VAC_15 - Development of an HPLC method for the determination of sorbitol and sodium glutamate in the thermostabilizer employed in yellow-fever vaccine

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Introduction: Thermostabilizers offer a viable solution for ensuring the availability and supply chain of the Yellow-Fever Vaccine in regions severely affected by this disease, where maintaining the Cold Chain is challenging. Quantifying Sorbitol and Sodium Glutamate in the Thermostabilizer used in the yellow fever vaccine is crucial for maintaining its quality, safety and efficiency.

Objectives: Development and validation of a single analytical HPLC method for simultaneous quantication of Sorbitol and Sodium Glutamate, intended for implementation in the Quality Control of yellow fever vaccine.

Methodology: Analysis was performed by an HPLC with isocratic elution of mobile phase 7 mM Calcium Sulfate with pH = 6,0, Shodex Sugar SC1011 column, and Refractive Index Detector. Two standard calibration curves, one for each component, were prepared together by mixing and diluting from standard sorbitol and glutamic acid solutions. Thermostabilizer was provided by Bio-Manguinhos and diluted at the mobile phase. The analytical method validation evaluated selectivity, linearity, accuracy, precision and robustness parameters.

Results: The analytical method is shown to be selective to the analyses with no co-elution of the sorbitol and sodium glutamate and no other peaks with the same retention time. The calibration curve for both standards, sorbitol, and glutamic acid, proved to be linear, with R2 values of 0.9998 and 0.9995, respectively. The results were accurate, with recovery rates between 96-102% for sorbitol and 97%-101% for glutamate. Precision was tested by two analysts on different days, and both analyses were within the acceptable range. It was also evaluated the robustness of the method by varying various parameters, and the results demonstrated that the method is robust, except for the pH of the mobile phase higher than the original, where it was obtained 94% recovery. Overall, validation confirms that this method presents an acceptable and reliable approach for measuring sorbitol and sodium glutamate.

Conclusion: A single analytical HPLC method was developed to quantify Sorbitol and Sodium Glutamate in the Thermostabilizer used in the yellow fever vaccine. The method was validated and shown to be selective, linear, accurate, precise, and robust. It is implemented in the quality control routine.

Keywords: HPLC; Thermostabilizer; Yellow fever vaccine