VAC.20 - Reduction of the cycle of lyophilization of the vaccine Attenuated Yellow Fever presentation 02 and 05 doses of Bio-Manguinhos

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Introduction: With the outbreak of Yellow Fever in mid-2017, WHO recommended vaccination in risk areas and other regions of Brazil, made it necessary to increase the vaccine offer at the national level (PNI) and also international, backed by law 13801 -2019 sanctioned by the federal government in January 2019 which increases the Institutional commitment with the supply of vaccines for PAHO and UNICEF (www.fiocruzbrasil.fiocruz.br). Bio-Manguinhos, maintaining an institutional commitment to the supply of vaccines, has articulated to increase its productive capacity without generating additional financial costs as well as to increase the supply of this vaccine through the optimization of its freeze-drying cycle.

Objective: Increase the productive capacity of the Attenuated Yellow Fever Vaccine 02 and 05 doses by obtaining an optimized cycle that ensures the quality of the final product, reducing the processing time of vaccine lots and applying low impact process design or changing regulatory framework.

Methodology: The proposed optimization included preliminary evaluation of the sublimation kinetics of the original cycle and candidate cycles tested using mass reduction methodologies (Mred); pressure test in the chamber (delta P test) and by obtaining residual moisture curves (UR%) by coulometric titration, in the primary and secondary phases. Subsequently, by means of differential scanning calorimetry (DSC) and cryomicroscopy (FDM) analyzes, the critical temperatures were specified and the thermophysical nature of the formulation was evaluated. The limits imposed by these analyzes were obeyed during the elaboration of the optimized cycle, which guarantees the obtainment of a higher quality product.

The work also consisted of the production of vaccine lots 02 and 05 doses, in pilot scale 4000 bottles, and industrial lots, 48000 bottles, making use of the optimized cycle, where the quality parameters were monitored for residual moisture, appearance, potency, stability and solubility.

Results: The results showed the viability of the optimized cycle to reduce the processing time of the vaccine from originally 52 to 40 hours. The final product from the optimized cycle proved to be in accordance with values within the specification ranges for appearance, residual moisture, power, stability and solubility.

Conclusion: The use of the optimized cycle for processing the Yellow Fever vaccine ensures the quality of the final product and enables an increase of up to 63% in annual productivity, being able to reach the production of seven lots per week instead of four lots using the current cycle.

Keywords: Attenuated Yellow Fever; Increase in Productive Capacity; Lyophilization