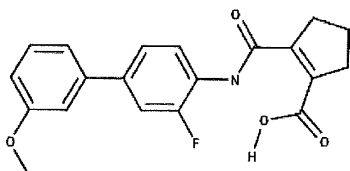


Claims

1. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof



Formula I

- 5 with a molar ratio of said compound according to formula I to calcium 2 ± 0.3 .
2. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to claim 1 which is characterized by an X-ray powder diffraction pattern having characteristic peaks expressed in degrees 2theta at ± 0.2 of the values shown below:
 10 2 theta = 5.91° , 9.64° , 16.78° , 17.81° , 19.81° , 25.41°
3. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to claim 1 or 2, wherein the characteristic peaks
 15 which have 2theta at ± 0.2 of the values shown below:

Table 1: Peak-list of Polymorph A of Ca salt of vidofludimus

Angle 2-Theta °	d value Angstrom	Intensity
5.91	14.95	vs
6.83	12.93	vw
9.64	9.17	w
11.33	7.80	w
11.82	7.48	w
12.98	6.81	vw
13.70	6.46	vw
14.27	6.20	vw
15.04	5.89	w
15.44	5.73	vw
16.78	5.28	s
17.81	4.98	m
18.25	4.86	w

18.58	4.77	vw
19.39	4.57	w
19.81	4.48	w
20.53	4.32	vw
21.26	4.18	vw
22.63	3.93	vw
23.16	3.84	vw
23.96	3.71	w
24.73	3.60	vw
25.41	3.50	s
26.12	3.41	w
26.44	3.37	w
27.25	3.27	w
27.55	3.24	w
28.45	3.13	w
28.91	3.09	vw
29.29	3.05	w
29.89	2.99	w
30.77	2.90	w
31.22	2.86	vw
31.60	2.83	w
32.13	2.78	w
33.25	2.69	vw
33.98	2.64	w
34.48	2.60	w
35.12	2.55	vw

4. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to claim 1 or 2, characterized by the x-ray powder diffraction pattern shown in Figure 1.

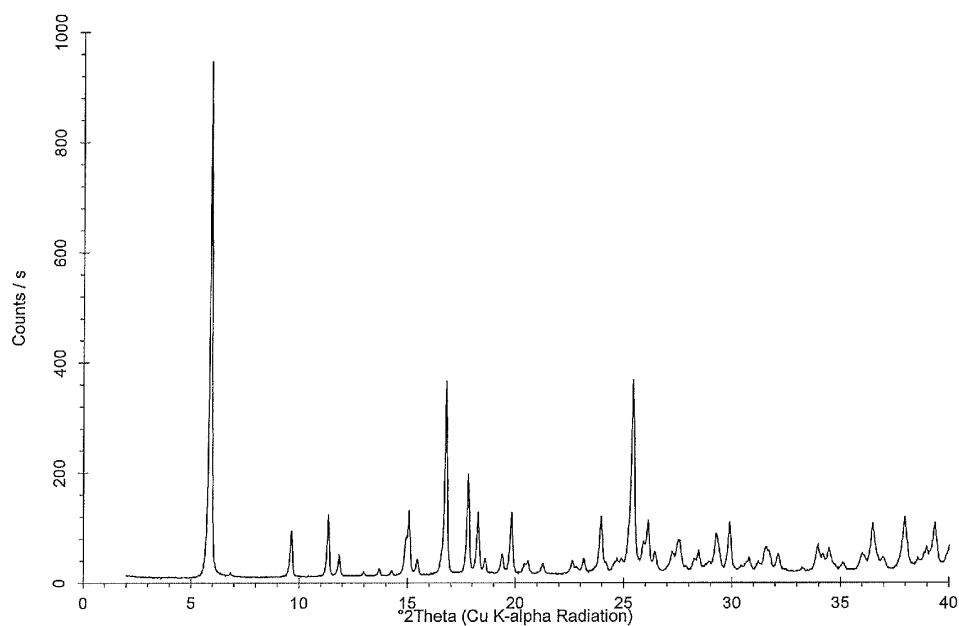


Figure 1: PXRD of Polymorph A of Ca vidofludimus

5. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 4 which is characterized by an FT Raman absorption spectrum having the following characteristic peaks expressed in cm^{-1} 1664, 1624, 1617, 1532, 1449, 1338 the spectrum is shown in Figure 2.

