Claims

1. A lobaplatin compound crystal is characterized in two molecules of crystal water existing in a crystal structure.

2. The lobaplatin compound crystal according to claim 1, wherein, a crystal form of said lobaplatin compound is crystal form A, and there are diffraction peaks at 2θ values of about 11.04, 12.32, 12.61, 13.85, 15.14,15.55, 16.68, 17.67, 17.86, 19.03, 20.06, 21.00, 22.68, 22.92, 23.76, 25.39, 25.58, 26.37, 26.77, 27.00, 27.71, 28.13, 29.71, 31.42, 31.94, 32.89, 34.29, 34.60, 36.10, 36.93, 37.66, 40.78, 43.41 in a PXRD pattern, wherein an error range of 2θ values is 0.2.

3. The lobaplatin compound crystal according to claim 2, wherein, a melting point $T_{m.p..}$of said lobaplatin compound crystal is 220±5℃.

4. The lobaplatin compound crystal according to claim 1, wherein, a crystal form of said lobaplatin compound crystal is crystal form A, which belongs to a orthorhombic system, with a space group of $P2_12_12_1$, unit cell parameters of a = 10.601 (2) Å, b = 14.020 (3), c = 9.759 (2) Å, α = β = γ = 90.0 °, a unit cell volume of V = 1450.5 (5) Å3, and an asymmetric numbers of Z = 4 in the unit cell.

5. A method of preparing said lobaplatin compound according to any one of claims 1 to 4, is characterized in that the method comprises the following steps:

adding lobaplatin trihydrate to a solvent for suspension crystallization to form a mixture in suspension state, stirring the mixture, precipitating crystal , removing the solvent and then drying to get the crystal.

6. The method according to claim 5, wherein, after removing the solvent, the crystal is washed with ethyl ether before drying, and said drying is vaccum drying.

7. The method according to claim 5 or claim 6, wherein, a ratio of mass of said lobaplatin trihydrate to volume of solvent for crystallization is 1(g):15-30(ml).

8. The method according to any one of claims 5 to 7, wherein, said solvent for crystallization is selected from methyl tert-butyl ether, toluene, ethyl ether, butyl acetate, 1,4-dioxane or n-heptane.

9. The method according to any one of claims 5 to 8, wherein, said suspension state is performed at room temperature, preferably, said suspension state is performed for 45-50h.

10. A lobaplatin compound crystal is characterized in that a crystal form of said lobaplatin compound is crystal form B, and there are diffraction peaks at 2θ values of about 8.25, 9.77, 11.70, 13.13 ,15.28, 16.48, 17.22, 17.74, 19.01, 19.56, 22.28, 23.72, 24.04, 24.30, 25.62, 26.20, 28.57, 30.22, 30.61 in a PXRD pattern, wherein an error range of 2θ values is 0.2.

11. The lobaplatin compound crystal according to claim 10, is characterized in that a melting point $T_{m.p..}$ of said lobaplatin compound crystal is 230±5℃.

12. A method of preparing said lobaplatin crystal according to claim 10 or claim 11, wherein, the method comprises the following steps:

adding anhydrous methanol or anhydrous ethanol to lobaplatin trihydrate to obtain a mixture, stirring the mixture at room temperature until solids are dissolved, removing insolutes from the mixture, evaporating the mixture slowly, precipitating crystal, separating the crystal, and then drying the crystal to obtain white powder which is lobaplatin crystal form B.

13. A method of preparing said lobaplatin crystal according to claim 10 or claim 11, wherein, the method comprises the following step b):

adding anhydrous methanol to lobaplatin dihydrate to obtain a mixture, stirring the mixture at room temperature until solids are dissolved, removing insolutes from the mixture, evaporating the mixture slowly, precipitating crystal, separating the crystal, and then drying the crystal to obtain white powder which is lobaplatin crystal B.

14. The method of preparing said lobaplatin crystal according to claims 10 or claim 11, wherein, the method comprises the following step b):

adding an organic solvent to lobaplatin dihydrate to form a mixture in suspension state, stirring the mixture at room temperature, precipitating crystal, separating the crystal, and then drying the crystal to get white powders which is

lobaplatin crystal form B.

15. The method according to claim 13 or claim 14, wherein, the method of preparing said lobaplatin dihydrate comprises the following step a):

adding a solvent for suspension crystallization to lobaplatin trihydrate to form a mixture in suspension state, stirring the mixture, precipitating crystal, and washing the crystal with ethyl ether after removing solvent, and then vacuum drying the crystal to obtain the lobaplatin dihydrate crystal.

16. The method according to claim 15, wherein, said solvent for crystallization in step a) is selected from methyl tert-butyl ether, toluene, ethyl ether, butyl acetate, 1,4-dioxane or n-heptane, and a ratio of mass of said lobaplatin trihydrate to volume of solvent for crystallization is 1(g):15-30(ml).

17. The method according to any one of claims 13 to 14, or claims 15 to 16, wherein, in step b), after separating the crystal, washing the crystal with ethyl ether before drying the crystal, said drying is vaccum drying.

