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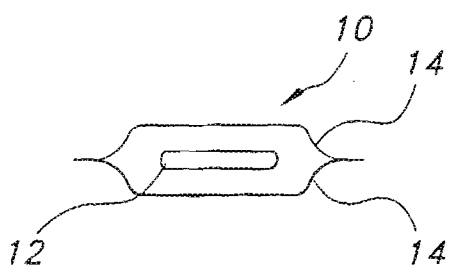


FIG 1

(57) Abstract: This invention relates to films incorporating high amounts of pharmaceutical agents and methods for the preparation of the same. Moreover, the invention relates to the film products and methods of their preparation that demonstrate a non-self-aggregating uniform heterogeneity. Desirably, the films disintegrate in water and may be formed by a controlled drying process, or other process that maintains the required uniformity of the film. Desirably, the films contain a pharmaceutical and/or cosmetic active agent with no more than a 10 % variance of the active agent pharmaceutical and/or cosmetic active agent per unit area of the film.



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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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B. FIELDS SEARCHED

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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)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/031209 A (MONOSOLRX LLC [US]) 23 March 2006 (2006-03-23) claims; table 28	1-8, 14-24, 26-33, 39-49, 51,52
X	WO 2004/045537 A (ZENGEN INC [US]; DAVIDSON R STEVEN [US]) 3 June 2004 (2004-06-03) page 25, lines 3-5; claims	1, 15-19, 21, 24, 26, 40-44, 49, 51, 52
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Further documents are listed in the continuation of Box C.

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	<p>WO 03/030881 A (KOSMOS PHARMA [US]; YANG ROBERT K [US]; FUISZ RICHARD C [US]) 17 April 2003 (2003-04-17)</p> <p>claims; tables 2,3</p>	<p>1-4,6,7, 9-11,15, 16,19, 26-29, 31, 34-36, 40,51-54</p>
X	<p>WO 01/70194 A (WARNER LAMBERT CO [US]) 27 September 2001 (2001-09-27)</p> <p>claims 1,2,4,21,22; example 2</p>	<p>1,2,4-6, 22,23, 26,27, 29-31, 47,48, 51,52</p>
X	<p>EP 0 460 588 A (LOHMANN THERAPIE SYST LTS [DE]) 11 December 1991 (1991-12-11)</p> <p>claims</p>	<p>1,15-19, 21,24, 26, 40-44, 49,51,52</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/051015

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2006031209	A	23-03-2006	AU 2004319243	A1 12-01-2006
			BR PI0410956	A 04-07-2006
			CA 2544776	A1 23-03-2006
			CN 1812773	A 02-08-2006
			EP 1663178	A1 07-06-2006
			JP 2007500252	T 11-01-2007

WO 2004045537	A	03-06-2004	AU 2003295577	A1 15-06-2004
			CA 2505833	A1 03-06-2004
			EP 1560571	A2 10-08-2005
			JP 2006515598	T 01-06-2006
			MX PA05005243	A 10-03-2006

WO 03030881	A	17-04-2003	AU 2002332118	B2 26-06-2008
			AU 2008227076	A1 16-10-2008
			CA 2473975	A1 17-04-2003
			EP 1463490	A1 06-10-2004
			JP 2005528328	T 22-09-2005

WO 0170194	A	27-09-2001	AR 029494	A1 02-07-2003
			AT 324864	T 15-06-2006
			AU 2972001	A 03-10-2001
			AU 2001229720	B2 02-02-2006
			AU 2006201888	A1 25-05-2006
			AU 2006201899	A1 25-05-2006
			BR 0109378	A 03-06-2003
			CA 2402988	A1 27-09-2001
			CN 1419441	A 21-05-2003
			CN 1651092	A 10-08-2005
			CZ 20023108	A3 16-04-2003
			DE 60119298	T2 31-08-2006
			DK 1267829	T3 11-09-2006
			EP 1267829	A1 02-01-2003
			ES 2261455	T3 16-11-2006
			HU 0300035	A2 28-05-2003
			IS 6523	A 23-08-2002
			JP 4145048	B2 03-09-2008
			JP 2003527410	T 16-09-2003
			MX PA02008425	A 13-12-2002
			NO 20024513	A 20-09-2002
			NZ 520961	A 31-10-2003
			PA 8513901	A1 24-10-2002
			PL 357135	A1 12-07-2004
			PT 1267829	T 31-07-2006
			SK 13432002	A3 03-06-2003
			SV 2001000345	A 25-09-2001
			TW 290474	B 01-12-2007
			US 2006204559	A1 14-09-2006
US 7067116	B1 27-06-2006			
UY 26628	A1 29-06-2001			
ZA 200206963	A 21-07-2003			

EP 0460588	A	11-12-1991	AT 127016	T 15-09-1995
			CA 2044043	A1 08-12-1991
			DE 4018247	A1 12-12-1991
			DK 460588	T3 30-08-1995
			ES 2078994	T3 01-01-1996
			GR 3018233	T3 29-02-1996

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/051015

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0460588	A	JP 2559301 B2 JP 7100186 A	04-12-1996 18-04-1995
