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(54) Title: COLORED GELATIN-BASED FORMULATIONS AND METHOD

(57) Abstract: The present invention is a process for coloring gelatin-based formulations involving adding a saturated fatty acid to the gelatin-based formulation along with lake pigment, whereby the saturated fatty acid is added in an amount so as to prevent cross-linking between the gelatin-based formulations and the aluminum cations released by the lake pigments. Preferably, this amount is about 10 % to about 300 % by weight of the added lake pigment content. With this process, the resulting colored gelatin exhibits acceptable machineability characteristics and disintegration. As an example, the colored gelatin produced by this process has a viscosity of less than approximately 10,000 cP at about 60 °C. Additionally, the present invention is a gelatin-based formulation made from the above-described process. The gelatin-based formulation includes gelatin, lake pigment(s), and a sufficient amount of fatty acid to prevent cross-linking between and the cations released from the lake pigment(s). Further, the present invention includes a dosage form that includes the described gelatin-based formulation as the sheath material. The dosage form may encapsulate a liquid, suspension, semi-solid, or solid pharmaceutical, nutritional, herbal, or personal care product, or combination thereof.

## INTERNATIONAL SEARCH REPORT

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## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/48

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)

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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)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages                          | Relevant to claim No.                       |
|------------|---|---|
| X          | US 2 431 001 A (SULLIVAN DAVID J)<br>18 November 1947 (1947-11-18)<br><br>example 4, 5<br><br>---           | 1-5,<br>7-10,<br>12-18,<br>25-31            |
| X          | US 5 260 073 A (PHIPPS ROGER J)<br>9 November 1993 (1993-11-09)<br><br>example 6, 11<br><br>---<br><br>-/-- | 1-4,<br>7-10,<br>12-17,<br>25-28,<br>30, 31 |

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| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT |   |                                  |
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| Category °   | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.            |
| Y  | DIGENIS G A ET AL: "CROSS-LINKING OF GELATIN CAPSULES AND ITS RELEVANCE TO THEIR IN VINTRO-IN VIVO PERFORMANCE" JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN PHARMACEUTICAL ASSOCIATION. WASHINGTON, US, vol. 83, no. 7, 1 July 1994 (1994-07-01), pages 915-921, XP000454800 ISSN: 0022-3549 page 919, left-hand column, penultimate and ultimate paragraph<br>--- | 1-31                             |
| Y  | US 5 874 106 A (STACH PAUL EDWARD ET AL) 23 February 1999 (1999-02-23) column 1, line 8-15; column 2, line 15-33; column 3, line 56 - column 4, line 8<br>---   | 1-31                             |
| A  | EP 0 092 908 A (WARNER LAMBERT CO) 2 November 1983 (1983-11-02) page 26, second to fourth paragraph<br>---  | 1-31                             |
| A  | US 3 231 592 A (MCCORD ANDREW T) 25 January 1966 (1966-01-25) column 1, line 60 - column 2, line 14<br>---  | 1-31                             |
| P,X  | WO 01 32036 A (MENON VINOD P ;MONSANTO CO (US); KINLEN PATRICK J (US); PIRAKITIKU) 10 May 2001 (2001-05-10)<br><br>formulation C, D<br>-----  | 1-5,<br>7-10,<br>12-18,<br>25-31 |

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

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PCT/US 01/50714

| Patent document cited in search report |   | Publication date | Patent family member(s) | Publication date |
|--|---|------------------|-------------------------|------------------|
| US 2431001                             | A | 18-11-1947       | NONE                    |                  |
| -----                                  |   |                  |                         |                  |
| US 5260073                             | A | 09-11-1993       | AU 2050895 A            | 03-08-1995       |
|  |   |                  | AU 7992091 A            | 10-12-1991       |
|  |   |                  | EP 0530311 A1           | 10-03-1993       |
|  |   |                  | IE 911711 A1            | 04-12-1991       |
|  |   |                  | JP 5509300 T            | 22-12-1993       |
|  |   |                  | MX 173793 B             | 25-03-1994       |
|  |   |                  | PT 97730 A              | 28-02-1992       |
|  |   |                  | WO 9117746 A1           | 28-11-1991       |
|  |   |                  | ZA 9103831 A            | 26-02-1992       |
| -----                                  |   |                  |                         |                  |
| US 5874106                             | A | 23-02-1999       | AU 1925697 A            | 01-10-1997       |
|  |   |                  | WO 9733568 A1           | 18-09-1997       |
| -----                                  |   |                  |                         |                  |
| EP 0092908                             | A | 02-11-1983       | AU 552634 B2            | 12-06-1986       |
|  |   |                  | AU 1277683 A            | 13-10-1983       |
|  |   |                  | BG 42672 A3             | 15-01-1988       |
|  |   |                  | BR 8301538 A            | 06-12-1983       |
|  |   |                  | CA 1209910 A1           | 19-08-1986       |
|  |   |                  | CS 8302125 A2           | 15-04-1988       |
|  |   |                  | DD 210293 A5            | 06-06-1984       |
|  |   |                  | DK 134183 A             | 14-11-1983       |
|  |   |                  | EG 16027 A              | 30-12-1986       |
|  |   |                  | EP 0092908 A2           | 02-11-1983       |
|  |   |                  | ES 520961 D0            | 16-05-1984       |
|  |   |                  | ES 8404848 A1           | 01-09-1984       |
|  |   |                  | FI 831001 A ,B,         | 27-09-1983       |
|  |   |                  | GR 78492 A1             | 27-09-1984       |
|  |   |                  | IL 68234 A              | 30-11-1986       |
|  |   |                  | IN 159315 A1            | 02-05-1987       |
|  |   |                  | JP 58185648 A           | 29-10-1983       |
|  |   |                  | KR 9103739 B1           | 10-06-1991       |
|  |   |                  | MX 162351 A             | 26-04-1991       |
|  |   |                  | NO 831062 A ,B,         | 27-09-1983       |
|  |   |                  | NZ 203783 A             | 11-06-1986       |
|  |   |                  | PH 23356 A              | 14-07-1989       |
|  |   |                  | PL 241173 A1            | 02-07-1984       |
|  |   |                  | PT 76443 A ,B           | 01-04-1983       |
|  |   |                  | RO 86882 A1             | 20-05-1985       |
|  |   |                  | US 4790881 A            | 13-12-1988       |
|  |   |                  | US 4655840 A            | 07-04-1987       |
|  |   |                  | ZA 8302104 A            | 28-12-1983       |
| -----                                  |   |                  |                         |                  |
| US 3231592                             | A | 25-01-1966       | FR 1325217 A            | 26-04-1963       |
|  |   |                  | GB 1005957 A            | 29-09-1965       |
|  |   |                  | NL 278128 A             |                  |
| -----                                  |   |                  |                         |                  |
| WO 0132036                             | A | 10-05-2001       | AU 1463601 A            | 14-05-2001       |
|  |   |                  | WO 0132036 A1           | 10-05-2001       |
| -----                                  |   |                  |                         |                  |