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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 August 2006 (03.08.2006)

PCT

(10) International Publication Number
WO 2006/080029 A1

(51) International Patent Classification:
A61K 31/4015 (2006.01) *A61K 9/30* (2006.01)

(21) International Application Number:
PCT/IN2005/000275

(22) International Filing Date: 12 August 2005 (12.08.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
81/MUM/2005 27 January 2005 (27.01.2005) IN

(71) Applicant *(for all designated States except US)*: **ALEMBIC LIMITED** [IN/IN]; Alembic Campus, Alembic Road, Gujarat, Vadodara 390 003 (IN).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **KSHIRSAGAR, Rajesh** [IN/IN]; Alembic Limited, Alembic Campus, Alembic Road, Gujarat, Vadodara 390 003 (IN). **JOSHI, Mayank** [IN/IN]; Alembic Limited, Alembic Campus, Alembic Road, Gujarat, Vadodara 390 003 (IN). **RAICHANDANI, Yogesh** [IN/IN]; Alembic Limited, Alembic Campus, Alembic Road, Gujarat, Vadodara 390 003 (IN).

(74) Agents: **MAJUMDAR, Subhatosh** et al.; S. Majumdar & Co., 5, Harish Mukherjee Road, Calcutta 700 025 (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, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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).

Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
— *of inventorship (Rule 4.17(iv))*

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.

(54) **Title:** EXTENDED RELEASE FORMULATION OF LEVETIRACETAM

(57) **Abstract:** An extended release pharmaceutical composition of Levetiracetam with once a day dosage regime and the process of preparing it. The extended release tablet of Levetiracetam with the core comprising of Levetiracetam and water dispersible rate controlling polymer, and the tablet core optionally functional coated comprising a combination of water non-dispersible and/or water dispersible polymer. It provides extended therapeutically effective plasma levels over a twenty four hour period with diminished incidences of neuropsychiatric adverse events by eliminating the troughs and peaks of drug concentration in a patients blood plasma, which comprises administering orally to a patient in need thereof, an extended release tablet that provides a peak blood plasma level of Levetiracetam in from about eight to about Sixteen hours. The core is prepared by Wet granulation, Dry granulation or Direct compression and optionally the tablet core is coated either in a coating pan or in a Fluidized bed system.

WO 2006/080029 A1