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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 June 2012 (07.06.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/075455 A3

(51) International Patent Classification:
A61K 9/14 (2006.01)

(21) International Application Number:
PCT/US2011/063172

(22) International Filing Date:
2 December 2011 (02.12.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/419,114 2 December 2010 (02.12.2010) US

(71) Applicant *(for all designated States except US)*: **APTALIS PHARMATECH, INC.** [US/US]; 845 Center Drive, Vandalia, Ohio 45377 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **VENKATESH, Gopi M.** [US/US]; 780 Waldsmith Way, Vandalia, Ohio 45377 (US). **SWAMINATHAN, Vijaya** [IN/US]; 2727 Monterey Circle, Apt. B, Beavercreek, Ohio 45431 (US). **LAI, Jin-Wang** [US/US]; 149 Harbor Drive, Springboro, Ohio 45066 (US). **CLEVENGER, James M.** [US/US]; 1866 Old Springfield Rd., Vandalia, Ohio 45377 (US).

(74) Agents: **TUSCAN, Michael S.** et al.; Cooley LLP, 777 6th Street, NW, Suite 1100, Washington, District of Columbia 20001 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, 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, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(88) Date of publication of the international search report:
27 June 2013

(54) Title: RAPIDLY DISPERSING GRANULES, ORALLY DISINTEGRATING TABLETS AND METHODS

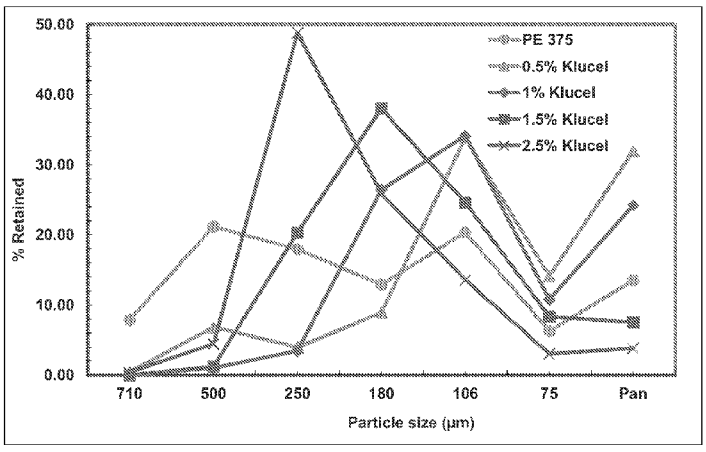


FIG. 1

(57) Abstract: This invention relates to rapidly dispersing microgranules comprising at least one sugar alcohol or saccharide, at least one super disintegrant, and a pharmaceutically acceptable additive with multi-functionality (e.g., starch acting as a binder, disintegrant, diluent/filler, glidant, etc) at a low level, which can be formed by not only eliminating a wet milling step but also avoiding an extensive dry milling step. Furthermore, such rapidly dispersing microgranules could also comprise a pharmaceutically active agent thereby providing for a pharmaceutical composition, or the rapidly dispersing microgranules thus produced are suitable for blending with a pharmaceutically active agent that is optionally taste-masked and/or controlled release coated microparticles to also provide for a pharmaceutical composition and the invention is also directed to a method for manufacturing such rapidly dispersing microgranules in a high useable yield, as well as orally disintegrating tablets comprising such rapidly dispersing microgranules. The rapidly dispersing microgranules are also free flowing.

WO 2012/075455 A3