

VAC_20 - Virucidal activity evaluation of hydrogen peroxide wipes against the AZD1222-chimpanzee adenovirus in active pharmaceutical ingredient and the recombinant COVID-19 vaccine

Vinícius Pessanha Rhodes¹; Ana Carolina Ferreira Ballestê Ajourio¹; Anderson Peclat Rodrigues¹; Luciana Veloso da Costa¹; Rebeca Vitória da Silva Lage de Miranda¹; Igor Barbosa da Silva¹; Marcelo Luiz Lima Brandão¹.

¹Fiocruz/Bio-Manguinhos.

Introduction: Viral contaminations in cell culture-based biotech manufacturing can result in substantial plant downtimes, financial losses, and in delay in delivery of life-saving products. For an effective risk mitigation strategy preventive measures, including disinfection of surfaces, should be validated. Disinfectants with based on hydrogen peroxide have been used due to their practicality and non-residue generation. However, the effectiveness of these products on surfaces must be previously evaluated in different surfaces, including the presence of the matrix.

Objective: This study aimed to evaluate the virucidal activity of a disinfectant product based on hydrogen peroxide present in soaked wipes against chimpanzee adenovirus AZD1222 vaccine strain used in the production of recombinant COVID-19 vaccine for application in cleaning validation in a pharmaceutical industry.

Methodology: Two matrixes were tested: formulated recombinant COVID-19 vaccine (FCV) and active pharmaceutical ingredient (API) in two different surface carries: stainless steel (2 cm diameter discs) and low-density-polyethylene (LDP) (3 cm² squares); based on the methodology described on standard NF-T-72-281:2014. The FCV and API samples were inoculated on the carriers, dried on and disinfected with the wipe for 5 min. Non-disinfected carriers were used to determine the initial inoculum. Non-inoculated disinfected carries were used for the evaluation of the inhibitory activity of the disinfectant residue. The titres were determined using the infectious unit (IFU) methodology described by Oxford University/AstraZeneca and implemented in Bio-Manguinhos. A reference material was used to validate the assays.

Results: Absence of inhibition by residual effect was observed. The initial inoculum of FCV was 7.88 and 7.91 log₁₀ IFU on stainless steel and LDP; and of API was 9.21 and 9.20 log₁₀ IFU, respectively. The disinfection procedure resulted in complete virus inactivation in FVC (≥ 7.46 log₁₀ IFU) and API (≥ 8.78 log₁₀ IFU).

Conclusion: In conclusion, wipes soaked with hydrogen peroxide showed efficacy for reducing of AZD1222 chimpanzee adenovirus strain in FVC and API matrixes on stainless steel and LDP surfaces. This procedure is simple and can be applied on safety unit cabins and sampling bags made of LDP.

Keywords: Cleaning validation; Virucidal activity; Hydrogen peroxide