VAC_21 - Influence of Collapse Temperature on Freeze Drying of an Immunobiological Product: Cryomicroscopy - Overview of the Technique, Results and Applications

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Introduction: Yellow fever is an infectious disease transmitted by arthropod vectors, associated with epidemic outbreaks, notable for its severity and impact on public health. In 2016, a recommendation made by the WHO, aligned with FIOCRUZ's strategic plan, suggested improvements in processes, aiming to meet global demands in order to eliminate epidemic outbreaks (EYE Strategy-2017- 2026). In this context, freeze-drying is the crucial step in the vaccine production process, being critical, with a moderate impact according to RDC073/2016, bringing relevance to the study.

Objectives: This study aims to study critical product parameters, in the freeze-drying of an optimized 2-dose yellow fever vaccine, using the freeze-drying microscopy technique -FDM. Specific Objective: To study the influence of the collapse temperature on the stability and quality of the product, to guarantee the safety and effectiveness of the vaccine in terms of product quality.

Methodology: The research made use of experimental batches with an Exploratory method and a technological nature, and aimed to guarantee the quality and safety of the new product in comparison with the quality targets of the commercial batch with the use of FDM, a technique for characterizing and establishing critical parameters temperature of the vaccine. The data was analyzed statistically, and determining the critical limits of the product, with a redesign of the freeze-drying cycle bringing better quality to the product and greater stability.

Results: Preliminary results of the experimental batches in comparison with the commercial batch indicated low variability between samples of the optimized 2-dose yellow fever vaccine. The results on the vaccine, after freeze-drying (redesign) using established product temperature limits, were consistent with commercial vaccine quality parameters ((potency 2° to 8° C: 5.1399 PFU/ml(α=0, 07); potency 37° C: 4.6305 PFU/ml(α=0.10); compliant appearance; homogeneity ok; RH% 0.94(α=0.04)), 95% confidence interval showing significance

Conclusion: This study presents an innovative approach, with technological prospecting to optimize the freeze drying of vaccines, with the potential to improve product quality on a global scale and strengthen public health.

Keywords: Attenuated Yellow Fever; FDM; Freeze drying