Pharmaceutical composition for bone implantation, method for its preparation and use in the manufacturing of implants for bone tissue treatment.

Product description

Albeit somewhat underappreciated by the media, skeletal disorders such as osteoporosis, osteomyelitis, and bone tumors pose a serious problem to the health care system. In 2000, a total of about 9 million osteoporotic bone fractures were reported, and the incidence of osteomyelitis has increased by a factor of three over the last 40 years. Necrotic bone lesions caused by progressive bacterial infection are detectable in X-ray studies only after about 50–75% of total bone matrix has been destroyed.

In clinical practice, chronic osteomyelitis due to bacterial infections or primary bone tumors are treated by surgical procedures with simultaneous antibiotic therapy and/or chemotherapy. In order to produce the desired therapeutic effect, such a treatment often requires the use of high doses of medicinal substances which significantly increases the risk of adverse reactions and generates additional costs for the healthcare systems.

Therefore, attention is being increasingly paid to modern treatments involving the delivery of medicinal substances directly to the bone tissue e.g. by means of implantable delivery systems. In this strategy, the implant should perform a dual function including (1) that of a modified (extended) release carrier, and (2) that of a bone replacement material for regeneration of disease-related bone losses. The objective of the treatment is to maintain prolonged availability of therapeutic levels of the medicinal substance at the affected site while reducing the toxic effects of that substance on other tissues and simultaneously promoting natural bone reconstruction processes. Therefore, the development and verification of such ideal systems for local delivery of medicinal substances in implantable forms is at the center of focus for many research centers and manufacturers of bone replacement implants.

The proposed composition facilitates the possibility of innovative delivery systems for the medicinal substance being developed in the form of pellets or tablets to act as dual-function bone implants (i.e. Implants presenting with the delivery function as well as the bone regeneration function) using small quantities of excipients and widely known formulation technologies used in the production of solid drugs (pelleting, tableting). The solution consisting in appropriate composition of such a formulation can be universally used in the manufacture of various solid drug forms. Implantable pellets/tablets manufactured on the basis of this composition present with satisfactory mechanical properties (e.g. hardness, abrasion).

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Key words

Bioglass, mesoporus silica (MCM-41, SBA-15); hydroxyapatite; pellets (granules), composites, bone drug delivery systems, regenerative medicine

Legal status of the product

Patent Office of the Republic of Poland, patent application "*Pharmaceutical composition for bone implantation, method for its preparation and use in the manufacturing of implants for bone tissue treatment*", 2020

Application No.: P.434120

Patentee:

Medical University of Gdańsk

Subject of the offer

The invention relates to a novel pharmaceutical composition and a method for its preparation from mesoporous silicate material with medicinal substance adsorbed thereto and gel-derived powder with high mineralization potential for the production of solid drug formulations for potential use in the treatment and regeneration of bone tissue.

Financing of the product research so far

The project has been financed in part from the OPUS 15 grant program of the National Science Center (grant no. OPUS 15 2018 29/B/NZ7/00533)

Competitive analysis

Methods for preparation of implantable systems for the delivery of antibiotics to bone infection sites are known in the art. The systems consist of poly(methyl methacrylate) (PMMA) and gentamycin granules (SEPTOPAL™).

A certain limitation to the general applicability of PMMA as a carrier for medicinal substances consists in the exothermic nature of its polymerization potentially leading to thermal decomposition of heat-sensitive substances introduced to the composition at the PMMA polymerization stage. Another limitation consists in PMMA's inability to integrate with bone tissue; as the result, the delivery system has to be removed after the therapeutic function of the product has been achieved.

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Another available product acting and a bone replacement material consists of bioglass granules only and contains no medicinal substances.

Advantages of the proposed product

The proposed composition facilitates preparation of innovative, dual-component delivery systems for medicinal products in the form of implantable tablets or pellets. The invention focuses on increasing the efficiency, safety and efficacy of bone tissue therapy. The target customer base consists of biomedical and/or pharmaceutical companies, surgery and orthopedics clinics, dental clinics, or veterinary clinics.

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