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April 15, 2005

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APPLICATION NUMBER: ***60/563,265***
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PTO/SB/16 (08-03)
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

SOLID STATE FORMS OF ICOFUNGIPEN

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

[X] Customer Number: 07278

OR

[ ] Firm or Individual Name	S. Peter Ludwig DARBY & DARBY P.C.				
Address	P.O. Box 5257				
City	New York	State	NY	Zip	10150-5257
Country	US	Telephone	(212) 527-7700	Fax	(212) 753-6237

ENCLOSED APPLICATION PARTS (*check all that apply*)

[X] Specification *Number of Pages*	15	[ ] CD(s), Number	
[ ] Drawing(s) *Number of Sheets*		[ ] Other (specify):	
[X] Application Data Sheet. See 37 CFR 1.76			

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

[ ] Applicant claims small entity status. See 37 CFR 1.27.

[X] A check or money order is enclosed to cover the filing fees.

[X] The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 04-0100

[ ] Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): 160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No [ ] Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

Date April 16, 2004

SIGNATURE _____

TYPED OR PRINTED NAME S. Peter Ludwig MARIE GILFILLAN 44085

REGISTRATION NO. (*if appropriate*) 25,351

TELEPHONE (212) 527-7770

Docket Number: 03818/0201177-US0

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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PTO/SB/17 (10-03)
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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003, Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 160.00

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	
Examiner Name	Not Yet Assigned
Art Unit	N/A
Attorney Docket No.	03818/0201177-US0

METHOD OF PAYMENT *(check all that apply)*

☒ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

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Deposit Account Number: 04-0100

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	160.00

SUBTOTAL (1) ($) 160.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims	-** =		x		=	
Independent Claims	-** =		x		=	
Multiple Dependent					=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($) 0.00

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	S. Peter Ludwig	*Registration No. (Attorney/Agent)*	25,351	*Telephone*	(212) 527-7770
Signature	[signature] 44085 MARIE GILFILLAN			*Date*	April 16, 2004

Express Mail Label No. Dated: _____

Application No. (if known):

Attorney Docket No.: 03818/0201177-US0

Certificate of Express Mailing Under 37 CFR 1.10

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Specification including 51 claims and abstract (15 pages)
Provisional Patent Application Transmittal (1 page)
Application Data Sheet (1 page)
Fee Transmittal (1 page)
Check in the amount of $160.00

SOLID STATE FORMS OF ICOFUNGIPEN

C07D 213/70

A61K 31/44

The present invention relates to the solid state forms of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid (in the further text of the application designated by its name "icofungipen", to processes for their preparation, as well as to pharmaceutical forms containing the said solid state forms as the active ingredient. Methods of using them are also disclosed.

Icofungipen is an active pharmaceutical ingredient used in the treatment of fungal infections. The product was described for the first time in European patent application EP 0571870 B1.

It has now been surprisingly found that by stirring of icofungipen in chloroform at about 61 °C, solid state form δ of icofungipen has been prepared.

Also, it has now been surprisingly found that by heating solid state form δ of icofungipen, high temperature solid state form δ1 of icofungipen has been prepared.

Also, it has now been surprisingly found that by cooling solid state form δ1 of icofungipen, solid state form ε of icofungipen has been prepared.

It has now been surprisingly found that by sublimation of icofungipen at high vacuum (0,05 mm Hg) and temperature gradient between about 130 °C to 160 °C solid state form ζ of icofungipen has been prepared.

An object of this invention is to provide solid state form δ of icofungipen.

Another object of this invention is to provide solid state form δ1 of icofungipen.

Another object of this invention is to provide solid state form ε of icofungipen.

Another object of this invention is to provide solid state form ζ of icofungipen.

Still further object of this invention is to provide pharmaceutical compositions such as tablets, capsules, suppositories, sachets, injections or spray containing solid state form δ of icofungipen, solid state form ε of icofungipen, solid state form ζ of icofungipen or any mixtures of solid state forms δ, ε and ζ of icofungipen as the active ingredient, without any additives or in combination with one or more pharmaceutically acceptable additives such as sugar, starch derivatives, cellulose, cellulose derivatives, mould release agents and antiadhesive agents and optionally agents for flowability regulation.

