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(54) Title: ORAL FAST-MELT DOSAGE FORM OF A CYCLOOXYGENASE-2 INHIBITOR

(57) Abstract: A process is provided for preparing an oral fast-melt composition of a selective cyclooxygenase-2 inhibitory drug comprising (a) a step of wet granulating the selective cyclooxygenase-2 inhibitory drug together with a binding agent selected from gums, polypeptides, natural and modified starches, cellulosic materials, alginate acid and salts thereof, polyethylene glycol, polyvinylpyrrolidone, polymethacrylates, silicate salts and bentonites, and (b) a step of blending with the drug a saccharide of low moldability, wherein the above steps (a) and (b) occur in any order or simultaneously to result in formation of granules. Optionally the process further comprises (c) a step of blending the granules with at least one of a lubricant, a sweetening agent and a flavoring agent to form a tableting blend, and (d) a step of compressing the tableting blend to form oral fast-melt tablets. Also provided is a composition prepared by such a process.

INTERNATIONAL SEARCH REPORT

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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

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| Y | page 1, paragraph 1 page 18, line 28 - line 31 page 2, line 24 -page 3, line 4 page 12, line 25 -page 13, line 4 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 --- -/-- | 7,21 |

Further documents are listed in the continuation of box C. Patent family members are listed in annex.

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| Date of the actual completion of the international search 7 May 2002 | Date of mailing of the international search report 22/05/2002 |
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| Name and mailing address of the ISA 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 | Authorized officer Marttin, E |
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INTERNATIONAL SEARCH REPORT

International Application No
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| X | <p>EP 0 748 628 A (AMERICAN HOME PROD) 18 December 1996 (1996-12-18)</p> <p>example 16</p> <p>---</p> | <p>1,2,8, 10,12, 13,15, 16,22, 24,26, 27,30,31</p> |
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| A | <p>column 3, line 33 - line 43; example 5</p> <p>---</p> <p style="text-align: center;">-/--</p> | <p>1-5, 16-19, 30,31</p> |

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| P, X | <p>WO 01 41761 A (NADKARNI SREEKANT ; DESAI SUBHASH (US); KONTNY MARK J (US); PHARMAC) 14 June 2001 (2001-06-14)</p> <p>page 2, line 20 -page 3, line 11 page 10, line 19 - line 20 page 12, line 13 - line 14 page 13, line 17 - line 20 page 13, line 29 -page 14, line 4 page 14, line 15 - line 30 page 18, line 25 - line 30 page 19, line 5 - line 14 page 30, line 28 -page 20, line 22; claims; examples 2,3; table 4 -----</p> | <p>1-5,7,8, 10-19, 21,22, 24-27, 30-33</p> |
| A | <p>EP 0 839 526 A (TAKEDA CHEMICAL INDUSTRIES LTD) 6 May 1998 (1998-05-06) page 2, line 39 - line 42; claims; examples 1,2; tables 1,2 -----</p> | <p>1-33</p> |

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Present claims 1-33 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 cannot 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 3-7 and 17-21, and those mentioned in the description on page 9, lines 11-17.

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.

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