

A simple and rapid quantitative method for determination of aluminum in recombinant hepatitis B vaccine

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Background and Aims: Aluminum (Al) salt-based adjuvants have been used for more than 80 years in vaccine production. This kind of adjuvant are present in a large variety of licensed vaccines and their use is widely considered for formulations, decrease in toxicity and increase in solubility in several vaccines such as Diphtheria, pertusis ,tetanus and recombinant hepatitis B vaccine. In addition, vaccines with adjuvants can induce longer and better immune response when compared with similar without adjuvant vaccines. However, increase uptake in Aluminum vaccine adjutants have been linked to a variety of serious autoimmune and inflammatory conditions. Chromogenic procedures for the determination of aluminium would be of limited value in production control; they are long and tedious and require an experienced analyst to obtain accurate results.

Objective: The aims of the present study were to find new simple, rapid and accurate method for measurement of AL salts in recombinant hepatitis B vaccine. Pulse polarography has been applied to the measurement of aluminum in Hepatitis B Vaccine. The validation, sensitivity, selectivity and reproducibility of the method are described by using several dilutions.

Methods: In order to find the optimum temperature, and PH, several dilutions have been used and rate of sweeping potential checked in parallel with tests.

Results: our results showed that the optimum temperature is 60 C° and the optimum PH is 4.5 with potentials limits of -0.25 to 0.1.

Conclusions: The finding of present study showed that pulse polarography method is the simple, accurate and rapid method for determination of aluminum salt-based adjuvant in recombinant hepatitis B vaccine when compared with chromogenic methods.

Keywords: Aluminum adjuvants; Hepatitis B vaccine; Polarography