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- as to applicant's entitlement to apply for and be granted
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- as to the applicant's entitlement to claim the priority of
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(54) Title: A MEDICINAL FUSIDIC ACID CREAM MADE USING SODIUM FUSIDATE AND INCORPORATING A BIOPOLYMER, A CORTICOSTEROID - CLOBETASONE BUTYRATE, AND AN ANTIFUNGAL AGENT -TERBINAFINE HYDROCHLORIDE AND A PROCESS TO MAKE IT

(57) Abstract: The invention discloses a dermatological cream containing Clobetasone Butyrate as a corticosteroid, an antifungal agent in the form of Terbinafine Hydrochloride and an antibacterial agent in the form of Fusidic acid, which Fusidic acid is formed in situ from Sodium Fusidate as the starting raw material, wherein Sodium Fusidate is converted into Fusidic acid under oxygen-free environment. The cream of the present invention has greater shelf-life stability and the finer particle size of the API than the conventional creams containing Fusidic acid. The cream of the present invention contains Fusidic acid as the API that has been formed in situ from Sodium Fusidate, Clobetasone Butyrate and Terbinafine Hydrochloride, in a cream base comprising a preservative, an acid, a co-solvent, emulsifiers and a waxy material along with water, preferably purified water.



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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, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2009/063493 A2 (GLENMARK PHARMACEUTICALS LTD [IN]; SEN NILENDU [IN]; GOLE KUSUM DINKAR) 22 May 2009 (2009-05-22) page 7, lines 3-8 page 8, lines 4-11 page 12, lines 12-16 page 13, line 11 page 16, line 23 - page 18, line 7; claims 1-22; examples 1-8; tables 1-6, 1A-6A -----	1-16
Y	WO 01/45645 A1 (IVREA INC [US]; CATTANEO MAURIZIO V [US]; DEMIERRE MARIE FRANCE [US]) 28 June 2001 (2001-06-28) page 9, lines 2-14 page 10, lines 17-27 page 13, lines 7-15 page 20, lines 1,2; claims 1-31 ----- -/--	1-16

Further documents are listed in the continuation of Box C.

See patent family annex.

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- "A" document defining the general state of the art which is not considered to be of particular relevance
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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.
Y	<p>RAVI KUMAR M N V: "A review of chitin and chitosan applications", REACTIVE & FUNCTIONAL POLYMERS, ELSEVIER SCIENCE PUBLISHERS BV, NL, vol. 46, no. 1, 1 November 2000 (2000-11-01), pages 1-27, XP004224437, ISSN: 1381-5148, DOI: 10.1016/S1381-5148(00)00038-9 page 9, right-hand column, paragraph 3 - page 10, right-hand column, paragraph 2 page 21, right-hand column, paragraphs 2,4 -----</p>	1-16
Y	<p>RAMSAY C A ET AL: "The treatment of atopic dermatitis with topical fusidic acid and hydrocortisone acetate", JEADV. JOURNAL OF THE EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 7, no. SUPPL. I, 1 July 1996 (1996-07-01), pages S15-S22, XP002582785, ISSN: 0926-9959, DOI: 10.1016/0926-9959(96)00032-3 [retrieved on 2002-10-11] abstract page 16, right-hand column, paragraph 2 - page 21, right-hand column, paragraph 3 -----</p>	1-16
Y	<p>ALSARRA ET AL: "Chitosan topical gel formulation in the management of burn wounds", INTERNATIONAL JOURNAL OF BIOLOGICAL MACROMOLECULES, ELSEVIER BV, NL, vol. 45, no. 1, 1 July 2009 (2009-07-01), pages 16-21, XP026116180, ISSN: 0141-8130, DOI: 10.1016/J.IJBIOMAC.2009.03.010 [retrieved on 2009-04-02] abstract page 2, left-hand column, paragraph 5 - page 5, right-hand column, paragraph 6 -----</p>	1-16

INTERNATIONAL SEARCH REPORT

Information on patent family members

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WO 0145645	A1 28-06-2001	CA 2394901 A1 JP 2003524635 A	28-06-2001 19-08-2003