Applications in Pharmaceutical Manufacturing

The Benefits of Aqueous Critical Cleaning

The use of aqueous cleaning in pharmaceutical manufacturing can provide numerous benefits in terms of effectiveness, minimal surface residue, and easier cleaning validation. Virtually any pharmaceutical manufacturing equipment — from tablet presses to a stainless steel mixing tanks — can be cleaned to stringent critically clean criteria by aqueous cleaning.

About Aqueous Cleaners

Aqueous cleaners are typically formulated to ensure maximal cleaning performance by using key ingredients such as surface active agents (surfactants) — excellent wetting agents that allow the cleaning solution to penetrate into crevices while getting under soils to allow for removal. Often very dilute solutions of aqueous cleaner will effectively remove even worst-case substances from a variety of hard surfaces, including stainless steel, glass, plastic, or porcelain.

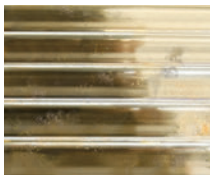
The proper use of aqueous cleaning helps manufacturers minimize surface residue and makes cleaning validation easier. Aqueous cleaners are available in low toxicity formulations that make achieving acceptable residue levels easy during cleaning validations. Even multi-product facilities can often find a single aqueous cleaner that cleans all residues on all surfaces. This lowers costs for the manufacturer because only one cleaner has to be validated.

Aqueous cleaners are suitable for all variety cleaning methods commonly used in pharmaceutical manufacturing:

- Manual
- Soak
- Machine
- Automated clean-in-place (CIP)

The range in aqueous cleaner formulations — from acidic to basic, high emulsifying to low foaming, liquid concentrates to powder blends — ensures that a cleaner can be found to handle whatever residues are encountered using any cleaning method. Most pharmaceutical companies use liquids because they tend to be easier to handle when dispensing doses, though powders are more economical, especially for manual cleaning.

Aqueous cleaners are usually biodegradable, causing them to have low environmental impact, and are readily disposable after use without further treatment. Moreover, aqueous cleaners have excellent worker safety characteristics and replace semi-aqueous or solvent-containing cleaners that tend to have more worker safety and environmental concerns.



Before:
Coating residue from pharmaceutical tablet presses and packaging equipment can be tough to clean.

After:
Tablet presses and packaging equipment cleaned with CITRANOX meet stringent pharmaceutical cleaning validation standards.

The Aqueous Critical Cleaning Process

The aqueous critical cleaning process involves using aqueous cleaners to remove residues from those surfaces which without successful cleaning would prevent the device from functioning properly. This is distinguished from simple cleaning for appearance. Aqueous critical cleaning is often used on surfaces that are involved in manufacturing high value products. In pharmaceutical manufacturing, the glass, ceramic, plastic, and metal surfaces of tools and production equipment must be free of any interfering cross-contamination that can render the high value product unusable. Furthermore, releasing contaminated pharmaceuticals for human or animal use — thereby putting their health at risk — exposes the manufacturer to liability. For these reasons, cleaning pharmaceutical manufacturing equipment is among the most critical of all aqueous critical cleaning processes.

Pharmaceutical process equipment, tools and R&D implements are typically made from fairly robust and cleanable materials such as stainless steel, Teflon, polypropylene, synthetic elastomers, glass and ceramic. Although the materials are relatively easy to clean, the tools and equipment often have difficult-to-clean structures. The kinds of residues found in pharmaceutical manufacturing can include many water-insoluble and otherwise hard-to-clean residues.

Given the range of available aqueous cleaners formulations, it is possible to find one that will work on even the most difficult structures and residues by whatever cleaning method is preferred. In addition, aqueous cleaners offer the benefits of being economical and relatively safe for workers and the environment.

Selecting the Proper Aqueous Cleaner in Pharmaceutical Manufacturing

Typically, surfaces to be cleaned are composed of glass, 316L stainless steel, Teflon, polypropylene, and synthetic elastomers used in seals. Residues found in pharmaceutical cleaning range from easy-to-clean water-soluble excipients to difficult-to-clean petrolatum/metal oxide mixtures. To simplify regulatory compliance, it's desirable to use as few cleaners as possible to remove the full range of possible residues.

