

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, 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.
3. The crystal according to claim 1 or 2, exhibiting an endothermic peak determined by thermogravimetry-differential thermal analysis at a temperature of around 262°C.
4. The crystal according to any of claims 1 to 3, which shows, in single-crystal analysis, the following crystal data:

Crystal system: monoclinic system

Space group: $P2_1/n$ (No. 14)

Lattice constant:

$a = 11.6006$ (9) Å

$b = 10.3106$ (11) Å

$c = 10.3036$ (10) Å

$\alpha = 90^\circ$

$\beta = 101.951$ (7)°

$\gamma = 90^\circ$

Unit lattice volume: 1205.7 (2) Å³.

5. The crystal according to any of claims 1 to 4, in an anhydrous form.
6. The crystal according to any of claims 1 to 5, having a purity of 90 % by mass or more.
7. The crystal according to any of claims 1 to 6, 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.
8. A production method of the crystal according to any of claims 1 to 7, 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.
9. A pharmaceutical composition comprising the crystal according to any one of claims 1 to 7 and a pharmaceutically acceptable carrier.