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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PHARMACEUTICAL COMPOSITIONS FOR ORAL ADMINISTRATION COMPRISING LITHIUM CARBONATE

(57) Abstract: The present invention pertains to a controlled release solid dose formulations of lithium carbonate, comprising lithium carbonate, optional pharmacologically acceptable excipients, lubricants including stearic acid, sodium stearyl fumarate, calcium stearate, and magnesium stearate, optionally glycine, and sodium carboxymethylcellulose. Tablet forms are compressed at various pressures. The sodium carboxymethylcellulose and optionally glycine increases the dissolution rate profiles for lithium carbonate formulations, particularly for those formulations stored for extended periods of time and at varying conditions of heat and humidity. A process of formulating such compositions, comprising the steps of mixing lithium carbonate with excipients, top spraying a solution of sodium carboxymethylcellulose and glycine onto the lithium mixture in a fluid bed granulator, milling, and pressing the resultant compound into tablets is also described. The formulations of the invention are useful in a method of treatment of Bipolar Disorder (Manic Depressive Disorder).

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US04/16135

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61K33/00, 9/20, 47/00; A61P 25/18, 25/24 US CL : 424/722, 465, 468, 470; 514/960, 961 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) U.S. : 424/722, 465, 468, 470; 514/960, 961 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 practicable, search terms used) Please See Continuation Sheet		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,365,196 A (VENKATESH et al.) 02 April 2002 (02.04.2002), column 1, lines 15-23.	1-7, 24, 36-39, 46, 47, 48, 59
X	US 4,572,833 A (PEDERSEN et al.) 25 February 1986 (25.02.1986), column 5, lines 32-68, columns 6-7, column 8, lines 1-65.	1-18, 36-39, 45-53
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Y	file MEDLINE on PUBMED, Doc. No. 3735097 (Chowhan et al., J. Pharm. Sci. (June 1986), Vol. 75, No. 6, pages 542-545), Abstract.	5, 21, 29, 32, 35, 42-44
Y	Gennaro et al., Ed., Remington's Pharmaceutical Sciences (17th Ed. 1985), pages 1088, 1089, 1280, 1603-1612.	1-60
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"B"	earlier application or patent published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 21 October 2005 (21.10.2005)		Date of mailing of the international search report 17 NOV 2005
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Sreeni Padmanabhan Telephone No. (571) 272-1600

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/16135

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
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 No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

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 additional fees, this Authority did not invite payment of any additional fees.
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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/16435L

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 1-18,23,30-32,36-53,57,58, drawn to compositions containing lithium carbonate and excipients.

Group II, claim(s) 19-22, 27-29, 54-56, drawn to processes for preparing a composition containing lithium carbonate and excipients.

Group III, claim(s) 24-26, 33-35,59, 60, drawn to method of treatment of bipolar disorder with compositions containing lithium carbonate and excipients.

The inventions listed as Groups I, II, III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Since a number of the claims do not appear to define a contribution over the prior art, i.e. one or more of the claims lack novelty and/or inventive step, unity of invention is lacking.

Continuation of B. FIELDS SEARCHED Item 3:

EAST

search terms:lithium carbonate, bipolar, manic-depressive, sodium carboxymethylcellulose,iron oxide, glycine,stearic acid, sodium stearyl fumarate, calcium stearate, magnesium stearate, fluid bed granulator