation to a respiratory system of a human subject in onset of an influenza virus infection, wherein the dose of the medicinal component to be administered is from 5 to 120 mg on an anhydrous basis, and the dose is to be used as a single dose or in two divided doses.

25. The use according to claim 23 or 24, wherein the dose of the medicinal component is 20 mg on an anhydrous basis, which is to be administered in a single inhaled dose.

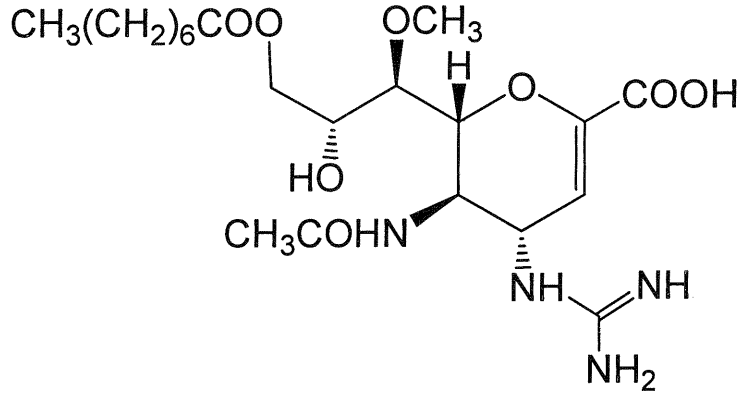
26. The use according to claim 24, wherein the dose of the medicinal component is 20 mg on an anhydrous basis, which is to be administered in two inhaled doses.

27. The use according to claim 23 or 24, wherein the dose of the medicinal component is 40 mg on an anhydrous basis, which is to be administered in a single inhaled dose.

28. The use according to claim 23 or 24, wherein the dose of the medicinal component is 80 mg on an anhydrous basis, which is to be administered in a single inhaled dose.

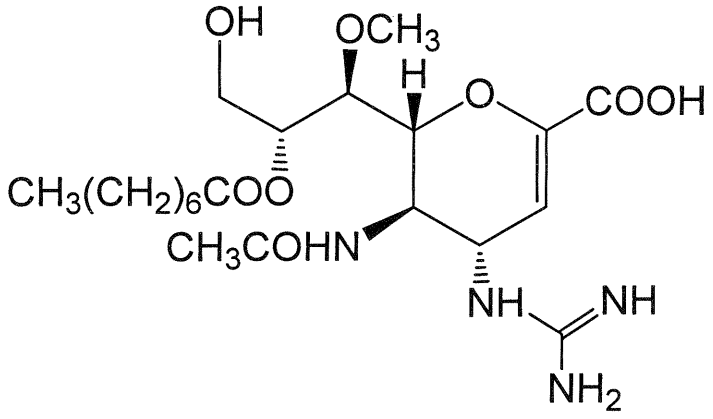
CLAIMS

1. A dry powder pharmaceutical composition for inhalation, comprising as a medicinal component a compound represented by formula (I):



(I)

and optionally a compound represented by formula (II):



(II)

,

a pharmacologically acceptable salt thereof, or a hydrate thereof, and further comprising a diluting agent, wherein the diluting agent comprises:

a lactose hydrate having a particle size distribution satisfying one of

(Condition-1): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 5 μm to 60 μm,

a 50% by weight particle size of 50 μm to 110 μm, and

a 90% by weight particle size of 75 μm to 160 μm or

(Condition-2): in the particle size distribution measured by an air entrainment method,

the fraction with a particle size of less than 32 μm,

the fraction with a particle size of less than 63 μm, and

the fraction with a particle size of less than 100 μm

make up 5 to 10% by weight, 70 to 100% by weight, and 100% by weight, respectively; and

another lactose hydrate having a particle size distribution satisfying one of

(Condition-3): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 3 μm or less,

a 50% by weight particle size of 20 μm or less, and

a 90% by weight particle size of 54 μm or less or

(Condition-4): in the particle size distribution measured by an air entrainment method,

the fraction with a particle size of less than 45 μm,

the fraction with a particle size of less than 63 μm, and

the fraction with a particle size of less than 150 μm

make up 90 to 100% by weight, 98 to 100% by weight, and 100% by weight, respectively.

2. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying

(Condition-1) further satisfies

(Condition-5): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 19 μm to 43 μm,

a 50% by weight particle size of 53 μm to 66 μm, and

a 90% by weight particle size of 75 μm to 106 μm.

3. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-6): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 5 μm to 15 μm,

a 50% by weight particle size of 50 μm to 100 μm, and

a 90% by weight particle size of 120 μm to 160 μm.

4. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-7): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 30 μm to 60 μm,

a 50% by weight particle size of 70 μm to 110 μm, and

a 90% by weight particle size of 110 μm to 150 μm.

5. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-3) further satisfies

(Condition-8): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 1 μm to 3 μm,

a 50% by weight particle size of 11 μm to 20 μm, and

a 90% by weight particle size of 37 μm to 54 μm.

6. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying (Condition-3) further satisfies

(Condition-9): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 50% by weight particle size of 5 μm or less and

a 90% by weight particle size of 10 μm or less.

7. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-3), and the lactose hydrate satisfying

(Condition-3) further satisfies

(Condition-8): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 1 μm to 3 μm,

a 50% by weight particle size of 11 μm to 20 μm, and

a 90% by weight particle size of 37 μm to 54 μm.

8. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-2) and a lactose hydrate satisfying (Condition-4).

9. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-4), and the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-5): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 19 μm to 43 μm,

a 50% by weight particle size of 53 μm to 66 μm, and

a 90% by weight particle size of 75 μm to 106 μm.

10. The dry powder pharmaceutical composition for inhalation according to claim 1, wherein the diluting agent comprises a lactose hydrate satisfying (Condition-1) and a lactose hydrate satisfying (Condition-3), the lactose hydrate satisfying (Condition-1) further satisfies

(Condition-5): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 19 μm to 43 μm,

a 50% by weight particle size of 53 μm to 66 μm, and

a 90% by weight particle size of 75 μm to 106 μm,

and the lactose hydrate satisfying (Condition-3) further satisfies

(Condition-8): the particle size distribution of the lactose hydrate measured by particle size analysis-laser diffraction methods has

a 10% by weight particle size of 1 μm to 3 μm,

a 50% by weight particle size of 11 μm to 20 μm, and

a 90% by weight particle size of 37 μm to 54 μm.

11. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 10, wherein the medicinal component has a 50% by weight particle size of 3.2 μm or less and a 90% by weight particle size of 8.0 μm or less as measured by particle size analysis-laser diffraction methods.

12. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 11, comprising 4% by weight to 30% by weight, on an anhydrous basis, of the medicinal component.

13. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 11, comprising 15% by weight to 25% by weight, on an anhydrous basis, of the medicinal component.

14. The dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 11, comprising 20% by weight, on an anhydrous basis, of the medicinal component.

15. The use of a dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 14 in the manufacture of a medicament for preventing influenza by inhalation to a respiratory system of a human subject before onset of an influenza virus infection, wherein the dose of the medicinal component to be administered is from 5 to 120 mg on an anhydrous basis.

16. The use of a dry powder pharmaceutical composition for inhalation according to any one of claims 1 to 14 in the manufacture of a medicament for treating influenza by inhalation to a respiratory system of a human subject in onset of an influenza virus infection, wherein the dose of the medicinal component to be administered is from 5 to 120 mg on an anhydrous basis, and the dose is to be used as a single dose or in two divided doses.

17. The use according to claim 15 or 16, wherein the dose of the medicinal component is 20 mg on an anhydrous basis, which is to be administered in a single inhaled dose.

18. The use according to claim 16, wherein the dose of the medicinal component is 20 mg on an anhydrous basis, which is to be administered in two inhaled doses.

19. The use according to claim 15 or 16, wherein the dose of the medicinal component is 40 mg on an anhydrous basis, which is to be administered in a single inhaled dose.

20. The use according to claim 15 or 16, wherein the dose of the medicinal component is 80 mg on an anhydrous basis, which is to be administered in a single inhaled dose.