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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: WO 98/47491 (11) International Publication Number: **A3** A61K 9/22 (43) International Publication Date: 29 October 1998 (29.10.98)

PCT/CA98/00274 (21) International Application Number:

(22) International Filing Date: 3 April 1998 (03.04.98)

(30) Priority Data: 60/036,551 21 April 1997 (21.04.97)

US

(71)(72) Applicants and Inventors: ODIDI, Isa [NG/CA]; 2136 Opal Court, Mississauga, Ontario L5K 2S5 (CA). ODIDI, Amina [NG/CA]; 2136 Opan Court, Mississauga, Ontario L5K 2S5 (CA).

(74) Agent: BARTOSZEWICZ, Lola, A.; Sim & McBurney, 6th floor, 330 University Avenue, Toronto, Ontario M5G 1R7

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

(88) Date of publication of the international search report: 21 January 1999 (21.01.99)

(54) Title: CONTROLLED RELEASE FORMULATIONS USING INTELLIGENT POLYMERS

(57) Abstract

An extended release dosage composition of pharmaceutically active substances that have a water contact angle (θ) such that cos θ is between +0.9848 and -0.9848 presented as a matrix tablet containing the said pharmaceutically active substances, with/without suitable pharmaceutical excipients in intimate mixture with two groups of intelligent polymers having opposing wettability characteristics, one demonstrating a stronger tendency towards hydrophobicity and the other a stronger tendency towards hydrophilicity, the polymer combination being between the ratios of 1:50 and 50:1 amounts effective to control the release of said pharmaceutically active substances in a mathematically predictable manner, wherein the polymer demonstrating a stronger tendency towards hydrophobicity is not less than 5 % wt/wt and preferably between 5-70 % wt/wt of the final formulation composition. The intelligent polymers being ethylcellulose (EC) as a more strongly hydrophobic and hydroxyethylcellulose (HEC) and/or hydroxypropyl methylcellulose (HPMC) as more strongly hydrophilic (the ratio of HEC to HPMC being between 1:100 and 100:1). The matrix tablet is optionally coated with an enteric coat, 0-5% - 15%wt/wt to prevent the initial burst effect seen in such systems and to impart gastrointestinal tract (GIT) "stealth" characteristics especially in the presence of food.

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