(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 July 2003 (03.07.2003)

PCT

(10) International Publication Number
WO 03/053416 A1

(51) International Patent Classification[7]: A61K 9/20, 31/7052

(21) International Application Number: PCT/IB02/05222

(22) International Filing Date: 9 December 2002 (09.12.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/343,480 21 December 2001 (21.12.2001) US

(71) Applicant *(for all designated States except US)*: **PFIZER PRODUCTS INC.** [US/US]; Easter Point Road, Groton, CT 06340 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MURPHY, Brendn, John** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **COLLIER, Steven, William** [US/US]; 189 3rd Street #411, Oakland, CA 94607 (US). **QUAN, Ernest, Shing** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **JOHNSON, Barbara, Alice** [US/US]; Pfizer Global Research and Development, Estern Point Road, Groton, CT 06340 (US).

(74) Agents: **LUMB, J., Trevor** et al.; Pfizer Inc., 201 Tabor Road, Morris Plains, NJ 07950 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/053416 A1

(54) Title: DIRECTLY COMPRESSIBLE FORMULATIONS OF AZITHROMYCIN

(57) Abstract: The present invention relates to a dry blend, used for forming azithromycin tablets by direct compression, comprising non-dihydrate azithromycin and at least one pharmaceutically acceptable excipient. This invention also relates to an azithromycin tablet comprising non-dihydrate azithromycin and at least one pharmaceutically acceptable excipient. Preferably, the azithromycin tablet is formed by direct compressing the dry blend, of the present invention, to form said azithromycin tablet. Preferably, the azithromycin tablet, of the present invention, contains a dosage of 250 mgA, 500 mgA or 600 mgA of azithromycin. This invention further relates to an azithromycin tablet which is produced by forming a dry blend of a non-granulated azithromycin form A and at least one pharmaceutically acceptable excipient. The azithromycin tablet is then formed by formed by direct compressing the dry blend.