

Quality control of hyperimmune sera by Neutron Activation Analysis: parametric and k_0 -standardization methods

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The hyperimmune sera are immunological products that contain antibodies used for the treatment of victims of poisonous animals and of patients with diseases caused by toxins of infectious agents, as the causers of the diphtheria, botulism, tetanus. Nowadays, Butantan Institute (São Paulo city, Brazil) take care a demand of production that supplies 80% of the Brazilian market, without counting on it grew number of exportations that carry through of its products. In the case of the hyperimmune sera production several steps are involved: first, horses are immunized with toxins or anatoxins from one or several species (mainly snakes and spiders); in the end of each cycle of immunization the horses are submitted to a bleeding for plasma extraction. The next step is the plasma treatment: it must be treated and purified in order to diminish the possibility of adverse reactions in patients who will receive the hyperimmune sera. This treatment imply in the accomplishment of a series of biological and chemical tests that assure the quality, effectiveness and security of the product.

Considering that only chlorine, sodium and sulfur can be present the final product, in this study two experimental procedure involving Neutron Activation Analysis – k_0 -standardization method and the parametric procedure (using the thermal flux distribution) have been applied to check concentrations of chlorine and sodium in the final of sera purification. These results must be inside of the limits established for the World health Organization (WHO – OMS) together with the Brazilian Pharmacopeia (Pharmaceutical Code Official of the Country) for its certification and commercialization.