Claims

1. A crystalline form of L-ornithine phenylacetate, wherein said crystalline form exhibits an X-ray powder diffraction pattern comprising at least three characteristic peaks, wherein said characteristic peaks are selected from the group consisting of 6.0°±0.2° 2θ, 13.9°±0.2° 2θ, 14.8°±0.2° 2θ, 17.1°±0.2° 2θ, 17.8°±0.2° 2θ and 24.1°±0.2° 2θ.

2. The crystalline form of Claim 1, wherein said crystalline form exhibits an X-ray powder diffraction pattern comprising characteristic peaks at 6.0°±0.2° 2θ, 13.9°±0.2° 2θ, 14.8°±0.2° 2θ, 17.1°±0.2° 2θ, 17.8°±0.2° 2θ and 24.1°±0.2° 2θ.

3. The crystalline form of any one of Claims 1-2, wherein said crystalline form has a melting point of about 202° C.

4. The crystalline form of any one of Claims 1-3, wherein said crystalline form exhibits a single crystal X-ray crystallographic analysis with crystal parameters approximately equal to the following:

unit cell dimensions: a=6.594(2) Å, b=6.5448(18) Å, c=31.632(8) Å, α=90°, β=91.12(3)°, γ=90°;

Crystal System: Monoclinic; and

Space Group: $P2_1$.

5. The crystalline form of any one of Claims 1-4, wherein the said crystalline form is represented by the formula $[C_5H_{13}N_2O_2][C_8H_7O_2]$.

6. A composition comprising a crystalline form of L-ornithine phenylacetate according to any one of Claims 1 to 5.

7. A method of compressing L-ornithine phenylacetate, the method comprising applying pressure to a metastable form of L-ornithine phenylacetate to induce a phase change, wherein the metastable form exhibits an X-ray powder diffraction pattern comprising at least three characteristic peaks, wherein said characteristic peaks are selected from the group consisting of 4.9°±0.2° 2θ, 17.4°±0.2° 2θ, 13.2°±0.2° 2θ, 20.8°±0.2° 2θ and 24.4°±0.2° 2θ, wherein the phase change yields a composition exhibiting an X-ray powder diffraction pattern comprising at least three characteristic peaks, wherein said characteristic peaks are selected from the group consisting of 6.0°±0.2° 2θ, 13.9°±0.2° 2θ, 14.8°±0.2° 2θ, 17.1°±0.2° 2θ, 17.8°±0.2° 2θ and 24.1°±0.2° 2θ..

8. The method of Claim 7, wherein the pressure is applied for about 1 second or less.

9. The method of Claim 7 or 8, wherein the pressure is at least about 500 psi.

10. The method of any one of Claims 7-9, wherein the phase change yields a composition having a density in the range of about 1.1 to about 1.3 kg/m^3 after applying the pressure.

11. A composition prepared according to the method of any one of Claims 7-10.

12. A composition according to Claim 6 or 11, for use in the treatment of hyperammonemia in a subject.

13. The composition for use according to Claim 12, wherein the subject has hepatic encephalopathy.

14. A crystalline form of L-ornithine phenylacetate according to any one of Claims 1 to 5 for use in the treatment of hyperammonemia in a subject.

15. The crystalline form for use according to Claim 14, wherein the subject has hepatic encephalopathy.

16. A composition comprising a combination of at least two crystalline forms of L-ornithine phenylacetate for use in treating hyperammonemia in a subject, wherein said crystalline forms are selected from the group consisting of Form I, Form II, and Form III, wherein:

said Form I exhibits an X-ray powder diffraction pattern having at least three characteristic peaks selected from the group consisting of 4.9°±0.2° 2θ, 13.2°±0.2° 2θ, 17.4±0.2° 2θ °, 20.8°±0.2° 2θ and 24.4°±0.2° 2θ;

said Form II exhibits an X-ray powder diffraction pattern having at least three characteristic peaks selected from the group consisting of6.0°±0.2° 2θ, 13.9°±0.2° 2θ, 14.8°±0.2° 2θ, 17.1°±0.2° 2θ, 17.8°±0.2° 2θ and 24.1°±0.2° 2θ; said Form III exhibits an X-ray powder diffraction pattern having at least three characteristic peaks selected from the group consisting of 5.8°±0.2° 2θ, 14.1°±0.2° 2θ, 18.6°±0.2° 2θ, 19.4°±0.2° 2θ, 22.3°±0.2° 2θ and 24.8°±0.2° 2θ; and

wherein at least one crystalline form in the composition is Form II.

17. The composition for use according to Claim 16, wherein:

said Form II exhibit an X-ray diffraction pattern having characteristic peaks at 6.0°±0.2° 2θ, 13.9°±0.2° 2θ, 14.8°±0.2° 2θ, 17.1°±0.2° 2θ, 17.8°±0.2° 2θ and 24.1°±0.2° 2θ;

said Form I exhibits an X-ray powder diffraction pattern having characteristic peaks at 4.9°±0.2° 2θ, 13.2°±0.2° 2θ, 17.4°±0.2° 2θ, 20.8°±0.2° 2θ and 24.4°±0.2° 2θ; and

said Form III exhibits an X-ray powder diffraction pattern having characteristic peaks at 5.8°±0.2° 2θ, 14.1°±0.2° 2θ, 18.6°±0.2° 2θ, 19.4°±0.2° 2θ, 22.3°±0.2° 2θ and 24.8°±0.2° 2θ.

18. The composition for use according to Claim 16 or 17, wherein said combination of crystalline forms are Form I and Form II.

19. The composition for use according to Claim 16 or 17, wherein said combination of crystalline forms are Form II and Form III.

20. The composition for use according to Claims 16 or 17, wherein said combination of crystalline forms are Form I, Form II and Form III.

21. The composition for use according to any one of Claims 16 to 20, wherein the composition is for administration from 1 to 3 times daily.

22. The composition for use according to any one of Claims 16-21, wherein the total amount of L-ornithine phenylacetate is in the range of 500 mg to 50 g.

23. The composition for use according to any one of Claims 16-22, wherein the subject has hepatic encephalopathy.

24. A method comprising dissolving a crystalline form of L-ornithine phenylacetate according to any one of Claims 1 to 5 in an aqueous or isotonic solution, wherein said crystalline form is Form II.