Abstract

The AFCo1 cochleate is a potential novel adjuvant derived from Neisseria meningitidis B proteoliposome. The aim of this study was to assess the safety of AFCo1 by repeated doses in Sprague Dawley rats. Rats were grouped for treatment with AFCo1, placebo formulation or control. Four similar doses of the test substance were instilled every five days. Intranasal dose of 100 µL was used, and the body weight, water and food intakes were monitored as well as the clinical symptoms. Rats were sacrificed at 3, 14 and 28 days after the last inoculation and anatomopathological studies were conducted. Clinical observations were carried out for the study and a number of rats from each group were sacrificed 3 and 14 days after the last dose in order to conduct hematological, hemochemical and anatomopathological studies. Clinical symptoms, food and water intakes, and body weight did not show differences of toxicological relevance. The histological changes found were mild and similar in the three groups. AFCo1 is potentially safe by nasal route for human use as evidenced by the absence of local and systemic signs of toxicity in Sprague Dawley rats.

Keywords

Neisseria meningitidis, Sprague Dawley, repeated dose, proteoliposome.