VAC_22 - Maintenance of the stability of the trivalent influenza vaccine produced in Brazil

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Introduction: Vaccines has an important role in society, and this importance becomes even more visible when there is a pandemic situation, such as the recent COVID-19 and swine flu (caused by the H1N1 influenza virus). The trivalent vaccine for influenza is produced with subtypes H1N1, B, H3N2, and the equivalent strains of each type is updated annually as recommended by the World Health Organization (WHO). Once, the recommended strains were A/Michigan, B/Maryland and A/Switzerland respectively. The safety of these vaccines is extremely important, from the production until the end of the validity period, therefore, it is important to quantify the surface glycoprotein hemagglutinin (HA) for each strain of the vaccine throughout the entire period of validity, which is one year.

Objectives: Perform radial immunodiffusion tests to quantify the hemagglutinin content in the trivalent influenza vaccine to monitor the stability of the three strains for 12 months.

Methodology: Trivalent influenza vaccine samples, corresponding to the 3, 6, 9 and 12 months of the long-term stability study and the 3 and 6 months of the accelerated stability study, were tested using the simple radial immunodiffusion method. This method was performed by preparing agarose gels at a ratio of 1% (w/v) with buffered saline solution, where specific sera of each antigen were added to this agarose and after this applied to the samples. The halos had measured, after the end of diffusion, to quantify the hemagglutinin content of each strain in the vaccine. The results obtained were compared with the results of the previous stage of the study.

Results: The results show that during the 12 months of the long-term stability study, which is the same period of the shelf life for the end product, as well as the 06 months of the accelerated stability study, the hemagglutinin values remained stable, not varying more than 20%, percentage considered valid for biological methods. This was observed for all strains used in the production of the vaccine. In this case A/Michigan, B/Maryland and A/Switzerland.

Conclusion: Stability was effective for long-term stability, with storage at the correct temperature and the same was also observed in accelerated stability, which the storage condition was at a higher temperature than recommended. None of the three strains had high variation during the studies.

Keywords: Vaccine; Stability; Influenza