STERIS
Life Sciences

ADVANCING THE SCIENCE OF CONTAMINATION CONTROL

Benefits of Pharmaceutical Detergents with Proteinaceous Soils

Pharmaceutical Detergents

STERIS's detergents are engineered for your most difficult cleaning challenges. Unlike commodity chemicals, pharmaceutical detergents employ a combination of cleaning mechanisms to function synergistically:

- Dissolution
- Solvation
- Chelation
- Dispersion
- Surfactancy
- Wetting

This superior blend of cleaning mechanisms allows STERIS's pharmaceutical detergents to perform efficiently and effectively to reduce process wastes, such as:

- Process Time
- Maintenance Expenses
- Water Usage
- Energy Consumption

"Sinner's Circle" relates the dynamic action between time, action, chemistry, and temperature (TACT) during a cleaning cycle.

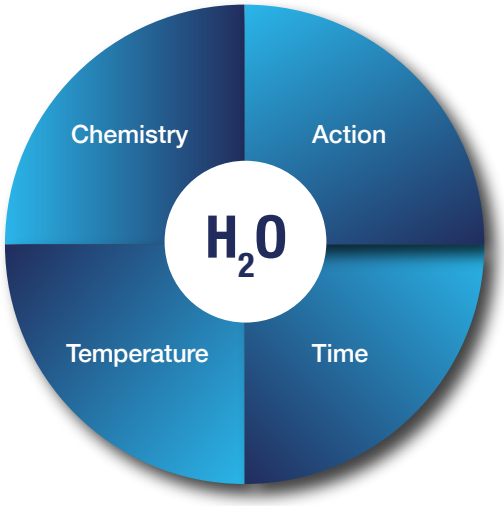

Figure 1 "Sinner's Circle"

When using a pharmaceutical detergent, multiple cleaning mechanisms are used during the cleaning process. A robust cleaning agent can reduce the time, temperature, chemistry concentration, and water required throughout the cleaning cycle. STERIS's pharmaceutical detergents improve process efficiency by helping Customers decrease cleaning and maintenance time while reducing water and energy consumption.

Case Study

During the manufacturing process, cleaning is completed to ensure product quality. The type and amount of cleaning agent used during the cleaning cycle impacts water usage, utility requirements, and cost which contribute to the overall manufacturing process. Using an effective and efficient detergent optimizes the cleaning process to improve operational efficiency and reduce cost, time, and utility wastes.

The purpose of this experiment is to compare the cleaning capabilities of STERIS pharmaceutical detergents and commodity chemicals. A 0.9% phosphate buffer saline (PBS) with bovine serum albumin (BSA) was selected as a common sample soil representative of the biotechnology industry.

Figure 2. Experimental procedure for the comparison of STERIS pharmaceutical detergents and certified grade sodium hydroxide.

This experiment was repeated for each of the following biotechnology industry cleaning agents:

1% v/v CIP 100TM Alkaline Cleaner
1% v/v ProKlenz® ONE Alkaline Cleaner
0.1 N Certified Grade Sodium Hydroxide (NaOH)
0.5 N Certified Grade Sodium Hydroxide (NaOH)

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Experimental Results

Table 1. Pass/Fail based on USP TOC Limit of 500 ppb and USP Conductivity Limit of 2.5 uS/cm.

Cleaner	Visual Inspection	TOC	Conductivity
CIP 100	PASS	PASS 470 ppb	PASS 2.498 uS/cm
ProKlenz ONE	PASS	PASS 420 ppb	PASS 2.470 uS/cm
0.1 N NaOH	FAIL	N/A	N/A
0.5 N NaOH	FAIL	N/A	N/A

Due to a visual failure, the TOC and conductivity samples were not analyzed, noted as not applicable (N/A) in Table 1. Therefore, the experiment was duplicated to double the wash and add a fifth rinse cycle using the cleaning agents that failed visual inspection during the first trial. Again both 0.1 N NaOH and 0.5 N NaOH failed visual inspection.

Water Conservation

An average of approximately 22% overall less water was required to meet the USP TOC and conductivity limits for pharmaceutical detergents compared to NaOH.

Time Savings

ProKlenz ONE detergent and CIP 100 detergent achieved visual cleanliness and met TOC and conductivity limits in 40% less time compared to NaOH.

WHY STERIS?

Sustainable

Pharmaceutical detergents use several cleaning mechanisms to work synergistically, providing more effective cleaning at lower temperature, in less time, and with less water.

Validatable

STERIS products have an extensive documentation package to meet your validation objectives.

Technical Support

Our Formulated Chemistries Technical Services group has the knowledge, the know-how, and the tools to deliver individualized application and validation assistance. The Process And Cleaner Evaluation (PACE®) Program is designed to provide our customers with recommendations for an effective cleaning protocol.

Globally Available

STERIS is a global company providing cleaning solutions for our Customers' sites to ensure harmonization initiatives are met.

Industry Leader

In addition to our years of hands-on experience, STERIS has an extensive documentation library of technical tips, laboratory reports, and analytical methods to support your application development.