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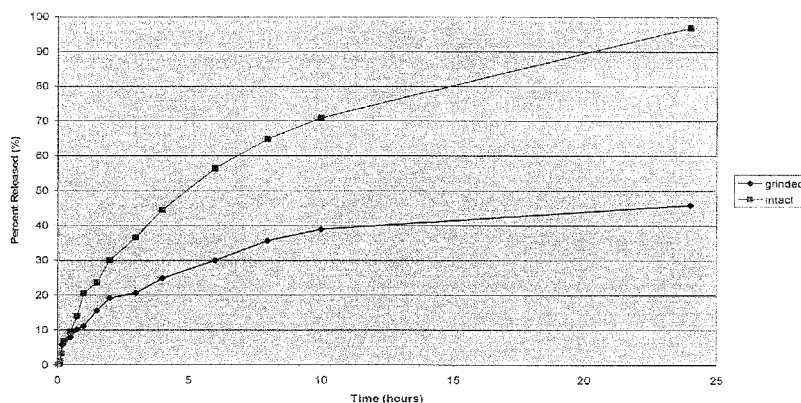
— with international search report (Art. 21(3))

(88) Date of publication of the international search report:

30 December 2009

(54) Title: ABUSE RESISTANT DRUGS, METHOD OF USE AND METHOD OF MAKING

Abuse-Resistant Oxycodone Tablet (Preferred Example)
Comparative in-vitro Release Rate in DI Water; 100 RPM; Basket; 900 mL
Intact tablet vs. Grinded tablet



(57) Abstract: An abuse resistant oral pharmaceutical composition, comprising: a barrier layer, comprising a first polymer; a diffusion layer, comprising a second polymer, substantially covering the barrier layer, wherein the diffusion layer is bonded to the barrier layer and comprises a drug that is substantially homogeneously distributed within the second polymer and diffuses from the diffusion layer within the gastrointestinal (GI) tract; and optionally an expansion layer comprising an expandable polymer, wherein the expansion layer is substantially covered by the barrier layer. Methods of making the same and methods of using the same are also provided.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/72914

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 9/22, A61K 9/24, A61K 9/26 (2008.04)

USPC - 424/468, 424/464, 424/469, 424/472

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)

USPC - 424/468, 424/464, 424/469, 424/472

IPC(8) - A61K 9/22, A61K 9/24, A61K 9/26 (2008.04)

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

USPC - 424/468, 424/464, 424/469, 424/472

IPC(8) - A61K 9/22, A61K 9/24, A61K 9/26 (2008.04) (text search)

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

PubWEST (USPT,PGPB,EPAB,JPAB), Google, Google Scholar

Search terms used: oral pharmaceutical, barrier layer, abuse deterrent drug, diffusion layer, expandable polymer, Cmax/AUC, release layer, expansion layer, bonded, substantially homogeneously, gastrointestinal (GI) tract, euphoria

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2007/0148097 A1 (Finn et al.) 28 June 2007 (28.06.2007), para [0013], [0018], [0032], [0050], [0014], [0034], [0036]	1, 32, 33 ----- 2-4, 34-36, 38
Y	US 20070004797 A1 (Meyers et al.) 04 January 2007 (04.01.2007), para [0025]-[0157]	2-4, 34-36, 38
Y	US 2005/0074493 A1 (Metha et al.) 07 April 2005 (07.04.2005), entire document, especially abstract; table 5.	13-21
Y	US 2005/0176646 A1 (Mickle et al.) 11 August 2005 (11.08.2005), entire document, especially abstract; table 3, 11, 15-20, 46; para [0430], [0602]	13-21
A	U.S. 5,395,626 A1 (Kotwal et al) 07 March 1995 (07.03.1995), col 4, ln 4-50	1-4 32-36, 38
A	US 20030198674 A1 (Curatolo et al) 23 October 2003 (23.10.2003), abstract	13-21

☐ Further documents are listed in the continuation of Box C.

* 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

Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/72914

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.: 5-12, 22-31, 37
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:
Two claim groups were found:

Group I: Claims 1-4, 32-36

Group II: Claims 13-21, 38

It is noted claims 5-12, 22-31, and 37 have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

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. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

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 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.

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Continuation of Box No. III -- Observations where unity of invention is lacking

Group I: is directed to an oral pharmaceutical composition, comprising: a barrier layer, comprising a first polymer, and a diffusion layer, comprising a second polymer, substantially covering the barrier layer, wherein the diffusion layer is bonded to the barrier layer and comprises a drug that is substantially homogeneously distributed within the second polymer and diffuses from the diffusion layer within the gastrointestinal (GI) tract.

Group II: is directed to an oral pharmaceutical composition, comprising a drug in a pharmaceutically effective amount, wherein the pharmaceutical composition is configured such that when the pharmaceutical composition is administered in physically compromised form to a subject, the C_{max} and/or A_{VC} achieved after administration is lower than the C_{max} and/or A_{VC} achieved after a time period selected from the group consisting of 2 hours, 4, hours, 8 hours, 12 hours, 24 hours, and 48 hours after administration, of a bioequivalent composition not comprising means for deterring abuse.

The inventions listed as Groups I-II 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:

Group I does not include the inventive concept of administration of a drug wherein the C_{max} and/or A_{VC} achieved after administration is lower than the C_{max} and/or A_{VC} achieved after a time period selected from the group consisting of 2 hours, 4, hours, 8 hours, 12 hours, 24 hours, and 48 hours after administration, of a bioequivalent composition not comprising means for deterring abuse, as required by group II.

Group II does not include the inventive concept of a barrier layer, comprising a first polymer, and a diffusion layer, comprising a second polymer, substantially covering the barrier layer, wherein the diffusion layer is bonded to the barrier layer and comprises a drug that is substantially homogeneously distributed within the second polymer and diffuses from the diffusion layer within the gastrointestinal (GI) tract, as required by Group I.

Groups I-II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.