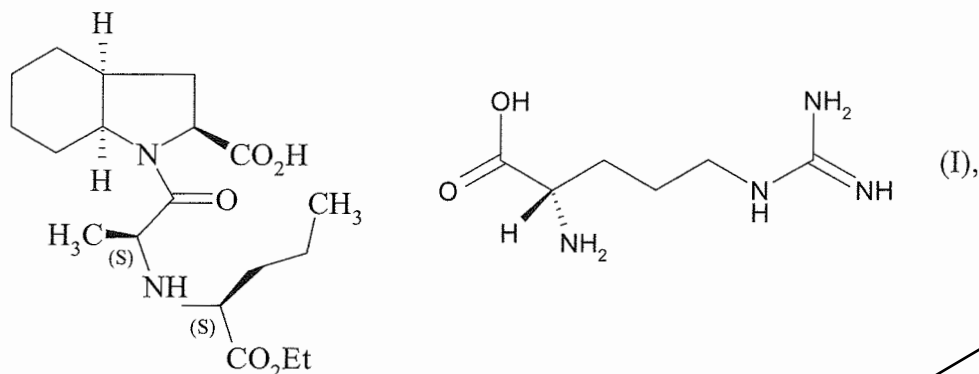


CLAIMS

1. Delta crystalline form of perindopril L-arginine salt of formula (I):



characterised by the following X-ray powder diffraction peaks measured using a diffractometer with a copper anticathode and expressed in terms of Bragg's angle 2 theta (°): 4.3, 11.0, 11.1, 13.2, 14.6, 16.0 and 21.9.

2. Delta crystalline form of the compound of formula (I) according to claim 1, characterised by the following X-ray powder diffraction peaks measured using a diffractometer with a copper anticathode and expressed in terms of Bragg's angle 2 theta: 4.3, 11.0, 11.1, 11.9, 12.5, 13.2, 14.6, 16.0, 19.2, 19.4, 20.0, 21.9, 22.2 and 22.6.

3. Delta crystalline form of the compound of formula (I) according to claim 1, characterised by the following X-ray powder diffraction diagram measured using a diffractometer with a copper anticathode and expressed in terms of interplanar spacing d, Bragg's angle 2 theta, and relative intensity expressed as a percentage in relation to the most intense line:

Angle 2 theta (°)	Interplanar distance d [Å]	Relative intensity [%]
4.34	20.37	66.2
5.57	15.86	5.2
11.04	8.02	57.5
11.15	7.94	47.5
11.87	7.454	35.0
12.47	7.09	17.9
13.21	6.70	33.6
14.06	6.30	6.6
14.64	6.05	31.8

Angle 2 theta (°)	Interplanar distance d [Å]	Relative intensity [%]
16.03	5.53	17.5
17.11	5.18	5.6
18.27	4.85	4.1
19.23	4.61	100
19.44	4.57	17.8
20.04	4.43	13.6
21.11	4.21	3.7
21.93	4.05	23.0
22.20	4.00	16.9
22.61	3.93	21.2
23.21	3.83	4.5
24.30	3.66	2.3
25.09	3.55	9.4
25.95	3.43	1.7
29.54	3.02	4.2

4. Delta crystalline form of the compound of formula (I) according to claim 1, characterised by a solid-state ^{13}C CPMAS NMR spectrum having the following peaks, expressed in ppm:

