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(54) Title: DOSAGE FORMS HAVING AN INNER CORE AND OUTER SHELL

(57) Abstract: In one embodiment, the dosage form of this invention comprises a core having an outer surface and a shell having outer and inner surfaces, wherein the shell surrounds the core such that the shell inner surface resides substantially conformally upon the core outer surface, the shell thickness is in the range of about 100-400 microns, the relative standard deviation of the shell thickness on the dosage form is less than about 30 %, the shell comprises less than about 50 % crystallizable sugar, and the dosage form is substantially free of charge control agents. In another embodiment, the dosage form comprises a core having an outer surface and a shell having outer and inner surfaces, wherein the shell surrounds the core, the dosage form moisture uptake at 60 minutes exposure to 40 °C and 75 % relative humidity is less than about 0.80 %, the shell thickness is in the range of about 100-400 microns, the relative standard deviation of the shell thickness on the dosage form is less than about 30 %, the dosage form is substantially free of charge control agents and the shell is substantially free of a raised seam.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K9/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\label{lem:minimum documentation searched (classification system followed by classification symbols)} IPC \ 7 \ A61K$

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, CHEM ABS Data

ategory °	Citation of document, with indication, where appropriate, of the relevant	passages Relevant to claim No.
,	US 5 415 868 A (CRIM MARK E ET AL) 16 May 1995 (1995-05-16) figures 1,2 column 1, line 40 - line 59 column 2, line 5 - line 62	1-34
	US 5 824 338 A (SHAH SHIRISH A ET A 20 October 1998 (1998-10-20) column 2, line 11 - line 27 column 2, line 58 - line 61 column 3, line 6 - line 30	

Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document 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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INTERNATIONAL SEARCH REPORT

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0.10	A DESCRIPTION OF THE PROPERTY	PC1/US UZ/31066				
C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT Category Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.						
Category °	Chauton of document, with indication, where appropriate, of the relevant passages	nelevant to daim No.				
Х	EP 0 279 682 A (MCNEILAB INC) 24 August 1988 (1988-08-24) column 4, line 27 -column 5, line 4 column 6, line 9 - line 34 column 9, line 6 - line 64	1-6,9, 10,13, 20-22, 28,34				
	claims; figures					
		•				

INTERNATIONAL SEARCH REPORT

In ation on patent family members

PCT/US 02/31066

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 5415868 A	16-05-1995	US	6126767 A	03-10-2000
US 5824338 A	20-10-1998	CA	2193248 A1	20-02-1998
EP 0279682 A	24-08-1988	US AU AU	4820524 A 604845 B2 1204588 A	11-04-1989 03-01-1991 25-08-1988
		BR CA	8800680 A 1317882 A1	04-10-1988 18-05-1993
		DE -	3882550-D1	02-09-1993
		DE Ep	3882550 T2 0279682 A2	18-11-1993 24-08-1988
		ES GR	2042731 T3 88100096 A ,B	16-12-1993 16-12-1988
		HK	37294 A	29-04-1994
		IE IN	63265 B1 165927 A1	05-04-1995 10-02-1990
		JP	2683010 B2	26-11-1997
		JP KR	63255067 A 9608471 B1	21-10-1988 26-06-1996
		MX	167754 B	12-04-1993
		NZ Ph	223449 A 24779 A	21-12-1990 30-10-1990
		PH	26940 A	03-12-1992
		PT US	86786 A ,B 4921108 A	01-03-1988 01-05-1990
		US	4921108 A 4867983 A	19-09-1989
		US	4966771 A 5314537 A	30-10-1990 24-05-1994
		US US	5314537 A 4990358 A	05-02-1994 05-02-1991
		US ZA	5234099 A 8801189 A	10-08-1993 25-10-1989