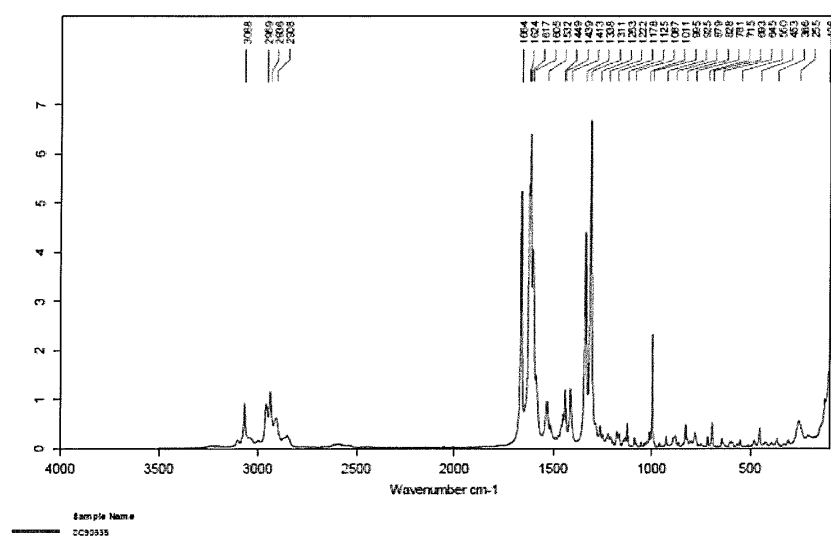


Figure 2: Raman spectrum of Polymorph A of Ca vidofludimus

6. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 5 which is characterized by an IR absorption spectrum having characteristic peaks expressed in cm^{-1} 1980, 1659, 1584, 1335, 1145, the spectrum is shown in Figure 3.

