

CLAIMS

1. A crystal of 5-chloro-6-(2-iminopyrrolidin-1-yl)methyl-2,4(1H,3H)-pyrimidinedione hydrochloride, which is crystal Form I, 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.

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 ($2\theta \pm 0.1^{\circ}$) in powder X-ray diffraction.

3. The crystal according to claim 1, exhibiting an endothermic peak determined by thermogravimetry-differential thermal analysis at a temperature of around 262°C .

4. The crystal according to claim 1, 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) $^{\circ}$

$\gamma=90^{\circ}$

Unit lattice volume: 1205.7 (2) Å³.

5. The crystal according to claim 1, in an anhydrous form.

6. The crystal according to claim 1, having a purity of 90% by mass or more.

7. The crystal according to claim 1, 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 after a 6-month preservation at 40° C. in a stability test.

8. A pharmaceutical composition comprising the crystal according to claim 1 and a pharmaceutically acceptable carrier.

9. A production method of the crystal according to claim 1, 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.