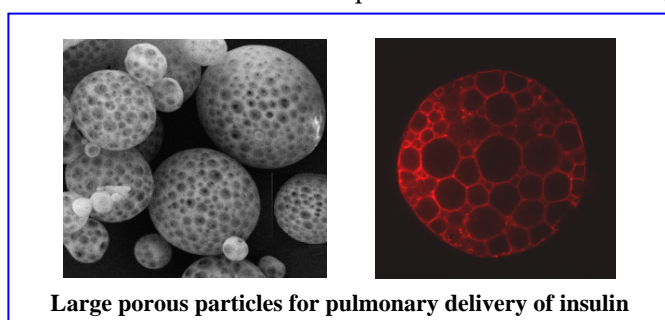


Biodegradable microparticulate systems for the controlled release of protein therapeutics and nucleic acids

Prof.ssa Maria Immacolata La Rotonda – University of Napoli Federico II – Consorzio TEFARCO Innova

The research group of Pharmaceutical Technology at the University of Naples has been studying microparticulate systems for the controlled release of proteins and nucleic acids. The carriers, made of biodegradable polymers, allow to protect the drug toward in vivo degradation, thus prolonging its pharmacological activity. The technological and analytical expertises of the group may support industrial partners or research institutes interested in the development of new biotechnological therapeutics.



1. Description of the product

The technology concerns the design and development of biodegradable microspheres for the controlled release of proteins and nucleic acids. One of the major issues in the microencapsulation of macromolecules is the preservation of their chemical and structural integrity during microsphere preparation and release phase. Proteins are microencapsulated in bioactive form optimizing formulation conditions in terms of encapsulation technique (i.e. emulsion or spray-drying) and additives used. Respirable microspheres for drug pulmonary delivery were prepared by using cyclodextrins in the formulation. Finally, the technology has been effectively applied to the microencapsulation of insulin, growth factors and single or double stranded oligonucleotides, for antisense or decoy strategy, respectively.

2. Innovative aspect of the product

Even if biodegradable microspheres for the delivery of proteins and nucleic acids have been widely studied, to date the number of medicines based on this technology is very limited. The main drawbacks to the development of these drug delivery systems are to microencapsulate the macromolecule in its native form and to set up simple analytical procedures for their characterization. On this matter, the developed technology seems versatile, taking into account the number of polymeric platforms and the strategies available to stabilize the incorporated drug. The potential of the technology in the pharmaceutical field is high considering not only its limited application in commercialized therapeutics, but also that many new therapeutically-active biotechnological products cannot be employed due to the lack of specific carriers. It is worth of note that cyclodextrin-containing large porous particles for pulmonary delivery may also help in promoting patient compliance, replacing multiple parenteral administration of the drug.

3. Main advantages of the offer

The main advantages of protein-loaded biodegradable microspheres include:

- full protection of the active ingredient toward chemical and enzymatic degradation and its sustained release;
- increased protein half-life;
- biocompatibility and biodegradability of the employed systems.

Microspheres may be also directly injected at the site of action or administered through non-invasive routes (e.g. pulmonary delivery). Finally, biodegradable microspheres for nucleic acid delivery allow a full improvement of oligonucleotide pharmacological effect avoiding risks related to the use of viral vectors.

4. Technology key words

Microspheres, biodegradable polymers, proteins, nucleic acids, growth factors

5. Current Stage of Development

Development phase – laboratory tested

6. Intellectual Property Rights

Partnership/other contractual agreements

Technical and scientific publications

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CONTACT

info@biopharmanet.eu

Tel.: +39 0521 905073 Fax: +39 0521 905006