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(21) International Application Number: PCT/US98/25933 (22) International Filing Date: 7 December 1998 (07.12.98) (30) Priority Data: 08/994,626 19 December 1997 (19.12.97) US (71) Applicant: BAYER CORPORATION [US/US]; 100 Bayer Road, Pittsburgh, PA 15205 (US). (72) Inventor: PURWAR, Shivaji; 119 Cross Hill Road, Monroe, CT 06468 (US). (74) Agents: GREENMAN, Jeffrey, M. et al.; Bayer Corporation, 400 Morgan Lane, West Haven, CT 06516 (US).	(81) Designated States: AU, CA, CN, IL, JP, KR, MX, NZ, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> (88) Date of publication of the international search report: 10 September 1999 (10.09.99)	
(54) Title: NOVEL STERILIZATION PROCESS FOR PHARMACEUTICAL SUSPENSIONS		
(57) Abstract <p>The invention is directed to a method for sterilizing a pharmaceutical formulation comprising a suspension of a water-insoluble pharmaceutical, comprising the steps of heat-sterilizing an aqueous solution of a viscosity enhancer, to result in a first sterile premix. Next is sterile-filtering an aqueous solution of a mixture of a pharmaceutically-active compound, which results in a second sterile pre-mix. Next is heat-sterilizing a mixture of water, a water-insoluble pharmaceutical, and at least a partial amount of an electrolyte to provide a sub-saturated solution of the electrolyte, and adding under aseptic conditions an aqueous surfactant, to give a third sterile pre-mix. Finally, combining all three pre-mixes in sterile fashion to achieve a sterile suspended pharmaceutical formulation. Thus, for the third pre-mix, use of either Sodium chloride (in varying proportion) or Sodium acetate (in one proportion, but not limited to) is given as an example. The invention is also directed to methods for making sterile suspensions of pharmaceutically active compositions including Ciprofloxacin and hydrocortisone, and pharmaceutical compositions made according to this process.</p>		

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US 98/25933

A. CLASSIFICATION OF SUBJECT MATTER A 61 L 2/04, A 61 K 9/10, A 61 K 31/56				
According to International Patent Classification (IPC) or to both national classification and IPC ⁶				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols) A 61 L, A 61 K				
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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.		
A	US 3962430 A (O'NEILL) 08 June 1976 (08.06.76), the whole document (cited in the application). -----	1, 4, 5, 13, 16, 17, 19, 30, 31		
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Date of the actual completion of the international search <p style="text-align: center;">16 March 1999</p>		Date of mailing of the international search report <p style="text-align: center;">16 APR 1999</p>		
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ANNEXE

au rapport de recherche international relatif à la demande de brevet international n°

PCT/US 98/25933 SAE 216981

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US A 3962430		DE A 1617625 NL A 6612607 NL B 159010	21-01-71 08-03-67 15-01-79