Still, further object of this invention is to provide compounds or any mixture of said compounds, prepared according to the processes of the present invention, useful for the treatment and prevention of all disease which are regarded as treatable or avoidable by the use of icofungipen in, particular, the compounds according to the invention that can be employed for treatment of fungal infections.

Solid state form δ of icofungipen, prepared according to the Example 1. of the present invention, is characterized by an characteristic x-ray powder diffraction pattern comprising 7.6±0.2°, 8.2.0±0.2°, 9.2±0.2°, 18.4±0.2 21.2±0.2° and 29.7±0.2° degrees two-theta.

Solid state form δ of icofungipen, prepared according to the Example 1. of the present invention, is characterized by an DSC thermogram comprising one

endothermic maximum at about 147 °C (onset at about 145 °C) and another endothermic maximum at about 158 °C (onset at about 150 °C) (heating rate of 10 °C/min).

Solid state form δ of icofungipen, prepared according to the Example 1. of the present invention, is characterized by solid-solid transformation into high temperature solid state form δ1 of icofungipen when is heated above about 158 °C.

High temperature solid state form δ1 of icofungipen, prepared according to the Example 2. of the present invention, is characterized by an characteristic x-ray powder diffraction pattern comprising 8.5±0.2°, 14.3±0.2°, 18.2±0.2°, 19.7±0.2°, 20.8±0.2°, and 29.3±0.2° degrees two-theta.

High temperature solid state form δ1 of icofungipen, prepared according to the Example 3. of the present invention, is characterized by an DSC thermogram comprising one endothermic maximum at about 211 °C (onset at about 202 °C) (heating rate of 10 °C/min) and one exothermic maximum at about 232 °C (onset at about 230 °C).

Solid state form δ1 of icofungipen, prepared according to the Example 2. and Example 3. of the present invention, is characterized by solid-solid transformation into solid state form ε of icofungipen when is cooled below about 78 °C.

Solid state form ε of icofungipen, prepared according to the Example 4. and Example 5. of the present invention, is characterized by an DSC thermogram comprising one endothermic maximum at about 81 °C (onset at about 79 °C) (heating rate of 10 °C/min).

Solid state form ε of icofungipen, prepared according to the Example 4. and Example 5. of the present invention, is characterized by solid-solid transformation into high temperature solid state form δ1 of icofungipen when is heating above about 81 °C.

Solid state form ζ of icofungipen, prepared according to the Example 6. of the present invention, is characterized by an DSC thermogram comprising one endothermic maximum at about 234 °C (onset at about 229 °C) (heating rate of 10 °C/min).

The present invention is illustrated but in no way limited by the following Examples.

Example 1 (Form δ)

Icofungipen (1.00 g) was suspended in chloroform (200 mL). Suspension was stirred for 5 hours at boiling temperature and then stirred at the room temperature for 18 hours to yield solid state form δ of icofungipen.

The x-ray powder diffraction patterns were obtained by x-ray diffraction on a powder sample by the methods known in the art. X-ray powder diffraction patterns were collected at Philips X'PertPRO powder diffractometer using CuKα radiation.

The differential scanning calorimeter thermograms were obtained by methods known in the art using DSC Mettler Toledo 822 Star^e. The weight of the samples was about 5 mg. The temperature range of scans was 25 °C – 250 °C at a rate of 10 °C/min. Samples were purged with nitrogen gas at a flow rate of 80 mL/min. Standard 40 μL aluminum crucibles with pierced lids were used.

Example 2 (Form δ1)

Solid state form δ of icofungipen (0.20 g) was heated above 158 °C by methods known in the art using Philips X'PertPRO powder diffractometer with Anton Paar TTK-450 Temperature Camera. The temperature of the sample was controlled with Anton Paar Temperature Control Unit TCU 100. This process results in forming high temperature solid state form δ1 of icofungipen.

Example 3 (Form δ1)

Solid state form δ of icofungipen (0.005 g) was heated above 158 °C by methods known in the art using DSC Mettler Toledo 822 Star^e yielded high temperature solid state form δ1. The temperature range of scans was 25 °C – 250 °C at a rate of 10 °C/min. Samples were purged with nitrogen gas at a flow rate of 80 mL/min. Standard 40 μL aluminum crucibles with pierced lids were used.

