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Comparison of Pharmaceutical Detergents for Effective OSD Soil Cleaning

Introduction

Pharmaceutical oral solid dose (OSD) manufacturers encounter many unique challenges throughout the manufacturing process, including substrate compatibility limitations and cleaning challenging soils like binding and coating agents that are used to manufacture pills, tablets and capsules.

ProKlenz® ALIGN Neutral Pharmaceutical Detergent from STERIS was developed for pharmaceutical OSD manufacturers to harmonize cleaning protocols. It features a balanced pH profile and offers effective but gentle cleaning for a wide range of process residues found in clean-in-place (CIP) and manual applications.

STERIS conducted a study to determine the effectiveness of ProKlenz ALIGN Detergent when cleaning common soils found in pharmaceutical OSD manufacturing.

This article will review the results of the study and the benefits of ProKlenz ALIGN Detergent compared to other detergents.

Procedure

To determine the parameters needed to remove various soils from stainless steel surfaces by agitated immersion up to 60° C and by manual cleaning up to 60° C, the following procedures were followed:

- Dry, clean stainless steel coupons were coated with 1-2 g of various soils
- Samples were airdried at an ambient temperature for 24 hours
- Coupons were cleaned by agitated immersion or by manual cleaning at a consistent temperature
- After the designated amount of cleaning time, the coupons were:
  - » Visually inspected for cleanliness
  - » Evaluated for water-break-free
  - » Dried and weighed on an analytical balance

Acceptance Criteria

The coupon samples were considered clean with a passing result if:

- The coupon was visually clean (V) (i.e., no residue was detected by the unaided eye)
- No breaks in the water surface were detected 30-60 seconds after the test began (WBF), per ASTM F22-13
- The residual weight (Grav) was less than 0.1 mg of the initial weight of the dry, clean coupon

Soils Tested

The following soils commonly found in pharmaceutical OSD manufacturing were tested for the study:

- [i]Afrin®
- Aluminum Hydroxide Gel
- Dextrose Solution
- Fish Oil
- Ibuprofen 200 mg Tabs
- [ii]METHOCEL™
- Mg Stearate
- Rifaximin
- Simethicone
- [iii]TUMS®
- Vitamin D
- Vitamin E
- Zinc Oxide

[i]Afrin is a registered trademark of Bayer Healthcare LLC.
[ii]METHOCEL is a registered trademark of The Dow Chemical Company.
[iii]TUMS is a registered trademark of Glaxosmithkline Consumer Healthcare.

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Results

Agitated Immersion

ProKlenz ALIGN Detergent successfully cleaned all sample soils listed in Table 1 below at the specified cleaning conditions through agitated immersion.

Agitated immersion involves immersing a coupon in a 1500 mL beaker filled with a cleaning solution. The solution is agitated at a mild speed using a magnetic stirrer. Typically, the coupon remains in the agitated solution for 15 minutes and is then evaluated.

Table 1. Results of using ProKlenz ALIGN Detergent to clean sample soils at the specified cleaning conditions through agitated immersion.

Sample Soil	Cleaning Conditions[+]	ProKlenz ALIGN Detergent Results
Afrin	1% v/v, Ambient, 15 Minutes	Pass (V/WBF/Grav)
Aluminum Hydroxide Gel	1% v/v, Ambient, 30 Minutes	Pass (V/WBF/Grav)
Dextrose Solution	1% v/v, Ambient, 15 Minutes	Pass (V/WBF/Grav)
Fish Oil*	5% v/v, 60° C, 60 Minutes	Pass (V/WBF/Grav)
Ibuprofen 200 mg Tabs	1% v/v, Ambient, 15 Minutes	Pass (V/WBF/Grav)
METHOCEL	1% v/v, 45° C, 60 Minutes	Pass (V/WBF/Grav)
Mg Stearate	1% v/v, Ambient, 30 Minutes	Pass (V/WBF/Grav)
Rifaximin	1% v/v, Ambient, 30 Minutes	Pass (V/WBF/Grav)
Simethicone	1% v/v, 45° C, 15 Minutes	Pass (V/WBF/Grav)
TUMS	1% v/v, Ambient, 15 Minutes	Pass (V/WBF/Grav)
Vitamin D	5% v/v, 60° C, 60 Minutes	Pass (V/WBF/Grav)

Manual Cleaning

ProKlenz ALIGN Detergent successfully cleaned all sample soils listed in Table 2 at the specified cleaning conditions through manual cleaning.