Today, many leading drug companies are finding that aqueous cleaners provide the rigorous cleaning necessary for healthcare products, including:

- **Capsules and tablets** — Can contain ingredients that resist going into solution, making tablet presses and dies difficult to clean. Even stubborn sustained-release products come clean quickly with the appropriate aqueous cleaners.
- **Suspensions** — Aqueous cleaners eliminate intensive scrubbing and human contact in cleaning large stainless steel tanks of up to 2000 gallons capacity used in manufacturing liquid suspensions.
- **Intermediates** — Aqueous cleaners are ideal for cleaning glass-lined chemical reactors used in processing pharmaceutical intermediates such as powders, fillers, binding agents, and other chemicals.

Removing Surface Pyrogens and Endotoxins from Equipment Substrates

Removing all endotoxins or pyrogens from production surfaces is critical to the process of cleaning pharmaceutical manufacturing equipment. These substances are fever-causing cell debris or cellular waste products widely present in the environment. Removing them requires the use of a high-emulsifying

cleaner, combined with heat, followed by a rinse with endotoxin/pyrogen-free water (often referred to as water for injection, or WFI, an exceedingly pure form of water derived from high-purity filtration systems).

Specialized cleaners, together with heat, are used to depyrogenate both heat-sensitive and non-heat sensitive surfaces. Standard cleaning of injectable manufacturing substrates with a 1% solution of a suitable cleaner at 120ºF (50ºC) using manual, soak, or ultrasonic agitation followed by a thorough WFI rinse can depyrogenate surfaces. Post-cleaning handling in a pyrogen- or endotoxin-controlled environment for packaging provides adequate control. Ports for injectable products are cleaned using suitable cleaner solutions. ALCONOX brand and LIQUINOX brand cleaners have been used for these ultrasonic depyrogenation processes. Maintaining a pyrogen-free state depends on handling and storage after cleaning.

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The Role of pH and Residue in Pharmaceutical Cleaning

A great deal is known about how pH affects aqueous critical cleaning. Typically, alkaline cleaners are used on oily residues and acidic cleaners are used on inorganic residues. Robust fully formulated cleaners that contain wetting agents, emulsifiers, dispersants, chelating agents and anti-redeposition agents will give the broadest and most robust residue removal. Different types of residues are best cleaned by either an alkaline or acidic cleaner. **Table 1** (following) outlines the types of chemical structures found in pharmaceutical residues and which are best cleaned by either acid or base. Some residues can be cleaned

TABLE 1: RESIDUES BEST CLEANED BY ACIDIC OR ALKALINE CLEANERS

Alkaline (High pH Generally)

Alkaline Cleaners from Alconox, Inc.

Application:	Phosphate	Powders	Liquids
Manual/Ultrasonic	Yes	ALCONOX	
	No	TERGAJET	LIQUINOX
Machine/Spray CIP	Yes	ALCOJET	DETOJET
	No	TERGAJET	SOLUJET

Neutral

Best Cleaned by Alkaline (descending order)
Oils, fats, greases
Alcohols, amino acids
Diols, triols
Phosphates
Organic acids
Acid salts

Either (alkaline to acid, top to bottom)
N-heterocyclics
Polysaccharides
Proteins, fermentation
Steroids
Sugars
Ethers and ketones
Pyrrolidines
Pyridines
N-heterocyclics

Best Cleaned by Acid (ascending order)
Amines, alkaloids
Amphoteric proteins
Starches
Carbonates and bicarbonates
Metal oxides
Insoluble hydroxides

Acid (Low pH)

Acid Cleaners from Alconox, Inc.

Application:	Phosphate	Liquids
Manual/Ultrasonic	No	CITRANOX
Machine/Spray CIP	No	CITRAJET

by either, but will tend to give better results with either an acid or alkaline cleaner, as shown.

Understanding the structure, functional groups, molecular polarity, solubility and molecular weight of a residue being removed makes it possible to identify the type of detergent that will work best for a given cleaning method. Difficult-to-classify residues may require bench-scale cleaning verification studies prior to doing larger scale cleaning trials.

The Role of pH and Substrate Properties in Aqueous Critical Cleaning

Understanding the properties of both the residue and the hard surface is important and can be used beneficially to improve the aqueous cleaning process. Often by using an aqueous cleaning solution above or below the defined isoelectric point of the hard surface and the inverse log of the acid dissociation constant (pKa) of the residue, a like-like charge repulsion can be created that facilitates and increases the efficiency of the cleaning process.

Difficult-to-classify residues may require bench-scale cleaning verification studies prior to doing larger scale cleaning trials.