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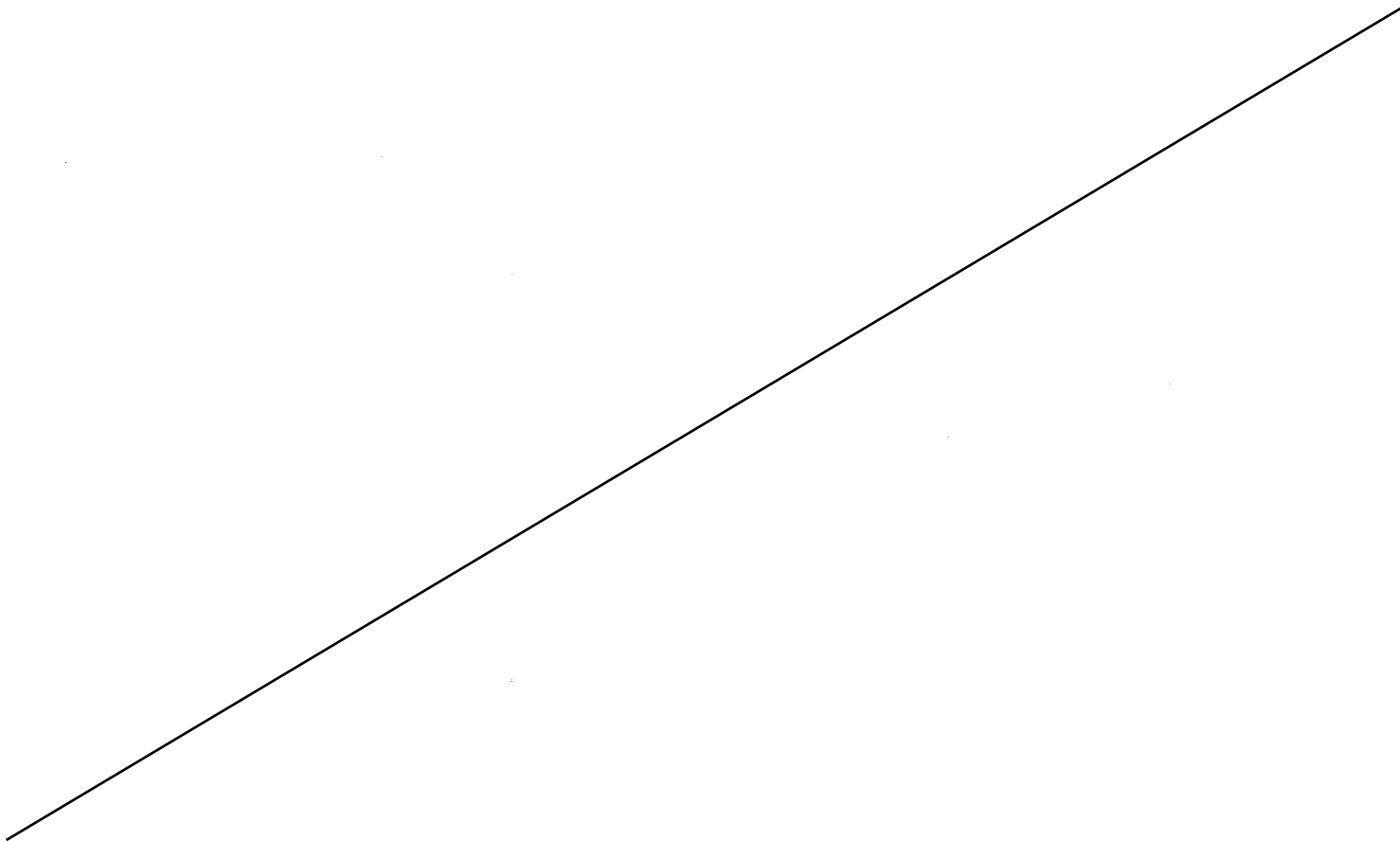
Peak no.	Chemical shift (ppm)	Peak no.	Chemical shift (ppm)
1	181.2	10	38.4
2	180.5	11	15.6
3	180.1	12	15.2
4	174.0	13	15.0
5	173.7	14	14.5
6	172.7		
7	172.0		
8	39.3		
9	38.8		

5. Process for the preparation of the delta crystallisation form of the compound of formula (I) according to any one of claims 1 to 4, by crystallisation or recrystallisation from a binary mixture of acetonitrile, ethyl acetate or methyl tert-butyl ether and dimethyl sulphoxide or a ternary mixture of acetonitrile, dimethyl sulphoxide and toluene, at a temperature higher than 20°C.

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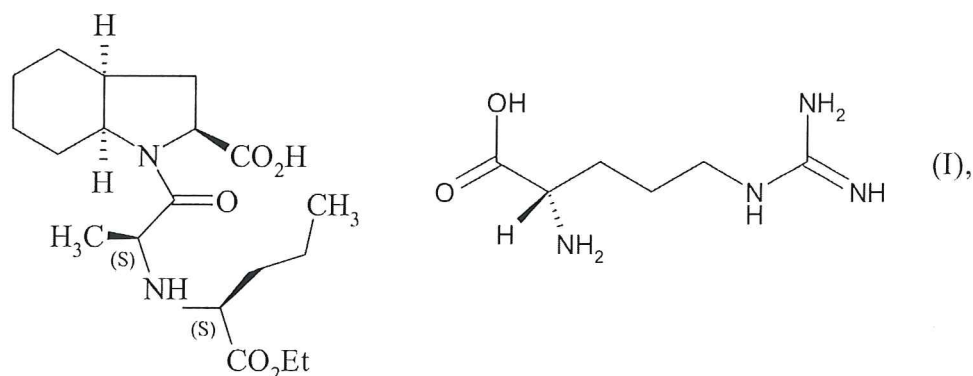
6. Process according to claim 5, wherein the binary mixture of acetonitrile, ethyl acetate or methyl tert-butyl ether and dimethyl sulphoxide has a ratio of acetonitrile/dimethyl sulphoxide, ethyl acetate/dimethyl sulphoxide or methyl tert-butyl ether/dimethyl sulphoxide ranging from 90/10 w/w to 10/90 w/w.
- 5 7. Process according to either claim 5 or claim 6, wherein the temperature of the medium is between 25 and 80°C, inclusive.
8. Process according to claim 7, wherein the mixture is heated to a temperature of from 60 to 80°C.
9. Process according to any one of claims 5 to 8, wherein the mixture is seeded with the delta crystalline form.
- 10 10. Pharmaceutical composition comprising, as active ingredient, the compound according to any one of claims 1 to 4, in combination with one or more inert, non-toxic, pharmaceutically acceptable carriers.
11. Pharmaceutical composition according to claim 10, characterised in that it also comprises a diuretic, a calcium antagonist or an If current inhibitor.
- 15 12. Pharmaceutical composition according to claim 11, characterised in that the diuretic is indapamide.
13. Pharmaceutical composition according to claim 11, characterised in that the calcium antagonist is amlodipine.
- 20 14. Pharmaceutical composition according to claim 11, characterised in that the If current inhibitor is ivabradine.
15. Compound according to any one of claims 1 to 4 for use in the treatment of cardiovascular diseases.

