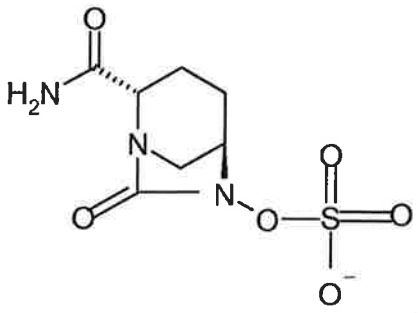
## CLAIMS

1. The sodium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide of formula (I)



(I)

in crystallized enantiomeric form, hydrated or anhydrous.

2. The sodium salt according to claim 1, characterized in that the salt is in its monohydrate pseudopolymorphic form "A", having an X-ray diffraction pattern with at least two characteristic peaks at about 8.5 +/- 0.5 degrees 2θ and at about 15.3 +/- 0.5 degrees 2θ.

3. The sodium salt according to claim 1, characterized in that the salt is in its monohydrate pseudopolymorphic form "A", having an X-ray diffraction pattern with at least three characteristic peaks at about 8.5 +/- 0.5 degrees 2θ, at about 15.3 +/- 0.5 degrees 2θ and at about 16.4 +/- 0.5 degrees 2θ.

4. The sodium salt according to claim 1,, characterized in that the salt is in its monohydrate pseudopolymorphic form "A", having an X-ray diffraction pattern with at least four characteristic peaks at about 8.5 +/- 0.5 degrees 2θ, at about 15.3 +/- 0.5 degrees 2θ, at about 16.4 +/- 0.5 degrees 2θ and at about 17.0 +/- 0.5 degrees 2θ.

5. The sodium salt according to claim 1, characterized in that the salt is in its monohydrate pseudopolymorphic form "A", having an X-ray diffraction pattern with at least five characteristic peaks at about 8.5 +/- 0.5 degrees 2θ, at about 15.3 +/- 0.5 degrees

2θ, at about 16.4 +/- 0.5 degrees 2θ, at about 17.0 +/- 0.5 degrees 2θ and at about 24.3 +/- 0.5 degrees 2θ.

6. The sodium salt according to claim 1, characterized in that the salt is in its monohydrate pseudopolymorphic form "A", having an X-ray diffraction pattern with five characteristic lines at 2θ (± 0.5°) 8.48, 15.34, 16.38, 17.04, 24.28 and a specific line at 8.48.

7. The sodium salt according to claim 1, characterized in that the salt is in its dihydrate pseudopolymorphic form "E" having an X-ray diffraction pattern with five characteristic lines at 2θ (± 0.5°) 13.65, 15.01, 15.38, 15.72, 19.42 and two specific lines at 15.01 and 24.57.

8. The sodium salt according to claim 1, characterized in that the salt is in its polymorphic form "B", having an X-ray diffraction pattern with at least two characteristic peaks at about 13.0 +/- 0.5 degrees 2θ and at about 16.5 +/- 0.5 degrees 2θ.

9. The sodium salt according to claim 1, characterized in that the salt is in its polymorphic form "B", having an X-ray diffraction pattern with at least three characteristic peaks at about 13.0 +/- 0.5 degrees 2θ, at about 16.5 +/- 0.5 degrees 2θ and at about 17.2 +/- 0.5 degrees 2θ.

10. The sodium salt according to claim 1, characterized in that the salt is in its polymorphic form "B", having an X-ray diffraction pattern with at least four characteristic peaks at about 13.0 +/- 0.5 degrees 2θ, at about 16.5 +/- 0.5 degrees 2θ, at about 17.2 +/- 0.5 degrees 2θ and at about 17.5 +/- 0.5 degrees 2θ.

11. The sodium salt according to claim 1, characterized in that the salt is in its polymorphic form "B", having an X-ray diffraction pattern with at least five characteristic peaks at about 13.0 +/- 0.5 degrees 2θ, at about 16.5 +/- 0.5 degrees 2θ, at about 17.2 +/- 0.5 degrees 2θ, at about 17.5 +/- 0.5 degrees 2θ and at about 22.3 +/- 0.5 degrees 2θ.

12. The sodium salt according to claim 1, characterized in that the salt is in its polymorphic form "B", having an X-ray diffraction pattern with at least five characteristic peaks at about 13.0 +/- 0.5 degrees 2θ, at about 16.5 +/- 0.5 degrees 2θ, at about 17.2 +/- 0.5 degrees 2θ, at about 17.5 +/- 0.5 degrees 2θ, at about 22.3 +/- 0.5 degrees 2θ and two specific peaks at about 10.4 +/- 0.5 degrees 2θ and at about 13.0 +/- 0.5 degrees 2θ.

13. The sodium salt according to claim 1, characterized in that the salt is in its polymorphic form "D" having an X-ray diffraction pattern with five characteristic lines at 2θ (± 0.1°) 16.23, 17.44, 17.75, 18.53, 22.22 and a specific line at 12.43.