For this cleaning method, the coupon was held with forceps and lightly scrubbed with a nylon-bristled brush or wiped with a polyester wipe on the coated side using the cleaning solution for up to 60 seconds.

Table 2. Results of using ProKlenz ALIGN Detergent to clean sample soils at the specified cleaning conditions through manual cleaning.

Sample Soil	Cleaning Conditions	ProKlenz ALIGN Detergent Results
Afrin	1% v/v, Ambient, 30 Seconds	Pass (V/WBF/Grav)
Aluminum Hydroxide Gel	1% v/v, Ambient, 30 Seconds	Pass (V/WBF/Grav)
Dextrose Solution	1% v/v, Ambient, 30 Seconds	Pass (V/WBF/Grav)
Ibuprofen 200 mg Tabs	1% v/v, Ambient, 60 Seconds	Pass (V/WBF/Grav)
METHOCEL	1% v/v, 45° C, 60 Seconds	Pass (V/WBF/Grav)
Mg Stearate	1% v/v, Ambient, 60 Seconds	Pass (V/WBF/Grav)
Rifaximin	1% v/v, Ambient, 60 Seconds	Pass (V/WBF/Grav)
Simethicone	1% v/v, Ambient, 30 Seconds	Pass (V/WBF/Grav)
TUMS	1% v/v. Ambient, 30 Seconds	Pass (V/WBF/Grav)
Vitamin D	1% v/v, 45° C, 60 Seconds	Pass (V/WBF/Grav)
Vitamin E*	3% v/v, Soak 5 Minutes, Scrub 60 Seconds	Pass (V/WBF/Grav)
Zinc Oxide*	1% v/v, 45° C, 60 Seconds	Pass (V/WBF/Grav)

Note: *Vitamin E and Zinc Oxide were not cleaned through agitated immersion. Fish Oil was not cleaned through manual cleaning.
[+]Ambient temperature was defined as between 20 - 25 C in these tests.

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ProKlenz ALIGN Detergent Compared to Competitor Detergents

For this study, Simethicone was cleaned with 1% v/v ProKlenz ALIGN Detergent at 45° C by agitated immersion for 15 minutes. Competitor detergents were used at 1% v/v and 45° C by agitated immersion, which resulted in visual failure after one hour of cleaning.

As a result, ProKlenz ALIGN Detergent provided more effective cleaning compared to competitors' neutral and alkaline detergents.

Figure 1. Stainless steel coupon coated in Simethicone soil prior to cleaning.

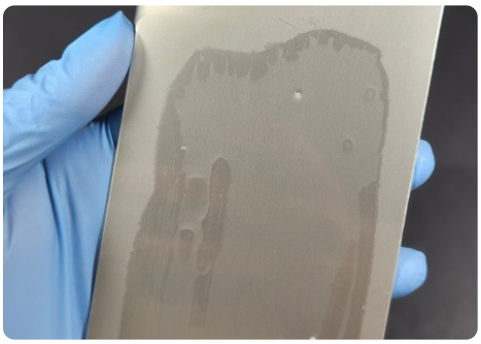
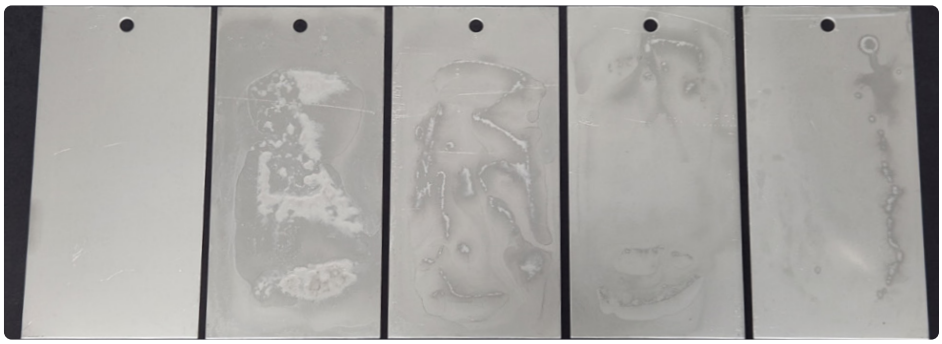
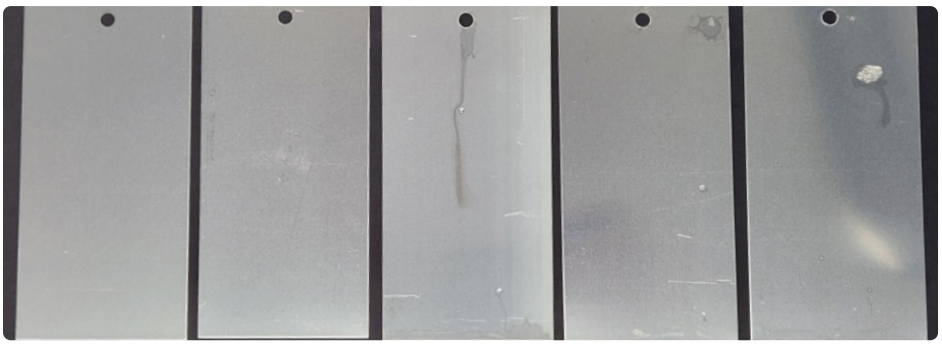


