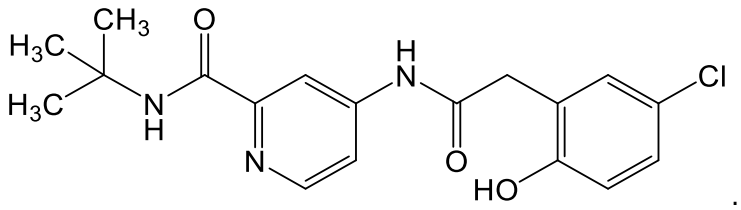
CLAIMS

1. A compound which is N-tert-Butyl-4-[[2-(5-chloro-2-hydroxy-phenyl)acetyl]amino]pyridine-2-carboxamide (Compound 1), having the following structural formula:



in the form of its Form A anhydrous solid crystalline polymorph, for example a form having an XRPD diffractogram substantially as shown in Figure 1; or in the form of its Form B hydrate solid crystalline polymorph, for example a form having an XRPD diffractogram substantially as shown in Figure 4; or in amorphous form.

2. A compound according to claim 1, which is Compound 1 in the form of its Form A crystalline polymorph characterised by an XRPD diffractogram comprising a major peak at 7.25 (± 0.2 degrees, 2-theta value) and at least three (for example three, four, five, six, seven, eight or all nine) of the peaks at positions 14.44, 20.42, 21.68, 24.38, 27.21, 29.01, 30.82, 36.46 and 41.49 (± 0.2 degrees, 2-theta values).

3. A compound according to claim 2 characterised by an XRPD diffractogram comprising a major peak at 7.25 (± 0.2 degrees, 2-theta value) and at least three (for example three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen or all fourteen) of the peaks at positions 10.20, 14.44, 17.79, 20.42, 20.69, 21.68, 24.22, 24.38, 26.13, 27.21, 29.01, 30.82, 36.46 and 41.49 (± 0.2 degrees, 2-theta values).

4. A compound according to claim 2 or claim 3 characterised by an XRPD diffractogram comprising a major peak at 7.25 (± 0.2 degrees, 2-theta value) and at least three (for example three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen or all nineteen) of the peaks at positions 10.20, 14.44, 16.13, 17.79, 20.42, 20.69, 21.07, 21.68, 24.09, 24.22, 24.38, 26.13, 27.21, 29.01, 29,30, 30.82, 32.50, 36.46 and 41.49 (± 0.2 degrees, 2-theta values).

5. A compound according to any one of claims 2 to 4, wherein the XRPD diffractogram comprises peaks at positions 21.68 and 29.01 (± 0.2 degrees, 2-theta values) and a cluster of peaks at 24.09, 24.22 and 24.3801 (± 0.2 degrees, 2-theta values).

6. A compound according to any one of claims 2 to 5, wherein the Form A polymorph is substantially free of other forms of Compound 1 such that at least 97% by weight of Compound 1 is present as the Form A polymorph.

7. A compound according to any one of claims 2 to 6 which is micronised.

8. A process for the preparation of a compound according to any one of claims 2 to 7 comprising crystallising Compound 1 from a solvent selected from acetone, butanol, ethanol, ethyl formate, isopropyl acetate, methyl acetate, nitromethane, 2-propanol, propionitrile and acetonitrile.

9. A process according to claim 8, wherein the process comprises the steps of:

i. preparing a saturated solution of Compound 1 in a solvent at a temperature of about 50 to 70°C;

ii. cooling the solution to a temperature of about 5 to 20°C;

iii. allowing the cooled solution to stand until crystals of Compound 1 form; and

iv. isolating the crystallised product;

wherein the solvent is selected from acetone, butanol, ethanol, ethyl formate, isopropyl acetate, methyl acetate, nitromethane, 2-propanol, propionitrile and acetonitrile.

10. A process according to claim 8 or claim 9 wherein the solvent is selected from acetonitrile, ethanol, ethyl acetate, methyl acetate, butanol, 2-propanol or isopropyl acetate.

11. A compound according to claim 1, which is Compound 1 in the form of its Form B hydrate solid crystalline polymorph characterised by an XRPD diffractogram comprising a major peak at position 11.03 (± 0.4 degrees, more suitably ± 0.3 degrees or ± 0.2 degrees, 2-theta value) and at least three (for example three, four, five, six, seven, eight or all nine) of the peaks at positions 5.56, 14.04, 17.28, 18.03, 18.86, 22.08, 23.69, 24.12 and 24.93 (± 0.4 degrees, more suitably ± 0.3 degrees or ± 0.2 degrees, 2-theta values).

12. A compound according to claim 11 characterised by an XRPD diffractogram comprising a major peak at position 11.03 (± 0.4 degrees, more suitably ± 0.3 degrees or ± 0.2 degrees, 2-theta value) and at least three (for example three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen or all fourteen) of the peaks at positions 5.56, 14.04, 17.28, 18.03, 18.86, 19.34, 22.08, 23.69, 24.12, 24.93, 25.98, 26.53, 27.28 and 28.79 (± 0.4 degrees, more suitably ± 0.3 degrees or ± 0.2 degrees, 2-theta values).

13. A compound according to claim 11 or claim 12 which has an XRPD diffractogram comprising peaks at positions 5.36 and 22.08 (± 0.4 degrees, more suitably ± 0.3 degrees or ± 0.2 degrees, 2-theta values).

14. A compound according to any one of claims 11 to 13, which is micronised.

15. A compound according to any one of claims 11 to 14, wherein the Form B polymorph is substantially free of other forms of Compound 1 such that at least 97% by weight of Compound 1 is present as the Form B polymorph.

16. A compound according to any one of claims 11 to 15 wherein the Form B polymorph is the Form B(I) pseudopolymorph and is characterised in that it undergoes unimodal dehydration

17. A process for the preparation of a compound according to any one of claims 11 to 16, comprising crystallising Compound 1 from an aqueous solvent such as water or water mixed with acetonitrile.

18. A process according to claim 17 comprising the steps of:

i. preparing a saturated solution of Compound 1 in a solvent at a temperature of about 60 to 80°C;

ii. cooling the solution to a temperature of about 5 to 20°C;

iii. allowing the cooled solution to stand until crystals of Compound 1 form; and

iv. isolating the crystallised product;

wherein the solvent is an aqueous solvent such as water or water mixed with acetonitrile, for example acetonitrile/water in a ratio of from 5:1 to 1:5 v/v.

19. A compound according to claim 1, which is Compound 1 in solid anhydrous amorphous form.