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(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.

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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))