16. Compound according to any one of claims 1 to 4 for use in the treatment of arterial hypertension, heart failure or stable coronary disease.



The claims defining the invention are as follows:

1. Delta crystalline form of perindopril L-arginine salt of formula (I):



characterised by the following X-ray powder diffraction peaks measured using a diffractometer with a copper anticathode and expressed in terms of Bragg's angle 2 theta (°): 4.3, 11.0, 11.1, 13.2, 14.6, 16.0 and 21.9.

2. The delta crystalline form of the compound of formula (I) according to claim 1, characterised by the following X-ray powder diffraction peaks measured using a diffractometer with a copper anticathode and expressed in terms of Bragg's angle 2 theta: 4.3, 11.0, 11.1, 11.9, 12.5, 13.2, 14.6, 16.0, 19.2, 19.4, 20.0, 21.9, 22.2 and 22.6.

3. The delta crystalline form of the compound of formula (I) according to claim 1, characterised by the following X-ray powder diffraction diagram measured using a diffractometer with a copper anticathode and expressed in terms of interplanar spacing d, Bragg's angle 2 theta, and relative intensity expressed as a percentage in relation to the most intense line:

Angle 2 theta (°)	Interplanar distance d [Å]	Relative intensity [%]
4.34	20.37	66.2
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Angle 2 theta (°)	Interplanar distance d [Å]	Relative intensity [%]
13.21	6.70	33.6
14.06	6.30	6.6
14.64	6.05	31.8
16.03	5.53	17.5
17.11	5.18	5.6
18.27	4.85	4.1
19.23	4.61	100
19.44	4.57	17.8
20.04	4.43	13.6
21.11	4.21	3.7
21.93	4.05	23.0
22.20	4.00	16.9
22.61	3.93	21.2
23.21	3.83	4.5
24.30	3.66	2.3
25.09	3.55	9.4
25.95	3.43	1.7
29.54	3.02	4.2

4. The delta crystalline form of the compound of formula (I) according to claim 1, characterised by a solid-state ^{13}C CPMAS NMR spectrum having the following peaks, expressed in ppm:

Peak no.	Chemical shift (ppm)	Peak no.	Chemical shift (ppm)
1	181.2	10	38.4
2	180.5	11	15.6
3	180.1	12	15.2
4	174.0	13	15.0
5	173.7	14	14.5
6	172.7		
7	172.0		
8	39.3		
9	38.8		

5. A process for the preparation of the delta crystallisation form of the compound of formula (I) according to any one of claims 1 to 4, the process comprising crystallisation or recrystallisation from a binary mixture of acetonitrile, ethyl acetate or methyl tert-butyl ether and dimethyl sulphoxide or a ternary mixture of acetonitrile, dimethyl sulphoxide and toluene, at a temperature higher than 20°C.

6. The process according to claim 5, wherein the binary mixture of acetonitrile, ethyl acetate or methyl tert-butyl ether and dimethyl sulphoxide has a ratio of acetonitrile/dimethyl sulphoxide, ethyl acetate/dimethyl sulphoxide or methyl tert-butyl ether/dimethyl sulphoxide ranging from 90/10 w/w to 10/90 w/w.

7. The process according to claim 5 or claim 6, wherein the temperature of the mixture is between 25 and 80°C, inclusive.

8. The process according to claim 7, wherein the mixture is heated to a temperature of from 60 to 80°C.

9. The process according to any one of claims 5 to 8, wherein the mixture is seeded with the delta crystalline form.

10. A pharmaceutical composition comprising, as active ingredient, the compound according to any one of claims 1 to 4, in combination with one or more inert, non-toxic, pharmaceutically acceptable carriers.

11. The pharmaceutical composition according to claim 10, further comprising a diuretic, a calcium antagonist or an If current inhibitor.

12. The pharmaceutical composition according to claim 11, wherein the diuretic is indapamide.

13. The pharmaceutical composition according to claim 11, wherein the calcium antagonist is amlodipine.

14. The pharmaceutical composition according to claim 11, wherein the If current inhibitor is ivabradine.
15. A method for the treatment of a cardiovascular disease in a mammal, the method comprising administering to a mammal in need of said treatment an effective amount of a compound according to any one of claims 1 to 4, or a pharmaceutical composition according to any one of claims 10 to 14.
16. A method for the treatment of arterial hypertension, heart failure or stable coronary disease in a mammal, the method comprising administering to a mammal in need of said treatment an effective amount of a compound according to any one of claims 1 to 4, or a pharmaceutical composition according to any one of claims 10 to 14.
17. Use of a compound according to any one of claims 1 to 4 in the manufacture of a medicament for the treatment of a cardiovascular disease.
18. Use of a compound according to any one of claims 1 to 4 in the manufacture of a medicament for the treatment of arterial hypertension, heart failure or stable coronary disease.
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