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(54) Title: ENCASED TAMPER RESISTANT CONTROLLED RELEASE DOSAGE FORMS

(57) Abstract: In certain embodiments, the present invention is directed to a solid controlled release dosage form comprising: a core comprising a first portion of an opioid analgesic dispersed in a first matrix material; and a shell encasing the core and comprising a second portion of the opioid analgesic dispersed in a second matrix material; wherein the amount of opioid analgesic released from the dosage form is proportional within 20% to elapsed time from 8 to 24 hours, as measured by an in-vitro dissolution in a USP Apparatus 1 (basket) at 100 rpm in 900 ml simulated gastric fluid without enzymes (SGF) at 37 C.



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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/20 A61K9/28 A61K31/485
ADD.

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)

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 practicable, search terms used)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/081290 A1 (MCKENNA WILLIAM H [US] ET AL) 26 March 2009 (2009-03-26) cited in the application [0006]-[0018]; example 12 -----	1-124, 127-133, 136
Y	US 2004/241234 A1 (VILKOV ZALMAN [US]) 2 December 2004 (2004-12-02) [0023], [0030]; figure 5 ----- -/--	1-124, 127-133, 136

☒ 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

"E" earlier application or patent 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

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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.
A	Hariharan M and Gupta V K: "A novel compression-coated tablet dosage form", Pharmaceutical Technology Yearbook 2001, 1 January 2001 (2001-01-01), pages 14-19, XP002678748, Retrieved from the Internet: URL: http://www.pharmtech.com/pharmtech/data/articlestandard/pharmtech/512001/5072/article.pdf [retrieved on 2012-06-25] page 18-19, paragraphs entitled "Application of compression-coated tablets to produce controlled-release tablets" and "Other possible applications of the compression-coated tablet process" -----	1-124, 129-133
X	US 2009/022798 A1 (ROSENBERG JOERG [DE] ET AL) 22 January 2009 (2009-01-22) example 15, in particular table XXXVII -----	125-127, 134-136
X	US 2009/215808 A1 (YUM SU IL [US] ET AL) 27 August 2009 (2009-08-27) example 3e and figure 9A and B -----	125,126, 134,135
X	US 2004/047907 A1 (OSHLACK BENJAMIN [US] ET AL) 11 March 2004 (2004-03-11) example 1 and 2, table 1B and 2B; claim 8 -----	125,126, 134,135
X	WO 2010/078486 A2 (UPSHER SMITH LAB INC [US]; EVENSTAD KENNETH L [US]; WERTZ CHRISTIAN F) 8 July 2010 (2010-07-08) example 2; figure 3 and 4 -----	125,126, 134,135

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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:

see additional 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 an additional fees, this Authority did not invite payment of 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-124, 130-133(completely); 129(partially)

A solid controlled release dosage form composed of a matrix core and a matrix shell, each comprising an opioid analgesic

2. claims: 125, 126, 134, 135(completely); 129(partially)

A solid controlled release dosage form providing release of hydrocodone that is substantially proportional to elapsed time and substantially independent of whether or not the the dosage form is flattened

3. claims: 127, 128, 136(completely); 129(partially)

A solid controlled release dosage form comprising in the central portion a higher amount of hydrocodone than in the outer portion

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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