

**Title :** Cleaning Method Validation and Determination of Residue Method Validation for Glassware and Sampling Equipment (by Ion Selective Electrode Meter)

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## ABSTRACT

In the pharmaceutical industry, cleanliness and product quality are critical aspects that cannot be compromised. However, the company initiated a study to develop a new cleaning method by decreasing the concentration of detergent from 20% to 5%. The proposed cleaning method was then evaluated to ensure its effectiveness in removing residues of the detergent and sodium fluoride, an active ingredient commonly found in manufacturing facilities. Sodium fluoride is one of the least water-soluble substances, making it more likely to remain on equipment surfaces. Through the development of the residue method, it was found that detergent residues can be analyzed using UV-Visible spectrophotometry. The maximum wavelength of the detergent residue was identified at 224 nm, with a limit of detection (LOD) of 2 ppm. Sodium fluoride can be analyzed using an ion-selective electrode. By swabbing fluoride from stainless steel surfaces, the recovery rate was calculated to be 95%. In practice, it is not feasible to entirely eliminate all residues. Therefore, a standard was established, allowing a maximum acceptable residue limit of 10 ppm, which does not impact the quality or safety of new products. The cleaning method was tested under two conditions: during cleaning and after the equipment had dried. A total of 50 equipment samples were randomly tested. The results showed that the residue levels were within acceptable limits, demonstrating that a 5% detergent concentration effectively removes residues. This experiment also achieved a 75% reduction in chemical costs.