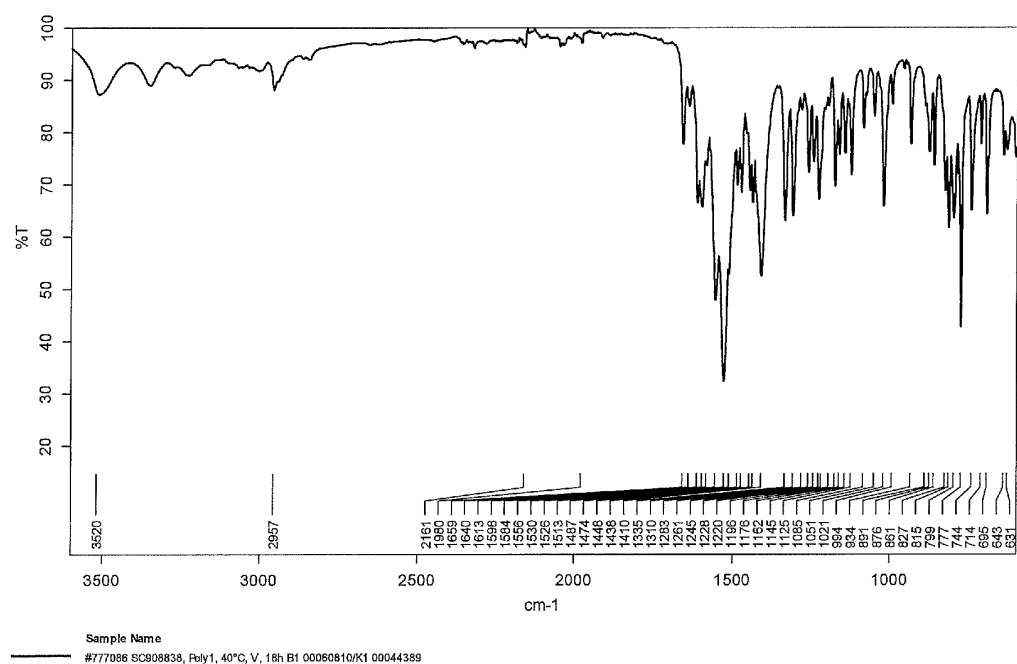


Figure 3a: IR spectrum of Polymorph A of Ca vidofludimus, complete region

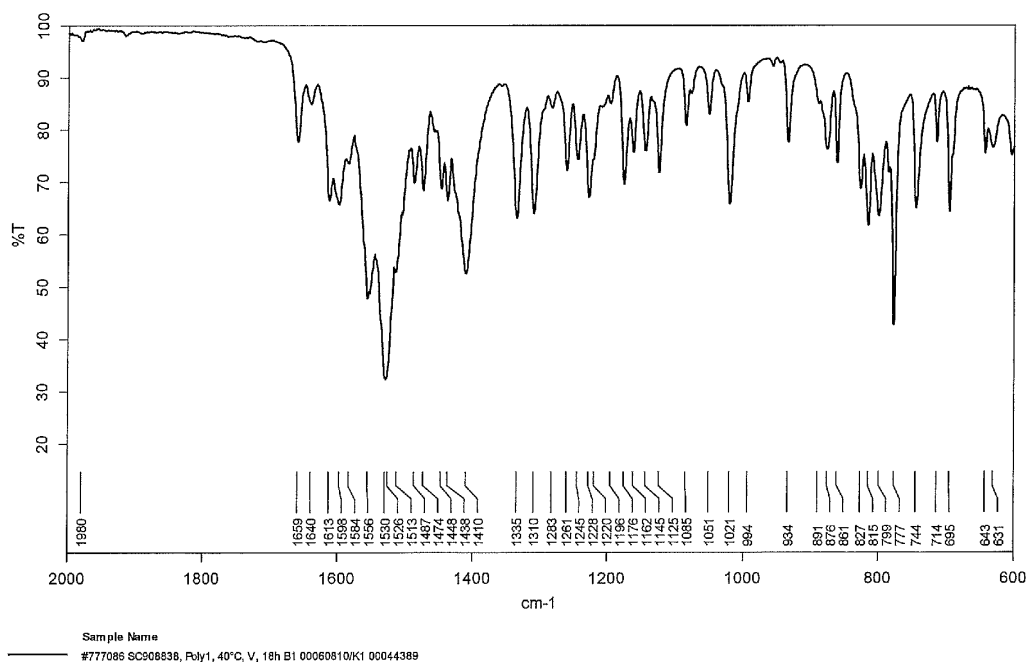


Figure 3b: IR spectrum of Polymorph A of Ca vidofludimus, fingerprint region

7. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 6 which is characterized by an ¹H-NMR spectrum having characteristic peaks expressed in ppm, 15.2, 8.3, 7.6, 7.5, 7.4, 7.2, 6.8, 3.8, 2.7, 1.6. The spectrum is shown in Figure 4.

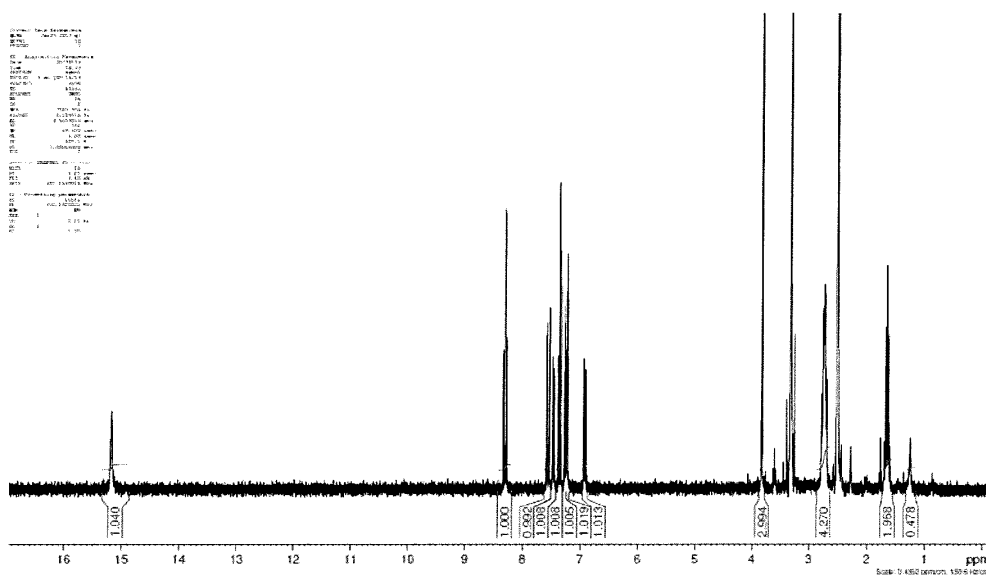


Figure 4: ^1H -NMR spectrum of Polymorph A of Ca vidofludimus

8. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 8 which is a hydrate with a molar ratio of a compound according to formula I to water of about 1:1.
9. A pharmaceutical formulation comprising a white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 8.