The isoelectric point of a surface is the pH at which the surface's electric charge is neutral with regard to its acid/base and electron donor-acceptor reactions. Moving to a higher or lower pH will shift the effective surface charge or electron density in a negative or positive direction. Two common hard surfaces in pharmaceutical manufacturing are stainless steel and glass. Stainless steel has an isoelectric point of 8.5 associated with the reactivity of the oxygen in the oxides Fe_3O_2, Fe_3O_4, and Cr_2O_3 on the surface of the metal. Glass has an isoelectric point of 2.5 associated with the SiO_2 on the surface. Raising the cleaner solution pH past the isoelectric point, causes the surface to become more negatively charged.

Likewise, if the residue is an acid or base or amphoteric compound, the charge can also be manipulated by pH. The pKa of most acids indicates the pH at which the hydronium ions and conjugate base are present in equal concentrations. Moving higher in pH shifts the equilibrium toward the right, thereby increasing the concentration of the negative conjugate base (see **Table 2**, below).

Thus, when cleaning acids off of stainless steel or glass, it is desirable to use a cleaning solution with a pH above the pKa of the acid and the isoelectric point of the stainless steel. A repelling negative charge between the acid conjugate base residue and the stainless steel surface will result.

Applying the Concept: Removing Stearic Acid from Stainless Steel

To apply this concept practically, lets examine stearic acid ($C_{17}H_{35}COOH$) residue on a steel manufacturing tank surface. In this case, stearic acid has an isoelectric point of around pH 5 that drives formation to the negatively-charged stearate ion ($C_{17}H_{25}COO^-$). If an aqueous alkaline cleaner is employed that is equal to or above pH 8.5, then the stearic acid will predominantly be in the negatively-charged conjugate base stearate ion ($C_{17}H_{25}COO^-$) form. In addition, stainless steel typically has an isoelectric point of 8.5, associated with the reactivity of oxygen in the oxides Fe_3O_2, Fe_3O_4, and Cr_2O_3 on the metal surface, as well as the hydrates and hydroxides formed in aqueous solutions. Therefore, given alkaline conditions or pH 8.5 or greater, the metal oxides in the stainless steel surfaces will also become negatively charged, setting up an appropriate repulsion between the stearic acid conjugate base and the steel surface. This repulsion is desirable as it facilitates cleaning and removal of the stearic acid residue from the surface.

The reverse holds true for base residues. By lowering the pH of the residue below the pKa and the isoelectric point of the surface being cleaned,

TABLE 2: RELATIONSHIP OF pKa, CONJUGATE BASE AND HYDRONIUM ION CONCENTRATION

$HA + H_2O \rightarrow H_3O^+ + A^-$

HA = acid concentration	H_2O = water	H^3O^+ = hydronium ion concentration	A^- = conjugate base concentration

$pKa = -\log [H_3O^+] [A^-]/[HA]$

TABLE 3: OPTIMIZING THERMODYNAMIC CLEANING CONDITIONS FOR SURFACE/RESIDUE ELECTROSTATIC REPULSION

Acidic residues	pH > pKa and isoelectric point of surface
Alkaline or basic residues	pH < pKa and isoelectric point of surface

positive-positive repulsion may be achieved. At the very least, by lowering the pH, a neutral residue and a positive surface are created, with no attraction between them that would make cleaning difficult (see **Table 3**).

Choosing the Right Method of Aqueous Cleaning in Pharmaceutical Manufacturing

According to FDA rationale, cleaning equipment is meant to be designed to "prevent contamination or adulteration of drug products."

According to FDA rationale, cleaning equipment is meant to be designed to "prevent contamination or adulteration of drug products." Typically pharmaceutical operations require transition from bench-scale R&D to pilot studies to full-scale manufacturing. Cleaning at each stage requires careful consideration of the size and configuration of the processing equipment and suitable cleaning techniques. In general, the equipment increases in size at each subsequent stage. Consequently, manual cleaning and soak cleaning tend to be adequate for bench-scale equipment, whereas pilot and large-scale manufacturing process equipment usually requires clean-in-place (CIP) cleaning by automated spray or immersion systems and/or by manual cleaning.

All stages of development and production may use manual cleaning or machine washers to clean various parts of equipment or utensils. If feasible, it is preferable to clean the pharmaceutical equipment in place, without disassembling or moving it, in order to rapidly get the equipment back into service.

Automated Clean-in-Place (CIP)

Automated clean-in-place systems for pharmaceutical manufacturing equipment typically use either spray or immersion cleaning. Automated CIP systems can be permanently integrated into a set of manufacturing tanks, or they can be on mobile skids that are moved from tank system to tank system, as needed. Typically, the best results with automated cleaning are achieved when the automated CIP system is integrated into the original design of the manufacturing equipment; however, existing tanks are often retrofitted with automated CIP systems.

