

Claims

1. A crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)-methyl-2,4(1H,3H)-pyrimidinedione hydrochloride exhibiting peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ($2\theta \pm 0.2^\circ$) in powder X-ray diffraction.
2. The crystal according to claim 1, wherein said crystal does not contain a crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)-methyl-2,4(1H,3H)-pyrimidinedione hydrochloride exhibiting peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ($2\theta \pm 0.1^\circ$) in powder X-ray diffraction.
3. The crystal according to claim 1 or 2, exhibiting peaks at angles of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ($2\theta \pm 0.2^\circ$) in powder X-ray diffraction.
4. The crystal according to any one of claims 1 to 3, exhibiting an endothermic peak determined by thermogravimetry-differential thermal analysis at a temperature of around 262°C.
5. The crystal according to any of claims 1 to 4, which shows, in single-crystal analysis, the following crystal data:
Crystal system: monoclinic system
Space group: $P2_1/n$ (No. 14)

Lattice constant:

$$a = 11.6006 \text{ (9) } \text{\AA}$$

$$b = 10.3106 \text{ (11) } \text{\AA}$$

$$c = 10.3036 \text{ (10) } \text{\AA}$$

$$\alpha = 90^\circ$$

$$\beta = 101.951 \text{ (7) }^\circ$$

$$\gamma = 90^\circ$$

Unit lattice volume: 1205.7 (2) $\text{\AA}^3$.

6. The crystal according to any of claims 1 to 5, in an anhydrous form.
7. The crystal according to any of claims 1 to 6, having a purity of 90 % by mass or more.
8. The crystal according to any of claims 1 to 7, exhibiting peaks at two or more angles selected from the group consisting of 11.6°, 17.2°, 17.8°, 23.3°, 27.1°, and 29.3° as a diffraction angle ($2\theta \pm 0.2^\circ$) in powder X-ray diffraction after a 6-month preservation at 40°C in a stability test.
9. A production method of the crystal according to any of claims 1 to 8, comprising,
dissolving 5-chloro-6-(2-iminopyrrolidin-1-yl)-methyl-2,4(1H,3H)-pyrimidinedione hydrochloride in a water-ethanol mixed solvent with heating, and
subjecting the solution to crystallization at a temperature of 40°C or higher, followed by cooling.
10. A pharmaceutical composition comprising the crystal

according to any one of claims 1 to 8 and a pharmaceutically acceptable carrier.