14. A pharmaceutical composition, characterized in that it contains, as ingredient, the sodium salt in crystallized enantiomeric form according to any one of claims 1 to 13 and, if appropriate, a pharmaceutically acceptable excipient.

15. A pharmaceutical composition according to claim 14, characterized in that it further contains, as ingredient, an antibacterial medicament of the beta-lactamine type.

16. Method for the preparation of the sodium salt according to any one of claims 1 to 13, characterized in that the tetrabutylammonium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide is treated, in a (1-6 C) alkanol containing between 0 and 50% water, with a sodium salt that is soluble in the reaction medium, and the crystals obtained are then isolated.

17. Method according to claim 16, characterized in that the sodium salt used is an acetate, a butyrate, a hexanoate, an ethyl-hexanoate or a dodecylsulfate.

18. Method according to claim 16 or 17, characterized in that the sodium salt is the 2-ethyl-hexanoate.

19. Method according to any one of claims 16 to 18, characterized in that it is carried out either by adding the alcoholic solution of the tetrabutylammonium salt to the alcoholic solution of the sodium salt, or vice versa.

20. Method according to any one of claims 16 to 19, characterized in that the alkanol is selected from ethanol, propanol, isopropanol and linear or branched butanol.

21. Method according to any one of claims 16 to 20, characterized in that the alkanol is ethanol.

22. Method according to any one of claims 16 to 21, characterized in that it is carried out in the presence of 0 to 10% water, at a temperature between 15 and 40°C.

23. Method according to any one of claims 16 to 22, for the preparation of the sodium salt of formula (I) in the crystallized polymorphic form "B", characterized in that a solution of sodium 2-ethylhexanoate in pure ethanol is added to a solution of the tetrabutylammonium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide, in an ethanol/water mixture in such a way that the final proportion of water is from 0 to 5 wt.% of the solvent, operating at a temperature from 10 to 40°C, in the presence of seed crystals of the polymorphic form "B" or of the pseudopolymorphic form "A".

24. Method according to claim 23, characterized in that it is carried out in the presence of seed crystals of the polymorphic form "B" and a final proportion of water less than 2%, by introducing the solution of sodium 2-ethylhexanoate over a period of 1 to 7 hours and operating at a temperature of 30 to 35°C.

25. Method according to any one of claims 16 to 22, for the preparation of the sodium salt of formula (I) in the crystallized polymorphic form "B", characterized in that a solution of the tetrabutylammonium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide in pure ethanol is added to an ethanol/water mixture of sodium 2-ethylhexanoate, moreover operating under the same conditions of solvent and temperatures as those described in claim 23 or 24.

26. Method according to any one of claims 16 to 22, for the preparation of the sodium salt of formula (I) in its crystallized pseudopolymorphic form "A", characterized in that a

solution of sodium 2-ethylhexanoate in pure ethanol is added to a solution of the tetrabutylammonium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide in an ethanol/water mixture in such a way that the final proportion of water is from 3 to 10 wt.% of the solvent, operating at a temperature from 10 to 40°C, in the presence or absence of seed crystals of the pseudopolymorphic form "A".

27. Method according to claim 26, characterized in that it is carried out at room temperature, in the presence of a final proportion of water greater than 5 wt.% of the solvent, and by introducing the solution of sodium 2-ethylhexanoate over a period of 30 minutes to 2 hours.

28. Method according to any one of claims 16 to 22, for the preparation of the sodium salt of formula (I), in its crystallized pseudopolymorphic form "A", characterized in that an ethanolic solution of the tetrabutylammonium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide is added to an ethanol/water mixture of sodium 2-ethylhexanoate, operating under the same conditions of solvent and temperatures as those described in claim 26 or 27.

29. Use of the polymorphic form "Form B", of the sodium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide in combination with ceftazidime to treat bacterial infections.

30. Use of the pseudopolymorphic form "Form A", of the sodium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide in combination with ceftazidime to treat bacterial infections.

31. Use of the polymorphic form "Form B", of the sodium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide in combination with ceftaroline fosamil to treat bacterial infections.

32. Use of the pseudopolymorphic form "Form A", of the sodium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide in combination with ceftaroline fosamil to treat bacterial infections.

33. A method of treating a bacterial infection comprising administering to a patient in need thereof, a therapeutically effective amount of a polymorphic or pseudopolymorphic crystalline form "A", "B", "D" or "E" of the sodium salt of (1R,2S,5R)-7-oxo-6-sulfooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide in combination with an antibacterial agent, such as, ceftazidime, ceftaroline or a prodrug of ceftaroline such as ceftaroline fosamil.

What is claimed is:

1. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 13.0 and about 17.3+/−0.5 degrees 2θ.

2. The crystalline form according to claim 1, wherein the salt is a sodium salt of (1R,2S,5R)-7-oxo-6-sulphooxy-1,6-diazabicyclo[3.2.1]octane-2-carboxamide.

