



STERIS

Life Sciences

WHITE PAPER

CLEANING PROTEINACEOUS SOILS:
**Pharmaceutical Detergents
vs. Commodity Cleaners**

Introduction

The ability to clean proteinaceous soils is a critical aspect of maintaining pharmaceutical equipment to ensure product quality and safety. Between 2006-2019, the FDA generated more than 3,078 Form 483 citations related to the FDA's Code 21 CFR 211.67 and 21 CFR.182 for [equipment cleaning, maintenance, and use log](#). To avoid FDA-related citations and ensure product quality and safety, it is important to use an effective, validatable cleaning agent in equipment cleaning and maintenance. This white paper takes a closer look at selecting cleaning detergents.

Using Commodity Chemistry For Cleaning And Maintenance

Commodity products, like Sodium Hydroxide (NaOH), are sometimes used in the cleaning process in place of a formulated cleaning detergent. Commodity chemicals may be integrated into the cleaning cycle because they are perceived as less expensive than pharmaceutical detergents. Additionally, these commodity chemicals are used in the manufacturing process, and therefore bulk quantities are conveniently already available on site. However, commodity chemicals only use hydrolysis to clean process residues which frequently result in an inefficient and ineffective cleaning process. This white paper takes a closer look at selecting cleaning detergents to achieve process optimization goals.

“Commodity chemicals only use hydrolysis to clean process residues which frequently result in an inefficient and ineffective cleaning process.”

Pharmaceutical Detergents

Benefits and Tradeoffs

Pharmaceutical detergents are engineered with performance-enhancing components, like surfactants and chelants, to clean tough residues using multiple mechanisms that function synergistically. These mechanisms include:

- | | | |
|---------------|--------------|---------------|
| • Dissolution | • Chelation | • Surfactancy |
| • Solvation | • Dispersion | • Wetting |

This engineered blend of cleaning mechanism allows pharmaceutical detergents to perform efficiently and effectively in cleaning biopharmaceutical residues. This efficiency results in:

- | | |
|------------------------------|----------------------------|
| • Reduced process time | • Less water usage |
| • Lower maintenance expenses | • Lower energy consumption |

Additionally, unlike commodity chemistries, leading pharmaceutical detergents may have EPA claims for disinfection applications.

