PARENTERAL COMPOSITION OF CASIOPEINE AND ITS USES

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Abstract

Here it is described for the very first time a stable composition in aqueous solution that includes a metallopharmaceutical compound (called Casiopein) and which can be used in the Oncology medicines manufacture. The composition is formulated with this metallopharmaceutical compound and some stabilizing agents, which allows its I.V. administration.

Background

In Mexico and all around the world, oncologic diseases are a highly relevant public health issue. According to data from the WHO, the 14 million cases of cancer detected in 2012 could increase in 70% in the next two decades.

There have been innumerable efforts in the research of new antineoplastic molecules and the development of new therapies that increase the patient's life time. Nevertheless, and despite the use of chemotherapy for cancer treatment, many of the tumors are completely refractory to the chemotherapy. This situation has stimulated the design, synthesis and evaluation of new compounds with low toxicity and different biologic properties. Cisplatin has been used to address the problem. Unfortunately, this compound has a high nephrotoxicity. Recently, the carboplatin has solved some of the toxicity issues of the cisplatin, but the price of these drugs is too high to be considered as part of a generalized therapy for the affected populations.

These aspects have been considered in the design of the casiopeins.

Description

Casiopeins are chelates, with metallic nucleus (Cooper), which have shown antineoplastic activity. The Casiopeins have covered the in vitro activity requirements as well as in animal models of isotrasplatation and heterotransplatation, showing comparable and higher activities to those seen with cisplatin. At the same time, researchers have obtained data about: apoptosis induction, action mechanism, Activity-Structure correlation, and they have started Phase I of clinical trials.

One of the advantages of the formulated Casiopein is that it was designed to specifically attack the tumors, which reduces healthy cells damage.

There were no formulations or compositions with a proved stability in aqueous medium that included any compound from the Casiopein family as active principle, that allowed the I.V. administration in cancer patients. Here, it is described this formulation.

Stage of research

According to the Technologic Maturation Classification Guideline this development is in the 5th level. The Casiopeins are known since several years ago and they're well characterized. This development has already been formulated, and it has been subjected to characterization and evaluation of its stability for I.V. administration, and currently Phase I clinical trials are being performed to assess the security and pharmacokinetics in healthy volunteers.

Applications fields and advantages

Until now it has not been reported nor suggested a composition in aqueous solution for the parenteral administration of Casiopeins for medicines used in treatment and/or prophylaxis of patients with cancer. This development includes a metallopharmaceutical compound (Casiopein) which integrate pharmacokinetics parameters and stability for the elaboration of a parenteral solution for intravenous administration in oncologic patients in need thereof. The cancer could be malignant glioma, leukemia, cervical cancer, breast cancer, colon cancer and neuroblastomas in humans.