Claims

1. A crystalline Form B of 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide that is characterized as having at least one of:

(a) an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta; or

(b) unit cell parameters according to the following at -173°C:

Crystal system	Monoclinic				
Space group	$P2_1/c$	*a*	17.7796(4)Å	α	90°
		b	12.9832(3)Å	β	100.897(2)°
		c	18.4740(4)Å	γ	90°
V	4187.57(16)Å^3				
Z	8				
Dc	1.515g.cm^{-1}				

and optionally:

(c) a DSC thermogram with an endotherm having an onset temperature at about 194°C.

2. The crystalline Form B of claim 1, wherein the crystalline form B has an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta.

3. The crystalline Form B of claim 1, wherein the crystalline form B has unit cell parameters according to the following at -173°C:

Crystal system	Monoclinic				
Space group	$P2_1/c$	*a*	17.7796(4)Å	α	90°
		b	12.9832(3)Å	β	100.897(2)°

		c	18.4740(4)Å	γ	90°
V	4187.57(16)Å^3				
Z	8				
Dc	1.515g.cm^{-1}				

4. The crystalline Form B of claim 1, wherein the crystalline form B has a DSC thermogram with an endotherm having an onset temperature at about 194°C.

5. The crystalline Form B of claim 1, wherein the crystalline form B that is characterized as having properties (a), (b), and (c).

6. The crystalline Form B of any one of claims 1 to 5, wherein the crystalline form B is unsolvated.

7. A pharmaceutical composition comprising 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide in the composition is the crystalline Form B of any one of claims 1 to 6.

8. The pharmaceutical composition according claim 7, wherein the pharmaceutical composition is in a form suitable for oral administration to a mammal.

9. The pharmaceutical composition according to claim 8, wherein the pharmaceutical composition is in an oral solid dosage form.

10. The pharmaceutical composition according to any one of claims 7 to 9, wherein the pharmaceutical composition comprises 0.5 mg to 1000 mg of crystalline Form B of

4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide.

11. Use of a pharmaceutical composition according to any one of claims 7 to 10 in the manufacture of a medicament for the treatment of prostate cancer in a mammal.

12. The use of the pharmaceutical composition according to claim 11, wherein the prostate cancer is hormone sensitive prostate cancer or hormone refractory prostate cancer.

13. The use of the pharmaceutical composition according to claim 11, wherein the mammal is a human patient.

14. Use of a crystalline Form B of 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide according to any one of claims 1 to 6 in the manufacture of a medicament for treating prostate cancer in a mammal.

15. The use of crystalline Form B of 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide according to claim 14, wherein the prostate cancer is hormone sensitive prostate cancer or hormone refractory prostate cancer.

16. The use of crystalline Form B of 4-[7-(6-cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide according to claim 14, wherein the mammal is a human patient.