

fresh Dup amended pages.
Amended on 11-8-2008

FORM 2
THE PATENTS ACT 1970
[39 OF 1970]
&
THE PATENTS RULES, 2003
COMPLETE SPECIFICATION

[See Section 10]

“(S)-N-[[3-[3-FLUORO-4-(4-MORPHOLINYL)PHENYL]-2-OXO-5-
OXAZOLIDINYLMETHYL] ACETAMIDE”

PHARMACIA & UPJOHN COMPANY, a Delaware corporation, of 301 Henrietta Street, Kalamazoo, Michigan 49001, United States of America,

The following specification particularly describes the invention and the manner in which it is to be performed:

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623/mumnp/04

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The present invention relates to (S)-N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl] acetamide.

1. Field of the Invention

The field of the invention is a novel crystal form of a known compound, linezolid which is pharmaceutically useful as an antibacterial agent.

2. Description of the Related Art

US Patent 5,688,792 discloses the antibacterial agent linezolid as well as a process for its preparation. EXAMPLE 5 reports the linezolid produced had a mp of 181.5-182.5°.

There are many other disclosures of processes to prepare linezolid. *J. Med. Chem.*, 39(3), 673-9 (1996) reports the linezolid was, "recrystallized from ethyl acetate and hexanes ...white crystals, m.p. 181.5-182.5C." It also sets forth the IR spectrum as "3284, 3092, 1753, 1728, 1649, 1565, 1519, 1447, 1435".

Tetrahedron Lett., 40(26), 4855 (1999) discloses linezolid and a process to prepare linezolid. However, this document does not set forth the melting point or IR spectrum of the linezolid prepared.

US Patent 5,837,870 (International Publication WO97/37980 of PCT/US97/03458) discloses a process to prepare linezolid. Linezolid is described in EXAMPLE 18, which does not set forth the melting point or IR spectrum of the linezolid prepared.

International Publication WO99/24393 of PCT/US98/20934 discloses a process to prepare linezolid. Linezolid is described in EXAMPLES 8, 9 and 12 which do not set forth the melting point or IR spectrum of the linezolid prepared.

The form of linezolid being used in the clinical trials to support the filing of the NDA is Form II.

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WE CLAIM:

1. (S)-N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide comprising a powder X-ray diffraction spectrum of:

Two-Theta Angle(°)
16.79

2. (S)-N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide of claim 1 comprising a powder X-ray diffraction spectrum of:

Two-Theta Angle(°)
14.23
16.79

3. (S)-N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide of claim 1 comprising a powder X-ray diffraction spectrum of:

Two-Theta Angle(°)
14.23
16.79
22.39

4. (S)-N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide of claim 1 comprising a powder X-ray diffraction spectrum of:

Two-Theta Angle(°)
14.23
16.79
21.61

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22.39
25.28

5. (S)-N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide of claim 1 comprising a powder X-ray diffraction spectrum of:

Two-Theta Angle(°)
9.54
13.88
14.23
16.79
19.93
21.61
22.39
23.52
25.28

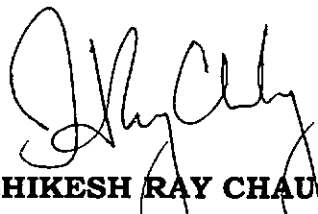
6. (S)-N-[[3-[3-fluoro-4-(4-morpholinyl)phenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide of claim 1 comprising a powder X-ray diffraction spectrum of:

Two-Theta Angle(°)
7.10
9.54
13.88
16.18
16.79
17.69

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19.41
19.69
19.93
21.61
22.39
22.84
23.52
24.16
25.28
26.66
27.01
22.77

Dated this 3rd day of October, 2004.


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 OF REMFRY & SAGAR
 ATTORNEY FOR THE APPLICANTS

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