

Protein nano- or microparticles as artificial inclusion bodies

Market sector:

nanomedicine, biotechnology

Type of opportunity:

licensing and/ or co-development

Patient need addressed:

Treatment of cancer, and any other pathology requiring intracellular or extracellular protein delivery

Competitive advantages:

First protein microparticles resembling natural IBs, and avoiding the problematic features existing in natural IBs. They can be used as actives in pharmaceutical compositions, for oral and transdermal or transmucosal delivery, and as subcutaneous implants. Also, they can be used as actives in cosmetic compositions

Scope of the problem

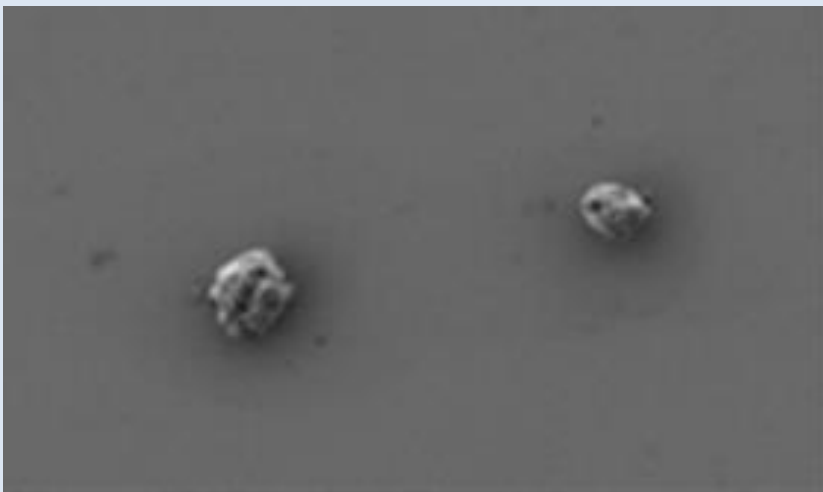
Bacterial inclusion bodies (IBs) are mechanically stable, insoluble, discrete, and particulate proteinaceous materials produced in recombinant bacteria, with particle sizes ranging from 50 to 1500 nm, and with shapes including cylindrical, amorphous, spherical or ellipsoid. They contain one or few functional protein species (together with other possible components) that can be released intracellularly or extracellularly under physiological conditions, mimicking the functioning of the hormone-releasing human endocrine system.

IBs are mechanically stable functional materials that are nontoxic when exposed to cells or to living beings, through oral administration or injection. Because of the combination of mechanical stability and functionality, IBs are then explored as self-immobilized catalysts, showing promises in biotechnological industries and applications. As catalysts, IBs do not pose any regulatory issues and are highly convenient. However, clinical applicability of IBs is not exempt of drawbacks. They contain irremovable bacterial components at variable composition incompatible with a drug formulation. Moreover, due to the cell factory base, IBs carry on with several homogeneity issues between manufacturing batches.

For all these reasons, the provision of alternative structures for delivering proteins of clinical value (hormones, enzymes, etc.) in cells or organs is needed, but the maintenance of the beneficial features of IBs is also a desired. In particular, their high penetration to cells, the mechanic stability and the depot/protein release functions.

Our innovation:

- Development of a new drug-delivery system comprising protein microparticles that mimic the protein release features of IBs (inclusion bodies) and human hormone secretory system
- These innovative artificial IBs have a slow release profile of any embedded protein at physiological conditions
- The artificial IBs have been prepared in vitro (cell-free engineered) without the presence of bacterial cells, thus in a fully synthetic mode
- These protein nano- or microparticles penetrate into cells, thus they can be used as a protein delivery system



Market size/ opportunity: Global nanomedicine market expected to reach \$261,063 Million by 2023 (Allied Market Research, Nov. 2, 2017).

Global Protein Therapeutics Devices Market is poised to grow at a CAGR of around 8.6% over the next decade to reach approximately \$315.90 billion by 2025 (Protein Therapeutics Market Analysis and Trends - Therapeutic Proteins, Application, Function - Forecast to 2025).

Intellectual property

European patent application (Priority date: October 17, 2019)

Suitable for International extension (PCT application)