23.6	3.76	67

[0032]

Example 2

The crystal obtained in Example 1 was milled and passed through No. 60 (250 μm) sieve to obtain a powder remaining on No. 282 (53 μm) sieve. Each vial was filled with the powder (1.41 g) to obtain an injectable preparation of a monohydrate crystal, which is useful in an injectable preparation.

[0033]

Example 3-1

The crystal (1.35 g) obtained in Example 1 was allowed to stand still at 40°C under vacuum (50 Pa or below) for 64 hours to obtain a crystal of an anhydrate.

Water content: 0.07%

In the powder X-ray diffraction pattern of the obtained crystal, peaks were observed at 2θ (°): 11.3, 13.0, 17.0, 19.7, 20.5, 22.0, 24.2, 26.4, 28.1.

[0034]

Example 3-2

The crystal (86 mg) obtained in Example 1 was allowed to stand still at 80 to 90°C for 5 minutes and thereafter at 90°C for 180 minutes to obtain a crystal of an anhydrate.

The result of powder X-ray diffraction of the crystal of the anhydrate is shown in Fig. 3 and Table 2.

The powder X-ray diffraction pattern coincided with that of Example 3-1.

[0035]

Powder X-ray diffraction measurement conditions:

X-rays to be used: CuKα1, CuKα2, CuKβ

Applied voltage: 45 kV

Supplied current: 40 mA

Scanning axis: 2θ

Scanning range: 2θ = 2 to 40°

Measurement temperature: 90°C

[0036]

[Table 2]

2θ	Relative intensity
10.2	12
11.3	19
13.0	64
15.9	14
17.0	44
18.7	27
19.7	100
20.5	37
22.0	30
24.2	53
26.4	42
28.1	40

[0037]

Example 4

The injectable preparation obtained in Example 2 was allowed to stand still at 40°C under vacuum (50 Pa or below) for 60 hours to obtain an injectable preparation of a crystal of the anhydrate is which [illegible].

Water content: 0.17%

[0038]

Example 5

To a suspension of Compound A (45.1 g) in Water for Injection (500 mL) was added meglumine (55.9 g), and the mixture was stirred to dissolve Compound A. After to the solution was added Water for Injection to give a total volume of 600 mL, the mixture was filtered through a 0.22-μm membrane filter to obtain a liquid preparation (pH 7.6). Each vial was filled with the liquid preparation (8 mL), lyophilized and then closed airtight to obtain a lyophilized preparation of an amorphous product.

Water content: 0.17%

The result of powder X-ray diffraction of the lyophilized preparation is shown in Fig. 2.

Lyophilization method

1. Vials were cooled at the shelf temperature of -60°C to freeze the content.

Claims

1. A meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or a hydrate thereof.

2. ~~A crystal of a~~ The meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or a hydrate thereof according to claim 1, wherein the meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or the hydrate thereof is a crystal.

3. ~~An amorphous~~ The meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or a hydrate thereof according to claim 1, wherein the meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or the hydrate thereof is an amorphous product.

4. An injectable preparation containing a meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or a hydrate thereof.

5. The injectable preparation according to claim 4, wherein the meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or a hydrate thereof is a crystal.

6. The injectable preparation according to claim 4, wherein the meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or a hydrate thereof is an amorphous product.

7. The injectable preparation according to claim 4 or 5, further containing an amino acid and a saccharide, or an amino acid and a sugar alcohol.

8. A lyophilized preparation containing a meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide.

9. The lyophilized preparation according to claim 8, wherein the meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide is a crystal.

10. The lyophilized preparation according to claim 8, wherein the meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide is an amorphous product.

11. The lyophilized preparation according to claim 8 or 9, further containing an amino acid and a saccharide, or an amino acid and a sugar alcohol.

12. A process for producing a lyophilized preparation containing a crystal of a meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide, comprising the steps:
(1) cooling an aqueous solution containing 6-fluoro-3-hydroxy-2-pyrazinecarboxamide and meglumine to produce an amorphous frozen product of a meglumine salt of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide;
(2) increasing ~~the~~ a temperature of the amorphous frozen product to produce a crystalline frozen product;
(3) cooling the crystalline frozen product again; and
(4) carrying out lyophilization.

13. The process according to claim 12, wherein the ~~achieving~~ temperature of the amorphous frozen product ~~falls within the~~ is increased to a range of -20 to -5°C in the step of increasing the temperature of the amorphous frozen product.