

(12) International Application Status Report

Received at International Bureau: 03 September 2017 (03.09.2017)

Information valid as of: 07 November 2018 (07.11.2018)

Report generated on: 17 September 2019 (17.09.2019)

(10) Publication number:

WO2018/039318

(43) Publication date:

01 March 2018 (01.03.2018)

(26) Publication language:

English (EN)

(21) Application Number:

PCT/US2017/048174

(22) Filing Date:

23 August 2017 (23.08.2017)

(25) Filing language:

English (EN)

(31) Priority number(s):

62/380,229 (US)

(31) Priority date(s):

26 August 2016 (26.08.2016)

(31) Priority status:

Priority document received (in compliance with PCT Rule 17.1)

(51) International Patent Classification:

A61K 9/14 (2006.01); **A61K 38/48** (2006.01); **A61K 9/16** (2006.01); **A61K 9/00** (2006.01); **A61K 47/34** (2017.01); **A61K 47/36** (2006.01); **A61K 9/113** (2006.01)

(71) Applicant(s):

AKINA, INC. [US/US]; 3495 Kent Avenue, Suite O 100 West Lafayette, IN 47906-1385 (US) *(for all designated states)*

(72) Inventor(s):

PARK, Kinam; 3525 Wakefield Drive West Lafayette, IN 47906 (US)

YUN, Yeonhee; 3338 Cardigan Court West Lafayette, IN 47906 (US)

SKIDMORE, Sarah Michelle; 4674 Glastonbury Way Lafayette, IN 47909 (US)

LEE, Byung Kook; 3338 Cardigan Court West Lafayette, IN 47906 (US)

GARNER, John Solomon; 809 Avondale Street West Lafayette, IN 47906 (US)

(74) Agent(s):

PABST, Patrea L.; Pabst Patent Group LLP 1545 Peachtree Street, N.E. Suite 320 Atlanta, GA 30309 (US)

(54) Title (EN): BIODEGRADABLE POLYMER FORMULATIONS FOR EXTENDED EFFICACY OF BOTULINUM TOXIN

(54) Title (FR): FORMULATIONS DE POLYMÈRE BIODÉGRADABLE POUR PROLONGER L'EFFICACITÉ DE LA TOXINE BOTULIQUE.

(57) Abstract:

(EN): Methods for the formulation of biodegradable microparticles for delivery of protein drugs, such as botulinum toxin, have been developed. The methods include the steps of precipitating and washing proteins with organic solvent to remove water prior to dispersing in polymer-dissolved organic solvent to prevent exposure to water/solvent interfaces and maintain bioactivity of the protein drugs and fabrication of microparticles by either template or emulsion method. Biodegradable microparticles, formed of one or more biodegradable polymers having entrapped in the polymer one or more protein agents, such as botulinum toxin, are also provided. Precipitated botulinum toxin and botulinum toxin-loaded microparticles can also be formulated into thermogels or crosslinked hydrogels. The stability of the protein within these microparticles, as well as the controlled release of the entrapped agents, provides for sustained efficacy of the agents.

(FR): Des procédés ont été développés pour la formulation de microparticules biodégradables pour l'administration de médicaments protéiques, tels que la toxine botulique. Les procédés comprennent les étapes consistant à précipiter et à laver des protéines avec un solvant organique, pour éliminer l'eau, avant la dispersion dans un solvant organique, dissous dans un polymère, pour empêcher l'exposition aux interfaces eau/solvant et maintenir la bioactivité des médicaments protéiques et la fabrication de microparticules par un procédé de matrice ou d'émulsion. L'invention concerne également des microparticules biodégradables, formées d'un ou de plusieurs polymères biodégradables ayant piégé dans le polymère un ou plusieurs agents protéiques, tels que la toxine botulique. La toxine botulique précipitée, et les microparticules chargées en toxine botulique, peuvent également être formulées en thermogels ou en hydrogels réticulés. La stabilité de la protéine dans ces microparticules, ainsi que la libération contrôlée des agents piégés, permet une efficacité prolongée des agents.

International search report:

Received at International Bureau: 11 December 2017 (11.12.2017) [EP]

International Report on Patentability (IPRP) Chapter II of the PCT:

Chapter II demand received: 26 June 2018 (26.06.2018)

(81) Designated States:

AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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

European Patent Office (EPO) : 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

African Intellectual Property Organization (OAPI) : BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG

African Regional Intellectual Property Organization (ARIPO) : BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW

Eurasian Patent Organization (EAPO) : AM, AZ, BY, KG, KZ, RU, TJ, TM

Declarations:

Declaration made as applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate

Declaration made as applicant's entitlement, as at the international filing date, to claim the priority of the earlier application, where the applicant is not the applicant who filed the earlier application or where the applicant's name has changed since the filing of the earlier application (Rules 4.17(iii) and 51bis.1(a)(iii))