VAC_18 - Establishment of a reference material for potency and identity assays of recombinant COVID-19 vaccine active ingredients, intermediary and final products

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Introduction: The Immunobiological Technology Institute (Bio-Manguinhos) has been producing the recombinant COVID-19 vaccine (RCV) due to a technology transfer (TT) with AstraZeneca and Oxford University. The RCV is a replication-deficient adenoviral vector vaccine that is offered free of charge to the Brazilian population through the National Immunization Program. Two of the specified tests for quality control release of the vaccine are the potency and the identity determination. To perform these assays, a reference vaccine provided by the transfers is used as a reference material (RM) in order to validate the results. After the TT completion, Bio-Manguinhos had to establish its own RM. Therefore, homogeneity and stability studies were carried out to verify the suitability of RM produced by Bio-Manguinhos.

Objective: The aim of this study was to establish a batch of RCV, produced by Bio-Manguinhos, as RM for potency and identity assays.

Methodology: Potency and identity assays were determined using the infectious unit and real-time PCR methodologies, respectively. Twenty vials, randomly selected, were analyzed for homogeneity evaluation according to International Harmonized Protocol. The long-term stability was evaluated at reference temperature (-50 ± 30)°C for 313 days and storage temperature at (5 ± 3)°C for 240 days; and short-term stability at (22.5± 2.5)°C for 14 days.

Results: The batch was sufficiently homogeneous for both parameters. The RM was considered sufficiently stable in all studies realized considering the established identity *C*t value (*C*t<30). Regarding potency assays, the RM was stable at (-50 ± 30)°C for the entire study period, at (5 ± 3)°C for 97 days, and at (22.5± 2.5)°C for 3 days.

Conclusion: It was concluded that the RVC batch can be used as a RM in routine analysis for potency and identity assays when stored at (-50 ± 30)°C and in aliquots stored at (5 ± 3)°C for 97 days, since its established properties were stable during this time period.

Keywords: Reference material; Recombinant COVID-19 vaccine; Quality control