10. A pharmaceutical formulation according to claim 1 having a THF content of less than 720 ppm
- 5 11. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 8 or a pharmaceutical formulation according to claim 9 or 10 for use as a medicament.
- 10 12. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 8 or a pharmaceutical formulation according to claim 9 or 10 for use as in the treatment of a disease selected from the group comprising rheumatism, acute immunological disorders, autoimmune diseases, diseases caused by malignant cell proliferation, inflammatory diseases, diseases that are caused by protozoal infestations in humans and animals, diseases that are caused by viral infections and *Pneumocystis carinii*, fibrosis, uveitis, rhinitis, asthma or arthropathy.
- 15 13. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof according to any of claims 1 to 8 or a pharmaceutical formulation according to claim 9 or 10 for use as in the treatment of a disease selected from the group comprising wherein the disease or a therapeutic indication is selected from the group comprising graft versus host and host versus graft reactions, rheumatoid arthritis, multiple sclerosis, amyotrophic lateral sclerosis, lupus erythematosus, inflammatory bowel disease, and psoriasis.
- 20 14. A process for the manufacture of a white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof as defined in any of claims 1 to 8, which process comprises the steps of
- Providing a Ca-Vidofludimus or a solvate and/or a hydrate thereof, preferably a crystalline polymorph of the Ca salt of vidofludimus or a solvate and/or a hydrate thereof,
 - 30 • washing the calcium salt of Calcium-vidofludimus or a solvate and/or a hydrate thereof with the an aprotic organic solvent preferably selected from the group comprising DMF,

DMSO, NMP, THF, Acetone, Dioxane, 2-Methyl-THF or (Methanol/CH₂Cl₂ (1:3)), preferably acetone, and

- slurring the isolated Calcium-vidofludimus or a solvate and/or a hydrate thereof obtained in an alcoholic solvent and adding water to the slurry.

5

15. A process for the manufacture of a white crystalline polymorph A of the Ca salt of a compound according to formula I or a solvate and/or a hydrate thereof as defined in any of claims 1 to 8, which process comprises the steps of

- 10 a) adding to a mixture of calcium hydroxide and free acid of a compound according to formula I or a solvate and/or a hydrate thereof an organic solvent and water
- b) stirring the suspension obtained in step a) until a solution is obtained,
- c) at least partially evaporating said organic solvent and water to obtain a suspension of the calcium salt of a compound according to formula I or a solvate and/or a hydrate thereof
- 15 d) adding an aprotic organic solvent, fully mixable with water to said suspension of the calcium salt of a compound according to formula I or a solvate and/or a hydrate thereof obtained in step c)
- e) stirring the suspension obtained in step d),
- f) recovering the calcium salt of a compound according to formula I or a solvate and/or a hydrate thereof from the mixture obtained in step e), and
- 20 g) washing the calcium salt of a compound according to formula I or a solvate and/or a hydrate thereof obtained in step f) with the aprotic organic solvent mentioned in step d).
- h) slurring the isolated calcium salt a compound according to formula I or a solvate and/or a hydrate thereof obtained in step g) in an alcoholic solvent at 15 – 80°C.
- 25 i) adding water to the slurry obtained in step h) at 15 – 85°C
- j) recovering the calcium salt of a compound according to formula I or a solvate and/or a hydrate thereof from the mixture obtained in step e), and
- k) washing the calcium salt of a compound according to formula I or a solvate and/or a hydrate thereof obtained in step j) with the aprotic organic solvent mentioned in step d).

30

16. A process for the manufacture of a crystalline polymorph according to claim 14 or 15

wherein after step g) and step k) a drying step is added, and optionally subsequently a milling step and optionally subsequently a recrystallization step is added.

17. A process for the manufacture of a crystalline polymorph according to any of claim 14 to
5 16 wherein after step b) and before step c) the solution is filtered and then the filter is washed with said organic solvent.
18. A process for the manufacture of a crystalline polymorph according to any of claims 14 to
10 17 wherein the suspension of step a) is heated to 25-30°C.
19. A process for the manufacture of a crystalline polymorph according to any of claims 14 to
15 18 wherein the suspension of step e) is heated to 15-25°C.
20. A process for the manufacture of a crystalline polymorph according to any of claims 14 to
19 wherein said organic solvent is selected from the group comprising DMF, DMSO, NMP, THF, Acetone, Dioxane, 2-Methyl-THF or (Methanol/CH₂Cl₂ (1:3))
21. A process for the manufacture of a crystalline polymorph according to any of claims 14 to
20 20 wherein said aprotic organic solvent is selected from the group comprising DMF, DMSO, NMP, THF, Acetone, Dioxane, 2-Methyl-THF or (Methanol/CH₂Cl₂ (1:3)), preferably acetone,
22. A white crystalline polymorph A of the Ca salt of a compound according to formula I or a
25 solvate and/or a hydrate thereof with a molar ratio of a compound according to formula I to calcium of 2±0.3 obtainable by a process according to any of claims 14 to 21.