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(54) Title: RAPIDLY DISINTEGRATING ORAL FORMULATION OF A CYCLOOXYGENASE-2 INHIBITOR

(57) Abstract: A molded article such as a tablet is provided for administration to an oral cavity of a subject to treat or prevent a cyclooxygenase-2 mediated condition, disorder or disease. The molded article comprises a moldable blend of a therapeutically effective amount of a selective cyclooxygenase-2 inhibitory drug with a pharmaceutically acceptable excipient carrier system consisting predominantly of one or more carbohydrates, wherein ingredients and amounts thereof in the molded article and a process for preparing the molded article are selected such that the molded article exhibits rapid disintegration in the oral cavity, and wherein the moldable blend is prepared by a process step not requiring wet granulation.

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INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/20 A61K31/635 A61K31/415

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, BIOSIS, MEDLINE, EMBASE, 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.
X	WO 00 32189 A (GAO DANCHEN ;SEARLE & CO (US); MAZHARY AHMAD M (US); HLINAK ANTHON) 8 June 2000 (2000-06-08) cited in the application page 1, line 1 page 8, line 23 - line 24 page 12, line 25 -page 13, line 4 page 18, line 28 - line 31 page 19, line 10 - line 16 page 20, line 6 - last line page 21, line 21 -page 22, line 16 page 31, line 11 - line 27 page 32, line 26 -page 33, line 18; claims; examples 3-5,9 --- -/--	1-5, 7-14, 16-23, 25-31, 35-39

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

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
7 May 2002	22/05/2002

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	Marttin, E

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 44028 A (MERCK FROSST CANADA INC ;HANCOCK BRUNO (CA); WINTERS CONRAD (CA);) 27 November 1997 (1997-11-27) page 1, line 9 - line 18 page 6, line 31 -page 7, line 7; example 2 page 8, line 21 -page 9, line 9	1-5,7, 9-14, 17-23, 25, 27-32, 35-37
X	WO 00 27382 A (LINES CHRISTOPHER R ;BLOCK GILBERT A (US); MERCK & CO INC (US)) 18 May 2000 (2000-05-18) page 20, line 1 - line 2; example 2	1-7, 9-14, 19-25, 27-32, 35-37
X	WO 99 04765 A (BRAMBILLA GAETANO ;MEZZADRI ROSA (IT); VENTURA PAOLO (IT); ACERBI) 4 February 1999 (1999-02-04) page 1, paragraph 1 page 7, line 22 - line 26; example 9	1,7-14, 19,25, 27-32, 35-37
X	EP 0 748 628 A (AMERICAN HOME PROD) 18 December 1996 (1996-12-18) examples 3,10-16 claims 1,6,8,9	1,7-14, 19, 25-33, 35-37
X	WO 99 47172 A (RECORDATI CHEM PHARM) 23 September 1999 (1999-09-23) page 1, line 10 - line 17 page 1, line 24 - line 25 page 4, line 14 - line 23 page 6, line 13 - line 18; claims 1-3,9; example 2	1,7, 9-14,19, 25, 27-32, 35-37
X	EP 0 396 335 A (BEECHAM GROUP PLC) 7 November 1990 (1990-11-07) page 3, line 27 - line 30; example 3	1,7-14, 19, 25-32, 35-37
X	US 5 501 861 A (MAKINO TADASHI ET AL) 26 March 1996 (1996-03-26) cited in the application column 2, line 39 -column 3, line 38 column 4, line 67 -column 5, line 13 column 7, line 23 - line 59; claims 1-7; example 3	1,7-19, 25-32, 35-37

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 01 39749 A (JAIN RAJESH ;SINGH AMARJIT (IN); PANACEA BIOTEC LTD (IN)) 7 June 2001 (2001-06-07) page 1, paragraph 3 -page 2, paragraph 1 page 3, paragraph 4 -page 4, paragraph 3 page 35, line 4 - line 15; examples 1,2 page 41, last paragraph -page 42, last paragraph; claims 1,2,4,5,7	1,7-14, 16-19, 25-32, 35-37

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1-39 relate to a compound, defined by reference to a desirable characteristic or property, namely a "selective cyclooxygenase-2 inhibitory drug". This term "selective cyclooxygenase-2 inhibitory drug" defines the active agent by its pharmacological effect. However, a compound canot be sufficiently characterised by its pharmacological effect as it is done by an expression like "selective cyclooxygenase-2 inhibitory drug", because it is impossible to know which substances are encompassed in this expression.

The claims cover all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the compound by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the concept of a "selective cyclooxygenase-2 inhibitory drug", and to the compounds mentioned in the dependent claims 2-6 and 20-24, and those mentioned in the description on page 10, lines 19-25.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

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