Abstract

The tetanus vaccine vax-TET® is indicated for the prevention of tetanus and it is effective if a complete and adequate immunization scheme is achieved. In order to investigate the toxic potential of this product, a toxicological test at single dose (0.2 ml), by intramuscular route was developed in Sprague Dawley rats using the same substance concentrations suggested by the manufacturer. The animals were daily observed looking for local and systemic symptoms of toxicity. Water and food consumption and body weight were also monitored during the experiment. Two weeks after inoculation, rats were slaughtered and submitted to necropsy studies. No deaths or toxicity symptoms were observed in the animals studied. No differences of toxicological interest were found among experimental groups regarding the variables measured. The anatomic-pathological study showed the presence of granulomatous formations mainly associated to aluminium hydroxide in the formulation. It was concluded that under the study conditions and following the established criteria, this vaccine does not produce any adverse reactions in the animal model used, suggesting a low potential toxicity in humans.

Keywords

Toxicology, single dose, tetanus, toxoid, vaccine, rat, Sprague Dawley.