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(54) Title: PHARMACEUTICAL COMPOSITION CONTAINING LAMOTRIGINE PARTICLES OF DEFINED MORPHOLOGY

(57) Abstract: The present invention provides a pharmaceutical composition comprising a plurality of lamotrigine particles having a specific surface area of from about two to about three and a half meters per gram. Pharmaceutical compositions falling within the surface area criteria for the lamotrigine particles include those having a particle diameter equal to or less than about 100 μm, preferably about 50 μm, and most preferably 10 μm. The pharmaceutical composition can be formulated into a wide variety of dosage forms.

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 03/13002

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/14 A61K31/53

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 17611 A (WELLCOME FOUND ;HISKETT SIMON PHILIP (GB); TAYLOR SUSAN ANN (GB)) 13 June 1996 (1996-06-13) cited in the application page 5, line 25 - line 27 example 1 ---	1-26
Y	ES 8 604 019 A (NIPPON SHINYAKU CO LTD) 1 June 1986 (1986-06-01) page 1, line 13 - line 22 page 6, line 29 -page 7, line 14 page 9, line 9 - line 29 examples --- -/--	1-26

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 August 2003	23/10/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Giménez Miralles, J

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 03/13002

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 00681 A (WELLCOME FOUND ;FLOYD ALISON GREEN (US); JAIN SUNIL (US)) 9 January 1997 (1997-01-09) cited in the application examples	1-26
A	WO 01 22938 A (VERRECK GEERT ;BAERT LIEVEN (BE); JANSSEN PHARMACEUTICA NV (BE)) 5 April 2001 (2001-04-05) page 39, line 17 - line 34 page 41, line 7 - line 8 page 75, line 11 - line 18	1-26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/13002

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 25, 26
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 25 and 26 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Claims Nos.: 25,26

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte nal Application No
PCT/US 03/13002

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Information on patent family members

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