18. The method according to claim 14, or any one of claims 15 to 17, wherein, said suspension state is performed at room temperature in step b), preferably, said suspension state is performed for 45-50h.

19. The method according to claim 13, or any one of claims 15 to 18, wherein, a ratio of mass of lobaplatin dihydrate to volume of anhydrous methanol is 1(g):40-50(ml) in said step b).

20. The method according to claim 14, or any one of claims 15 to 19, wherein, the organic solvent is selected from n-hexane, acetone, ethyl acetate, nitromethane, acetonitrile, tetrahydrofuran, 2-butanone or dichloromethane in said step b), and the ratio of mass of lobaplatin dihydrate to volume of organic solvent is 1(g):15-30(ml).

21. The method according to claim 12, wherein, the mass volume ratio of said lobaplatin trihydrate to anhydrous methanol is 1(g):40-50(ml); the mass volume ratio of said lobaplatin trihydrate to anhydrous ethanol is 1(g):80-90(ml).

22. A lobaplatin compound crystal is characterized in that a crystal form of

the compound crystal is crystal form F, and there are diffraction peaks at 2θ values of about 8.21, 11.60, 12.99, 15.24, 16.44, 17.11, 17.55, 18.42, 19.01, 19.20, 19.42, 21.81, 22.17, 22.42, 23.33, 23.85, 24.18, 24.40, 24.77, 25.46, 25.98, 26.13, 27.89, 28.42, 29.03, 30.32, 31.17, 31.94, 33.30, 36.20, 37.62, 39.66 in a PXRD pattern, wherein an error range of 2θ values is 0.2.

23. The lobaplatin crystal according to claim 22 is characterized in that a melting point $T_{m.p..}$ of said lobaplatin compound crystal is 229±5℃.

24. A method of preparing said lobaplatin crystal according to claim 22 or claim 23, is characterized in that the method comprises the following step b):

adding methanol or ethanol to lobaplatin dihydrate to obtain a mixture, stirring the mixture at room temperature until solids are dissolved, filtering the mixture to remove the insolutes, adding an organic solvent in the mixture slowly, precipating crystal, separating the crystal, and then drying the crystal to obtain white powder which is lobaplatin crystal form F.

25. The method according to claim 24, wherein, the method of preparaing said lobaplatin dihydrate comprises the following step a):

adding a solvent for suspension crystallization to lobaplatin trihydrate to form a mixture in suspension state, stirring the mixture, precipitating crystal from the mixture, washing the crystal with ethyl ether after removing the solvent, and then vacuum drying the crystal to obtain the lobaplatin dihydrate crystal.

26. The method according to claim 25, wherein, said solvent for crystallization in step a) is selected from methyl tert-butyl ether, toluene, ethyl ether, butyl acetate, 1,4-dioxane or n-heptane, and a ratio of mass of said lobaplatin trihydrate to volume of solvent for crystallization is 1(g):15-30(ml).

27. The method according to any one of claims 24 to 26, wherein, in step b), after separating the crystal, the crystal is washed with ethyl ether before drying the crystal, and said drying is vaccum drying.

28. The method according to any one of claims 24 to 26, wherein, the said organic solvent in said step b) is selected from ethylene glycol dimethyl ether, n-

hexane, ethyl acetate, acetone, nitromethane, acetonitrile, tetrahydrofuran, or methylene chloride.

29. The method according to any one of claims 24 to 28, wherein, the ratio of mass of said lobaplatin dihydrate to volume of organic solvent is 1(g):120-200(ml) in said step b).

30. The method according to any one of claims 24 to 29, wherein, the ratio of mass of said lobaplatin dihydrate to volume of methanol is 1(g):40-50(ml); the ratio of mass of said lobaplatin dihydrate to volume of ethanol is 1(g):80-90(ml) in said step b).

31. A pharmaceutical composition is characterized in that said lobaplatin crystal according to any one of claims 1 to 4, claim 10, claim 11, claim 22 or claim 23 is used as an active component.

32. The pharmaceutical composition according to claim 31 is characterized in that an amount of the lobaplatin crystal in a minimum unit of said pharmaceutical composition is 5mg, 10mg or 50mg.

33. The pharmaceutical composition according to claim 31 or claim 32 is characterized in that said pharmaceutical composition is any clinically acceptable pharmaceutical dosage form.

34. The pharmaceutical composition according to any one of claims 31 to claim 33 is characterized in that said dosage form is a lyophilized preparation for injection.

35. A use of said lobaplatin crystal according to any one of claims 1 to 4, claim 10, claim 11, claim 22 or claim 23, or said pharmaceutical composition according to claims 31 to 34 for the preparation of anti-cancer drugs.

36. The lobaplatin crystal according to any one of claims 1 to 4, claim 10, claim 11, claim 22 or claim 23, or the pharmaceutical composition according to claims 31 to 34 for use in the treatment of breast cancer, small-cell lung cancer or chronic myelogenous leukemia.