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[Continued on next page]

(54) Title: SOLID COMPOSITION FOR CONTROLLED RELEASE OF IONIZABLE ACTIVE AGENTS WITH POOR AQUEOUS SOLUBILITY AT LOW PH AND METHODS OF USE THEREOF

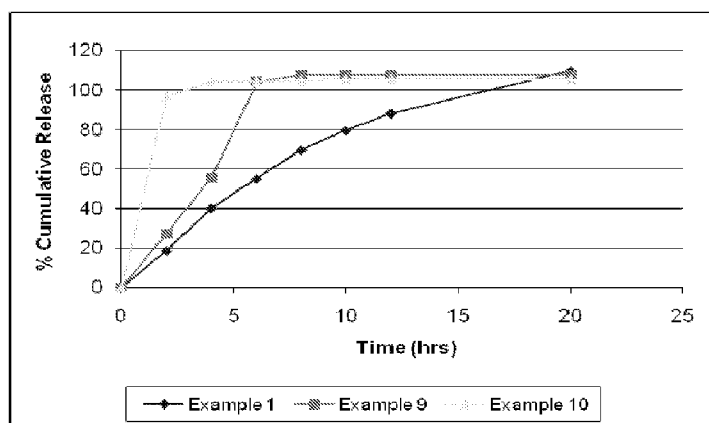


FIG. 1B

(57) Abstract: A novel solid composition and methods for making and using the solid composition are provided. The solid composition comprises: (a) at least one active agent with a solubility of less than about 0.3 mg/ml in an aqueous solution with a pH of at most about 6.8 at a temperature of about 37°C; and (b) a hydrophilic polymer matrix composition comprising: i) a hydrophilic polymer selected from the group consisting of METHOCEL™, POLYOX™ WSR 1105 and combinations thereof; and optionally ii) a hydrophobic polymer selected from the group consisting of Ethocel 20 premium; and (c) an alkaliizer selected from the group consisting of calcium carbonate, magnesium oxide heavy and sodium bicarbonate; wherein the composition provides at least about 70% release of the active between about 7 to about 12 hours following oral administration.



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A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61K9/20 A61K31/192 A61K31/405 A61K31/19 A61K31/517
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 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)
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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, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	RIIS ET AL: "pH-independent drug release of an extremely poorly soluble weakly acidic drug from multiparticulate extended release formulations", EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS, ELSEVIER SCIENCE PUBLISHERS B.V., AMSTERDAM, NL, vol. 65, no. 1, 1 December 2006 (2006-12-01), pages 78-84, XP005788727, ISSN: 0939-6411, DOI: DOI:10.1016/J.EJPB.2006.07.001	1-5, 8-12, 16-18, 22-24, 26,27,30
Y	figures 3-8; table 2 ----- -/--	6,7

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"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</p> <p>"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.</p> <p>"&" document member of the same patent family</p>
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Date of the actual completion of the international search 11 April 2011	Date of mailing of the international search report 21/04/2011
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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, Fax: (+31-70) 340-3016	Authorized officer Frelichowska, J
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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X	MEKA L. ET AL.: "Design and evaluation of polymeric coated minitablets as multiple unit gastroretentive floating drug delivery systems for furosemide.", JOURNAL OF PHARMACEUTICAL SCIENCES, vol. 98, no. 6, 13 November 2008 (2008-11-13), pages 2122-2132, XP002629134, DOI: 10.1002/jps.21562 page 2124; figure 2; table 1 -----	1-5,8, 11-14, 16, 22-27,30
Y	US 2008/279845 A1 (CONLEY PAMELA B [US] ET AL) 13 November 2008 (2008-11-13) page 13 -----	6,7
A	US 2007/123547 A1 (SCARBOROUGH ROBERT [US] ET AL) 31 May 2007 (2007-05-31) the whole document -----	1-30

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