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(54) Title: ORALLY-DISINTEGRATING SOLID PREPARATION

(57) Abstract: The present invention provides an orally-disintegrating solid preparation such as a tablet produced by tabletting fine granules showing controlled release of a pharmaceutically active ingredient and an additive, and the like, and the orally-disintegrating solid preparation containing fine granules coated with a coating layer containing a polymer affording a casting film having an elongation at break of about 100 - about 700%. With the preparation, breakage of fine granules during tabletting can be suppressed in the production of an orally-disintegrating solid preparation containing fine granules showing controlled release of a pharmaceutically active ingredient.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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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 practical, search terms used)
EPO-Internal, 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,P	WO 2008/081891 A1 (TAKEDA PHARMACEUTICAL [JP]; KURASAWA TAKASHI [JP]; WATANABE YASUKO [JP]) 10 July 2008 (2008-07-10)	1-39
L	paragraph [0016] - paragraph [0019] paragraph [0029] paragraph [0095] - paragraph [0102] paragraph [0115] - paragraph [0128] claims -& EP 2 098 250 A1 (TAKEDA PHARMACEUTICAL [JP]) 9 September 2009 (2009-09-09)	1-39
X	EP 1 813 275 A1 (TEVA PHARMA [IL]) 1 August 2007 (2007-08-01) paragraph [0026] - paragraph [0052] claims	1-39

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

[X] See patent family annex.

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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	US 2005/053660 A1 (BECKERT THOMAS [DE] ET AL) 10 March 2005 (2005-03-10) paragraph [0018] - paragraph [0050] paragraph [0053] paragraph [0125] - paragraph [0132]; examples claims	1-39
X	BECKERT T E ET AL: "COMPRESSION OF ENTERIC-COATED PELLETS TO DISINTEGRATING TABLETS" INTERNATIONAL JOURNAL OF PHARMACEUTICS, ELSEVIER BV, NL, vol. 143, 1 January 1996 (1996-01-01), pages 13-23, XP000653168 ISSN: 0378-5173 page 15 - page 21	1-39
X	US 2005/287211 A1 (YOSHIDA TAKAYUKI [JP] ET AL) 29 December 2005 (2005-12-29) paragraph [0001] page 13, column 2, line 29 page 17; example 1 page 25; example 22 claims	1-22,39

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008081891 A1	10-07-2008	EP 2098250 A1	09-09-2009
EP 2098250 A1	09-09-2009	WO 2008081891 A1	10-07-2008
EP 1813275 A1	01-08-2007	NONE	
US 2005053660 A1	10-03-2005	NONE	
US 2005287211 A1	29-12-2005	NONE	