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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 July 2007 (19.07.2007)

PCT

(10) International Publication Number
WO 2007/080601 A1

(51) International Patent Classification:
A61K 9/28 (2006.01) *A61K 31/44* (2006.01)

(21) International Application Number:
PCT/IN2006/000463

(22) International Filing Date:
20 November 2006 (20.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
114/DEL/2006 16 January 2006 (16.01.2006) IN

(71) Applicant *(for all designated States except US)*: **JUBILANT ORGANOSYS LIMITED** [IN/IN]; Plot 1A, Sector 16A, Noida 201 301, Uttar Pradesh (IN).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **GHOSH, Pradip** [IN/IN]; Village & P.O. - Panchgeria, District - Midnapur (West), Pin 721 156, West Bengal (IN). **MUKHERJI, Gour** [IN/IN]; E-12/31, Phase I, DLF Qutab Enclave, Gurgaon122 002, Haryana (IN).

(74) Agents: **NAIR, Manoj, V.** et al.; M/s. Lex Orbis, Intellectual Property Practice, 709/710, Tolstoy House, 15-17, Tolstoy Marg, New Delhi 110 001 (IN).

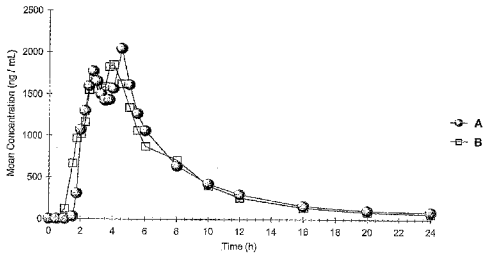
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:
— *with international search report*
— *with amended claims*

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.

(54) **Title:** STABLE PHARMACEUTICAL FORMULATION OF AN ACID LABILE COMPOUND AND PROCESS FOR PREPARING THE SAME



A --Reference "Zurcale" tablet

B – Test tablet of example 1

Linear plot of mean plasma concentration of pantoprazole versus time curves after administration of reference "Zurcale" tablet and test pantoprazole tablet of example 1 to healthy, adult, human male subjects under fasting conditions.

(57) **Abstract:** The disclosed invention provides oral pharmaceutical formulations of an acid labile benzimidazole derivative comprising (a) a core comprising an acid labile benzimidazole derivative, (b) a seal coating layer, and (c) an enteric coating layer, wherein the core of the composition is devoid of any disintegrant.

WO 2007/080601 A1