Figure 2. Simethicone cleaned with 1% v/v ProKlenz ALIGN Detergent at 45° C by agitated immersion for 15 minutes. Competitor detergents were used at 1% v/v at 45° C by agitated immersion, resulting in visual failure after one hour of cleaning.



ProKlenz ALIGN Detergent | Competitor A neutral detergent | Competitor A alkaline detergent | Competitor B neutral detergent | Competitor B alkaline detergent

Figure 3. Cleaning results for METHOCEL with 1% v/v cleaning agent at 45° C by agitated immersion for 60 minutes.



ProKlenz ALIGN Detergent | Competitor A neutral detergent | Competitor A alkaline detergent | Competitor B neutral detergent | Competitor B alkaline detergent

Table 3. Summarized cleaning results from Figure 3.

Sample Soil	Preparation Conditions	Cleaning Conditions	ProKlenz ALIGN Detergent Results	Competitor A Neutral Detergent Results	Competitor A Alkaline Detergent Results	Competitor B Neutral Detergent Results	Competitor B Alkaline Detergent Results
METHOCEL	Dried, Ambient, 24 Hours	1% v/v, 45° C, 60 Minutes	Pass (V/WBF/Grav)	Fail (FV/FWBF)	Fail (FV/FWBF)	Fail (FV/FWBF)	Fail (FV/FWBF)

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Summary

Of the 13 sample soils evaluated, ProKlenz ALIGN Detergent cleaned every soil through agitated immersion and/or manual cleaning.

Two competitor's neutral pH detergents were evaluated with identical soils and conditions but were not capable of cleaning all 13 sample soils through agitated immersion or manual cleaning.

Competitor A's detergents were unable to clean four soils through either cleaning method. Competitor B's detergents were unable to clean five soils through either cleaning method.

For some soils, ProKlenz ALIGN Detergent exhibited more effective cleaning over competitor alkaline detergents as well. Four soils were unable to be cleaned using Competitor A and Competitor B's alkaline detergents via agitated immersion for one hour. ProKlenz ALIGN Detergent was able to clean the same soils in less time.

Four Advantages to Using ProKlenz ALIGN

1. Streamlines products used in the cleaning process with broad substrate compatibility and an effective cleaning profile.
2. Safe and effective for manual cleaning.
3. No neutralization is required to discharge to drain.
4. Extensive technical documentation is available to support validation objectives.

A team of highly qualified, industry-recognized chemists, microbiologists and engineers is readily available to offer product and process consultation. STERIS Technical Support currently provides both on- and off-site seminars with topics focusing on process cleaning and cleaning validation. An extensive library of technical data, laboratory reports, analytical methods and case studies has been developed, including cytotoxicity, LD 50, substrate compatibility and many others.

To learn more about effective OSD soil cleaning, visit our website at sterislifesciences.com