

Title : Cleaning Method Validation and Determination of Residue Method Validation for Glassware and Sampling Equipment (by UV-Visible spectrophotometer)

Author : Sirintip Phonprasoet

Student ID : 640510184

Major : Chemistry

Advisor(s) : 1. Associate Professor Dr. Thapanee Sarakonsri

2. Associate Professor Dr. Phumon Sookwong

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ABSTRACT

The establishment and validation of cleaning methods are critical in the pharmaceutical manufacturing industry as they directly impact product quality and consumer safety. **This study aims to define and validate a newly developed cleaning method to reduce the cost of cleaning agents from the current 20% concentration to 5%**, while ensuring its effectiveness in removing residues found within the facility. The residues targeted for this evaluation include cleaning agent residues and fluoride. Testing of water solubility revealed that fluoride has low solubility and is more likely to remain on surfaces. The study identified appropriate analytical methods for detecting these residues. Cleaning agent residues were analyzed using a UV-Visible spectrophotometer, which measures the maximum wavelength shift resulting from the structural transformation of sodium lauryl sulfate in the cleaning agent into micelles. Fluoride residues were analyzed using an ion-selective electrode, which measures fluoride recovery rate of 95%.

According to the acceptance criteria for cleaning processes in the pharmaceutical industry, residue levels must not exceed 10 mg/L to ensure contamination is sufficiently low and does not compromise the quality or safety of new products. Residue analysis was performed on water samples used for rinsing equipment under two conditions: water used immediately after cleaning and water used after drying the equipment. Tests were conducted on laboratory glassware and 50 pieces of sampled equipment. The results indicated that residue levels for both cleaning agents and fluoride were within acceptable limits. This demonstrates that a 5% cleaning agent solution effectively removes residues and reduces the current cleaning agent consumption by 75%, while maintaining compliance with industry standards.

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