3. The crystalline form according to claim 2, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 19.9, about 22.0 or about 28.2+/−0.5 degrees 2θ.

4. The crystalline form according to claim 2, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 16.5+/−0.5 degrees 2θ.

5. The crystalline form according to claim 2, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 17.5+/−0.5 degrees 2θ.

6. The crystalline form according to claim 2, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at; about 22.3+/−0.5 degrees 2θ.

7. The crystalline form according to claim 2, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 19.2; about 19.5+/−0.5 degrees 2θ or a combination thereof.

8. The crystalline form according to claim 2, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 19.9; about 22.0; about 25.2; about 28.2+/−0.5 degrees 2θ or a combination thereof.

9. The crystalline form according to claim 2, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 23.2; about 30.2; about 30.9; about 36.1+/−0.5 degrees 2θ or a combination thereof.

10. The crystalline form according to claim 1, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 13.0; about 17.3; about 19.9; about 22.0; and about 28.2+/−0.5 degrees 2θ.

11. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 13.0; about 16.5; about 17.3; about 17.5; about 19.2; about 19.5; about 19.9; about 22.0; about 22.3; about 23.2; about 25.2; about 28.2; about 30.2; about 30.9 and about 36.1+/−0.5 degrees 2θ.

12. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 5.1 and about 6.8+/−0.2 nm.

13. The crystalline form according to claim 12, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 5.4+/−0.2 nm.

14. The crystalline form according to claim 12, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 3.2; about 4.0; about 4.5; +/−0.2 nm or a combination thereof.

15. The crystalline form according to claim 12, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 2.5; about 2.9; about 3.0; about 3.2; about 3.5; about 3.8; about 4.0; about 4.5; about 4.6; about 5.4; +/−0.2 nm or a combination thereof.

16. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 2.5; about 2.9; about 3.0; about 3.2; about 3.5; about 3.8; about 4.0; about 4.5; about 4.6; about 5.1; about 5.4; and about 6.8+/−0.2 nm.

17. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 8.7; about 11.3; about 12.5; about 16.3; about 17.5; about 17.8; about 18.6; about 21.0; about 22.3; about 26.2; about 26.6; about 26.9; about 27.6; about 28.7; about 29.8; about 30.4; about 31.2; about 32.9; about 33.4; about 34.4; about 37.1; about 37.3; about 37.6 and about 38.5+/−0.5 degrees 2θ.

18. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 2.3; about 2.4; about 2.6; about 2.7; about 2.9; about 3.0; about 3.1; about 3.2; about 3.3; about 3.4; about 4.0; about 4.2; about 4.8; about 5.0; about 5.1; about 5.4; about 7.1; about 7.8 and about 10.1+/−0.2 nm.

19. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 8.5 and about 24.3+/−0.5degrees 2θ.

20. The crystalline form according to claim 19, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 18.4; about 18.7; about 24.0; about 25.7; about 27.4; about 28.8; +/−0.5 degrees 2θ or a combination thereof.

21. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 17.8 and about 18.6+/−0.5 degrees 2θ.

22. The crystalline form according to claim 21, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 8.7; about 11.3; about 12.5; about 16.3; about 21.1; about 27.0; about 26.6; about 28.7 or a combination thereof.

23. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 17.8 and about 18.6+/−0.5 degrees 2θ.

24. The crystalline form according to claim 23, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 14.2; about 15.0; about 22.5; about 22.8; about 24.6; about 28.0+/−0.5 degrees 2θ or a combination thereof.

25. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 17.8 and about 18.6+/−0.5 degrees 2θ.

26. The crystalline form according to claim 25, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a characteristic peak at about 14.4; about 15.5; about 19.3; +/−0.5 degrees 2θ or a combination thereof.

27. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 3.7 and about 10.4+/−0.2 nm.

28. The crystalline form according to claim 27, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 3.1; about 3.3; about 3.5; about 3.7; about 4.7; about 4.8; +/−0.2 nm or a combination thereof.

29. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 4.8 and about 5.0+/−0.2 nm.

30. The crystalline form according to claim 29, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 3.1; about 3.3; about 3.4; about 4.2; about 5.4; about 7.1; about 7.8; about 10.1+/−0.2 nm or a combination thereof.

31. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 5.6 and about 9.0+/−0.2 nm.

32. The crystalline form according to claim 31, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 3.2; about 3.6; about 3.9; about 4.0; about 5.9; about 6.2+/−0.2 nm or a combination thereof.

33. A crystalline form of trans-7-oxo-6-(sulphooxy)-1,6-diazabicyclo[3,2,1]octane-2-carboxamide or a pharmaceutically acceptable salt thereof, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 4.9 and about 13.6+/−0.2 nm.

34. The crystalline form according to claim 33, wherein the crystalline form has an X-Ray powder diffraction pattern comprising a d-spacing value at about 4.6; about 5.7; about 6.1+/−0.2 nm or a combination thereof.