Claims

1. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D characterized by an X-ray powder diffraction pattern comprising peaks with the following 2θ±0.2° values: 7.8, 19.2, and 15.0 degree.

2. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to claim 1, wherein the X-ray powder diffraction pattern further comprises peaks at 16.4, 13.1, and 13.7 degree 2-theta ±0.2º.

3. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to claim 2, wherein the X-ray powder diffraction pattern is substantially as shown in FIG 1.

4. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D characterized by an X-ray powder diffraction pattern comprising (a) at least 3 peaks selected from 7.8, 19.2, 15.0, 16.4, 13.1, 13.7, 26.4, 19.8, 17.9, and 22.5 degree 2θ±0.2°; or (b) at least 5 peaks selected from 7.8, 19.2, 15.0, 16.4, 13.1, 13.7, 26.4, 19.8, 17.9, and 22.5 degree 2θ±0.2º.

5. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to any one of the claims 1 to 4, further characterized by a differential scanning calorimetry (DSC) curve that comprises an endotherm at about 214 ºC.

6. A pharmaceutical composition comprising crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to any one of claims 1 to 5 and a pharmaceutically acceptable carrier.

7. A pharmaceutical composition comprising an effective amount of (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide according to any one of claims 1 to 5 and a pharmaceutically acceptable carrier, wherein at

least about 85%, or at least about 90%, or at least about 95%, or at least about 96%, or at least about 97%, or at least about 98%, or at least about 99%, or at least about 99.5% of (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide is in Form D.

8. A pharmaceutical composition for use in treating cancer comprising an effective amount of crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to any one of claims 1 to 5.

9. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to any one of claims 1 to 5 for use in treating cancer.

10. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E characterized by an X-ray powder diffraction pattern comprising peaks with the following 2θ±0.2° values: 12.3, 18.8, and 9.3 degree.

11. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to claim 10, wherein the X-ray powder diffraction pattern further comprises peaks at 14.2, 14.1, and 19.8 degree 2-theta ±0.2º.

12. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E characterized by an X-ray powder diffraction pattern comprising (a) at least 3 peaks selected from 12.3, 18.8, 9.3, 14.2, 14.1, 19.8, 26.2, 17.3, 7.1 and 25.4 degree 2θ±0.2°; or (b) at least 5 peaks selected from 12.3, 18.8, 9.3, 14.2, 14.1, 19.8, 26.2, 17.3, 7.1 and 25.4 degree 2θ±0.2º.

13. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to any one of the claims 10 to 12, further characterized by a differential scanning calorimetry (DSC) curve that comprises an endotherm at about 125 ºC.

14. A pharmaceutical composition comprising crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to any one of claims 10 to 13 and a pharmaceutically acceptable carrier.

15. A pharmaceutical composition comprising an effective amount of (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to any one of claims 10 to 13 and a pharmaceutically acceptable carrier, wherein at least about 85%, or at least about 90%, or at least about 95%, or at least about 96%, or at least about 97%, or at least about 98%, or at least about 99%, or at least about 99.5% of (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide is in Form E.

16. A pharmaceutical composition for use in treating cancer comprising an effective amount of crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to any one of claims 10 to 13.

17. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to any one of claims 10 to 13 for use in treating cancer.

18. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to any one of claims 1 to 5 for use in therapy.

19. Use of crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form D according to any one of claims 1 to 5 in the manufacture of a medicament for treating cancer.

20. Crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to any one of claims 10 to 13 for use in therapy.

21. Use of crystalline (S)-2-amino-N-((3R,5R)-8-hydroxy-6-oxo-7-oxa-1-aza-8-boraspiro[4.7]dodecan-3-yl)-3-methylbutanamide Form E according to any one of claims 10 to 13 in the manufacture of a medicament for treating cancer.