VAC_20 - Optimization of viral dosing methodology of intermediate and final products of yellow fever vaccine (attenuated) using microdilution in megaplate

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Introduction: The Institute of Immunobiological Technology (Bio-Manguinhos) is responsible for producing vaccines for the Brazilian Health Immunization Program, which includes the attenuated Yellow Fever Vaccine (YFV). One of the requirements for quality control of the YFV is its dosage testing according to the Brazilian Pharmacopoeia. Nowadays Bio-Manguinhos performs viral dosing using serial dilution in tubes, and the optimization of the method is necessary to guarantee faster and more accurate results.

Objectives: This study aimed to optimize the dosing methodology of intermediate and final products of YFV using microdilution in megaplate using electronic micropipettes.

Methodology: The use of microdilution in megaplate was compared with the classical dilution in tubes (routine method). Three lots were analyzed by three different technicians. The analysis of one reference material was realized in each test to validate the results. Statistical analysis was performed to evaluate the differences between the two methods.

Results: The comparative tests of the equality of results obtained in the analysis of the reference material demonstrated that the two methodologies were equivalent. The test validation parameter "intra-batch variation", which must be equal to 0.3 log, was used in the analysis of inter-batch variances through the equivalence test for two samples, demonstrating that the methods were equivalent.

Conclusion: The use of the microdilution megaplate presented using electronic micropipettes was an improvement in the process in terms of test quality, with the use of single-use materials and filter tips, in addition to reducing consumable items when carrying out the test; possible reduction in invalid tests without a defined root cause, due to residue problems in the glassware; and reduction in dilution time and repetitive movements, in addition to improving employee ergonomics.

Keywords: Potency; Microdilution; Yellow fever vaccine