Detergent Study to Compare a Commodity Chemical And a Formulated Detergent

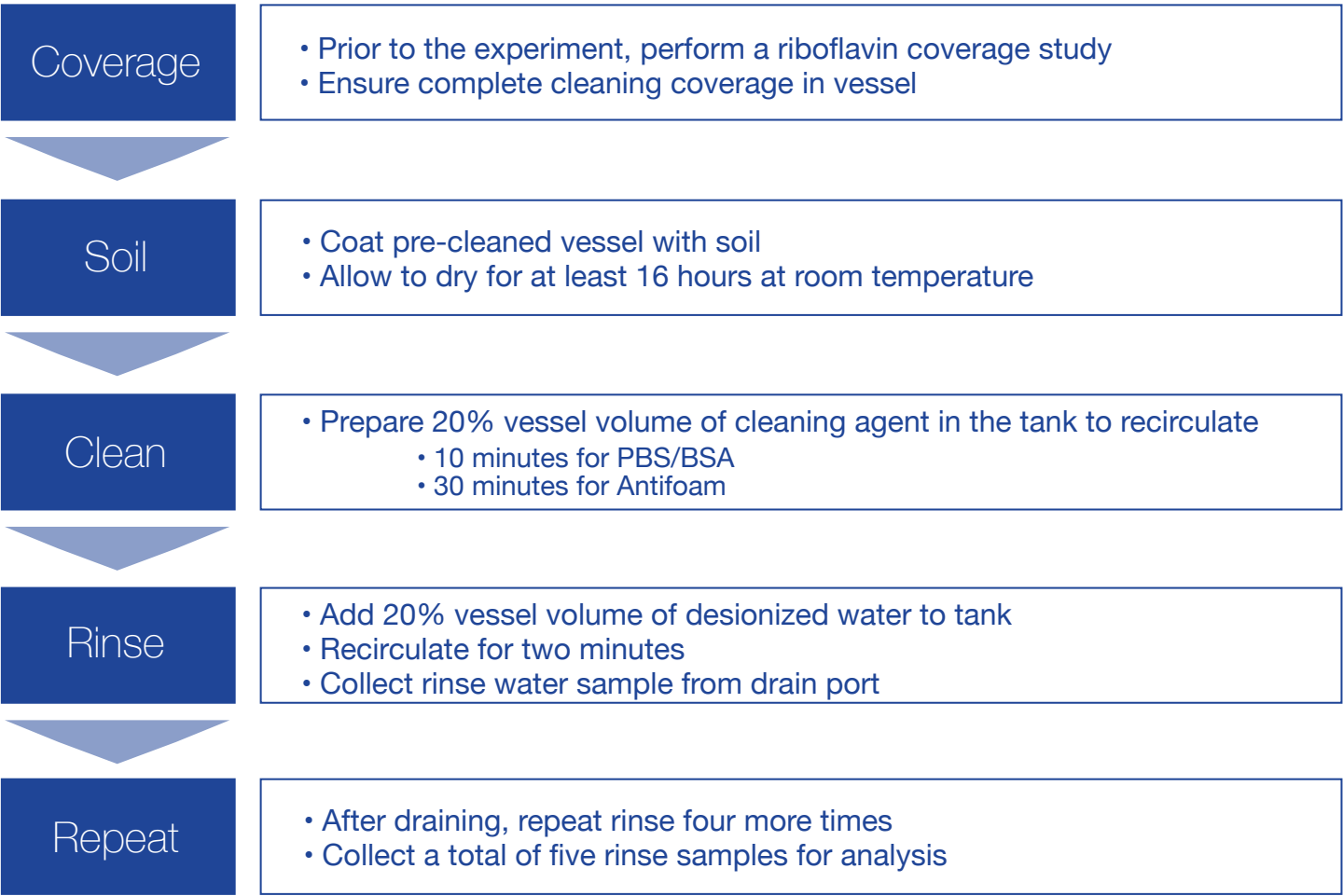
The purpose of this experiment is to compare the cleaning capabilities of STERIS's CIP 100™ Alkaline Process and Research Cleaner and commodity Sodium Hydroxide (NaOH) using a 65L pilot scale vessel. Two sample soils representative of the biopharmaceutical industry were selected for the experiment: 0.9% phosphate buffer saline (PBS) with bovine serum albumin (BSA) and undiluted antifoam.

Study Design

















The steps below (Figure 1) were followed to replicate the conditions found in pharmaceutical production environments and cleaning procedures. This methodology serves as the test-ground to see how well commodity chemicals and formulated detergents clean equipment.

Study Design

Figure 1



Results

	1% CIP 100	0.1 N NaOH
0.9% PBS/BSA	<p> Total cleaning time: 18 minutes*</p> <p> Total volume of rinse water consumed: 52 Liters*</p> <p> Cleaning temperature: Ambient</p> <p> Result: Visually Clean</p>	<p> Total cleaning time: 30+ minutes**</p> <p> Total volume of rinse water consumed: 78+ Liters**</p> <p> Cleaning temperature: Ambient</p> <p> Result: Visual Failure</p>
Undiluted Antifoam	<p> Total cleaning time: 30 minutes*</p> <p> Total volume of rinse water consumed: 65 Liters*</p> <p> Cleaning temperature: 55° Celsius</p> <p> Result: Visually Clean</p>	<p> Total cleaning time: 60+ minutes**</p> <p> Total volume of rinse water consumed: 78+ Liters**</p> <p> Cleaning temperature: 55° Celsius</p> <p> Result: Visual Failure</p>

* Required to achieve USP Total Organic Carbon (TOC) and Conductivity limits

** Maximum experimental cleaning results reports since visually clean was not achieved during experiment

Discussion

1% CIP 100 Detergent outperformed 0.1 N NaOH for cleaning PBS/BSA and antifoam residues under the same conditions, resulting in process efficiencies in both water and time savings.



