[P-25]

Acute and subacute toxicity studies of GX-12, a DNA vaccine for the treatment of HIV infection, in SD rats.

Seul Min Choi, Kyung Koo Kang, Yong Sung Sohn, Mi Ju Kim, Dae Hyun Baik, Byung Ok Ahn and Won Bae Kim

Research Laboratories, Dong-A Pharm. Co. Ltd.

The toxicity of GX-12, a naked DNA vaccine developed by research team of Dong-A Pharmaceutical Company, Green Cross Company and Genexine for the treatment of HIV infection, was investigated in Sprague-Dawley rats. In single-dose intramuscular/oral acute toxicity studies, animals were treated 0, 250, 1000 or 4000 μ g/kg/ml in sodium phosphate buffer. During the experimental period, no abnormality in mortality, clinical findings, body weight changes related to treatment of the test article was found. In serum chemistry and hematological examination, there were no changes in all parameters in rats treated with GX-12. Based on these results, the minimal lethal dose level of GX-12 was estimated to be more than 4000 mg/kg. For the subacute toxicity study, GX-12 was treated intramuscularly once a week to the both male and female rats at dose levels of 0, 250, 1000 or 4000 μ g/kg/ml for thirteen weeks. During the experimental period, there were no dead animal, notable clinical signs, treatment related changes in body weight, food and water consumptions. In the ophthalmic examination, urinalysis, hematology, and serum chemistry, no treatment related changes were observed. In addition, test article induced gross findings, organ weight changes, and histological changes were not observed. Therefore, the NOAEL (No-Observed-Adverse-Effect-Level) for GX-12 in rats was estimated to be more than 4000 μ g/kg under the present test system.

Keyword : GX-12, DNA vaccine, acute/subacute toxicity