Example 4 (Form ε)

Solid state form δ of icofungipen (0.10 g) was heated above about 158 °C by methods known in the art, and then cooled below about 78 °C, yielded solid state form ε.

The differential scanning calorimeter thermograms were obtained by methods known in the art using DSC Mettler Toledo 822 Star^e. The weight of the samples was about 5 mg. The temperature range of scans was 25 °C – 250 °C at a rate of 10 °C/min. Samples were purged with nitrogen gas at a flow rate of 80 mL/min. Standard 40 μL aluminum crucibles with pierced lids were used.

Example 5 (Form ε)

Solid state form δ of icofungipen (0.005 g) was heated above about 158 °C and then cooled below about 78 °C by methods known in the art using DSC Mettler Toledo 822 Star^e yielded solid state form ε. The temperature range of scans was 25 °C – 250 °C at a rate of 10 °C/min. Samples were purged with nitrogen gas at a

flow rate of 80 mL/min. Standard 40 μL aluminum crucibles with pierced lids were used.

Example 6 (Form ζ)

Icofungipen (0.125 g) was treated to heating in vacuum sublimation apparatus at oil bath temperature of about 170 °C and pressure of 0.05 mm Hg for 1 hour to yield solid state form ζ of icofungipen.

The differential scanning calorimeter thermograms were obtained by methods known in the art using DSC Mettler Toledo 822 Star^e. The weight of the samples was about 5 mg. The temperature range of scans was 25 °C – 250 °C at a rate of 10 °C/min. Samples were purged with nitrogen gas at a flow rate of 80 mL/min. Standard 40 μL aluminum crucibles with pierced lids were used.

WHAT IS CLAIMED IS:

1. Solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid having characteristic x-ray powder diffraction peaks, designated by 2Θ and expressed in degrees, at 7.6±0.2°, 8.2.0±0.2°, 9.2±0.2°, 18.4±0.2 21.2±0.2° and 29.7±0.2°.

2. Solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid having characteristic DSC endothermic maximum at about 147 °C (onset at about 145 °C) and another one at about 158 °C (onset at about 150 °C) (heating rate of 10 °C/min).

3. Solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid characterized in that when is heating above about 158 °C transfer to high temperature solid state form δ1 of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid characterized by the following data:

X-ray powder diffraction peaks, designated by 2Θ and expressed in degrees, at 8.5±0.2°, 14.3±0.2°, 18.2±0.2°, 19.7±0.2°, 20.8±0.2°, and 29.3±0.2°.

DSC characteristic endothermic maximum at about 211 °C (onset at about 202 °C) and exothermic maximum at about 232 °C (onset at about 230 °C) at heating rate of 10 °C/min.

4. Solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, characterized in that it does not contain water.

5. Solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, characterized in that it does not contain solvent.

6. Process for the preparation of the solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claims 1 to 3, characterized in that suspension of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclo-pentanecarboxylic acid and chloroform is stirred at about 61 °C.

7. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a polymorphic purity greater than 95.0 % .

8. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a polymorphic purity greater than 99.0 % .

9. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a polymorphic purity greater than 99.5 % .

10. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a polymorphic purity greater than 99.9 % .

11. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, which is polymorphic pure.

12. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a purity of greater than about 90.0 %.

13. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a purity of greater than about 95.0 %.

14. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a purity of greater than about 99.0 %.

15. The solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 1 to 3, having a purity of greater than about 99.9 %.

16. A pharmaceutical composition comprising the solid state form δ of (-)-

-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claims 1 to 3, and one or more pharmaceutically acceptable carriers or excipients.

17. A method of treating fungal infections in a human which comprises administering to a patient in need of such treatment an effective amount of the solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claims 1 to 4.

18. Solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid having characteristic DSC endothermic maximum at about 81 °C (onset at about 79 °C) (heating rate of 10 °C/min).

19. Solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid characterized in that when is heating above about 81 °C transfer to high temperature solid state form δ1 of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid characterized by the following data:

X-ray powder diffraction peaks, designated by 2Θ and expressed in degrees, at 8.5±0.2°, 14.3±0.2°, 18.2±0.2°, 19.7±0.2°, 20.8±0.2°, and 29.3±0.2°.

DSC characteristic endothermic maximum at about 210 °C (onset at about 204 °C) and exothermic maximum at about 232 °C (onset at about 230 °C) at heating rate of 10 °C/min.;

20. Solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, characterized in that it does not contain water.

21. Solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, characterized in that it does not contain solvent.

22. Process for the preparation of the solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid that includes heating of solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid up to about 158 °C and cooling to about 75 °C.

23. Process for the preparation of the solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid that includes heating of solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid up to about 158 °C and cooling to room temperature.

24. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a polymorphic purity greater than 95.0 % .

25. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a polymorphic purity greater than 99.0 % .

26. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a polymorphic purity greater than 99.5 % .

27. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a polymorphic purity greater than 99.9 % .

28. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, which is polymorphic pure.

29. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a purity of greater than about 90.0 %.

30. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a purity of greater than about 95.0 %.

31. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a purity of greater than about 99.0 %.

32. The solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claims 18 to 19, having a purity of greater than about 99.9 %.

33. A pharmaceutical composition comprising the solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claims 18 to 19, and one or more pharmaceutically acceptable carriers or excipients.

34. A method of treating fungal infections in a human which comprises administering to a patient in need of such treatment an effective amount of the solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claims 18 to 19.

35. Solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid having characteristic DSC endothermic maximum at about 234 °C (onset at about 229 °C) (heating rate of 10 °C/min).

36. Solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, characterized in that it does not contain water.

37. Solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, characterized in that it does not contain solvent.

38. Process for the preparation of the solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid that includes sublimation of icofungipen at about oil bath temperature 170 °C and pressure of about 0.05 mm Hg for 1 hour.

39. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a polymorphic purity greater than 95.0 % .

40. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a polymorphic purity greater than 99.0 % .

41. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a polymorphic purity greater than 99.5 % .

42. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a polymorphic purity greater than 99.9 % .

43. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, which is polymorphic pure.

44. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a purity of greater than about 90.0 %.

45. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a purity of greater than about 95.0 %.

46. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a purity of greater than about 99.0 %.

47. The solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentane-carboxylic acid according to claim 35, having a purity of greater than about 99.9 %.

48. A pharmaceutical composition comprising the solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claim 35, and one or more pharmaceutically acceptable carriers or excipients.

49. A method of treating fungal infections in a human which comprises administering to a patient in need of such treatment an effective amount of

the solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claim 35.

50. A pharmaceutical composition comprising any mixture of the solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claims 1 to 3, and solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claims 18 to 19, and solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid according to claim 35, and one or more pharmaceutically acceptable carriers or excipients.

51. A method of treating fungal infections in a human which comprises administering to a patient in need of such treatment an effective amount of any mixture of the solid state form δ of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid of claim 1 to claim 3, and the solid state form ε of (-)-(1*R*,1*S*)-2-amino-4-methylene-cyclopentanecarboxylic acid according to claims 18 to 19, and the solid state form ζ of (-)-(1*R*,1*S*)-2-amino-4-methylene-cyclopentanecarboxylic acid according to claim 35.

ABSTRACT

The present invention relates to the solid state forms δ, δ1 and ε of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid, to the processes for their preparation, to pharmaceutical compositions containing the said solid state forms of (-)-(1*R*,1*S*)-2-amino-4-methylenecyclopentanecarboxylic acid as the active ingredients as well as to a method of treatment using the same.

Application Data Sheet

Application Information

Application Type::	Regular
Subject Matter::	Utility
Suggested Group Art Unit::	N/A
CD-ROM or CD-R?::	None
Sequence submission?::	None
Computer Readable Form (CRF)?::	No
Title::	SOLID STATE FORMS OF ICOFUNGIPEN
Attorney Docket Number::	03818/0201177-US0
Request for Early Publication?::	No
Request for Non-Publication?::	No
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

Correspondence Information

Correspondence Customer Number::	07278

Representative Information

Representative Customer Number::	07278