Water Conservation

23% or more of rinse water was saved to meet the USP TOC and conductivity limits for 1% CIP 100 detergent compared to 0.1 N NaOH when cleaning PBS/BSA.



Time Savings

For PBS/BSA, 1% CIP 100 detergent achieved visual cleanliness and met TOC and conductivity limits in 40% less time compared to 0.1 N NaOH.

When tested against antifoam, a difficult process soil, CIP 100 achieved visual cleanliness, demonstrating superior cleaning efficacy compared to sodium hydroxide. The cleaning time was doubled for 0.1 N NaOH, but visual cleanliness was still not reached (Figure 2).

Figure 2. Visual comparison of vessels cleaned with formulated detergents and commodity chemicals.

1% CIP 100

Post-Wash and Rinse
(Visually Clean)



0.1 N NaOH

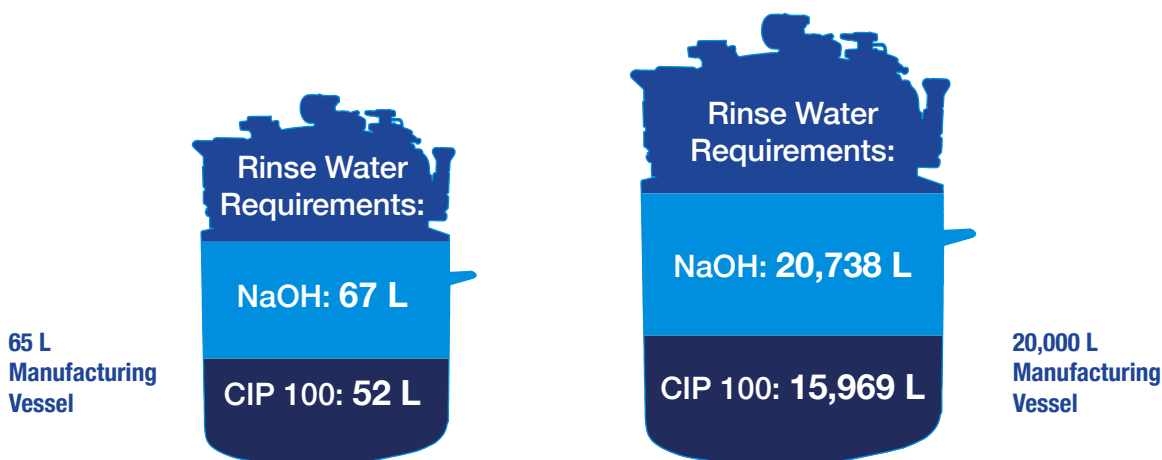
Post-Wash
(Not Visually Clean)

Conclusion

In testing, the pharmaceutical detergent cleaned better than the commodity chemical, both when measured by the resulting visual cleanliness and when measured by the conservation of water and time. These results demonstrate the importance of using a detergent that is engineered to perform with multiple cleaning mechanisms. CIP 100 successfully removed the proteinaceous soils, in less time and in a more environmentally-conscious fashion through lowered consumption of water.

The improved efficiency of cleaning with formulated detergents pays greater dividends when used in large scale operations (Figure 3). In these applications, one can expect to see cleaning efficacy and efficiency result in significant time and water savings in the cleaning process.

Figure 3. Formulated Pharmaceutical Detergents can reduce rinse water usage by 23% or more.



FIVE WAYS

Pharmaceutical Detergents

SAVE YOU MONEY

1

ProKlenz® ONE, CIP 200™ Acid-Based Cleaner and Disinfectant, and ProKlenz® TWO Acid Cleaner and Disinfectant are labeled for cleaning and disinfection which offers the potential to streamline your cleaning process: combining separate steps into one.

2

Acid-based pharmaceutical detergents [derouge and passivate](#) process equipment meaning you can reduce maintenance product inventory with a single solution that does more.

3

Free up valuable process time with pharmaceutical detergents that may clean in less time than commodities.

4

Better performing formulated detergents enable reduced consumption of utilities like electricity and water.

5

Achieve necessary standards and validation targets in less time and with fewer resources.

For more information on about this study and STERIS's family of formulated Pharmaceutical detergents, please visit www.sterislifesciences.com.