There are often monitoring systems, also known as process-control instrumentation, to ensure all parts of the system are functioning correctly and the process is being done according to the program. The automated equipment has sensors and data recorders to document the cleaning and can create reports that will become part of the batch log to document that the cleaning was done correctly for regulatory compliance.

Automated CIP systems typically comprise the following components and subsystems:

- **Primary water source** — Used to make up the cleaning solutions and as rinse water before and after the cleaning cycles. Can be heated, if necessary.
- **External tank** — Can be used for mixing and storing the cleaning solutions. Sometimes the manufacturing tank is used for this purpose.
- **Separate external tank** — Holds rinse water. A second source of water can also be employed if the final rinse requires purified water such as WFI or deionized (DI) water.
- **Pumps and piping** — Connects external CIP tanks to the manufacturing equipment to be cleaned. A water conservation system can be installed that pumps the final rinse water into the cleaning solution dilution tank for use in the first cleaning cycle of the next automated CIP run.
- **Automated controllers** — Run the pumps and control the dosing of cleaning agent and water. Either fully automated, or semi-automated programs that require operator intervention at key steps in the process.

Spray Clean-In-Place (CIP)

Spray CIP involves spraying or recirculating the initial flush, wash, and rinse solutions under pressure, with proper adjustments of time, temperature, and cleaner concentration through the pipes and spray balls to clean large internal areas of the equipment without having to fill them completely with solution.

Efficient cleaning of pilot and large scale mixers, tanks and blenders can be achieved by distributing flush, wash, and rinse solutions on the upper surfaces at pumping rates equal to 2.0–2.5 gallons per minute (gpm) per foot of circumference for vertical vessels, or 0.2–0.3 gpm per square foot of internal surface for horizontal and rectangular tanks.

Manual cleaning can be done in place on manufacturing equipment or at a sink or washroom where disassembled pieces of equipment, tools and utensils are brought for cleaning.

Piping systems can be effectively cleaned via recirculation at flow rates producing a velocity of 5 feet per second or more in the spray CIP circuit's largest diameter piping.

The advantage of spray CIP is that it can rapidly clean large pieces of equipment using minimal amounts of cleaning solution and relatively little energy to heat the solutions and rinse water. The disadvantage of spray CIP is that it requires very careful engineering design to assure successful cleaning. If there are difficult-to-clean places that the automated system fails to clean, manual cleaning may be required. If a new difficult-to-clean product is made in production equipment that has a spray CIP system which cannot successfully clean the new product, then a new cleaning agent or a change to immersion or manual cleaning may be necessary.

Immersion Clean-in-Place (CIP)

Pilot scale and smaller manufacturing tanks, blenders and mixers can be cleaned by completely filling all the pipes and equipment with cleaning solution — possibly while gently running any agitators in the equipment. This cleaning method is used in older large manufacturing tanks that do not have integrated spray CIP systems.

The advantage of immersion CIP cleaning is that is simple and does not require a carefully engineered spray CIP system. The disadvantage is that it typically takes longer because the equipment, such as a mixer, has to be filled, heated, and drained — as opposed to the faster cycles obtained by using much smaller amounts of cleaning solution in a spray CIP system. Additionally, only the areas that are in contact with the cleaning solution get cleaned, typically requiring some manual cleaning of tanks and mixers above the fill line.

A successful validation of this cleaning process will define the concentration of the cleaner, contact time, level of agitation, and temperature of the cleaning solution required to successfully clean the tank.

Manual Cleaning

Manual cleaning can be done in place on manufacturing equipment or at a sink or washroom where disassembled pieces of equipment, tools and utensils are brought for cleaning. Often brushes, abrasive pads, scrapers, buckets, spray bottles, or other appropriate equipment are used for manual cleaning. A good manual cleaning procedure will specify any necessary pre-rinsing, the cleaner concentration, the order in which parts of a particular piece of equipment should be cleaned, and final rinsing procedures.

The advantage of manual cleaning is that it is relatively simple and the operator can give special attention to difficult-to-clean areas or residue until clean criteria are achieved. The disadvantage is that it can take longer, has the cost of human labor, and is very directly subject to human error.

Machine Washers

Machine cleaning is performed on clean manufacturing tools, disassembled equipment, and bench-scale production equipment in clean-out-of-place (COP) procedures. A machine that is designed to meet current Good Manufacturing Practice (cGMP) requirements can provide rapid, reliable, validated cleaning while using minimum amounts of water, resources and space.

Compared to manual cleaning, machine washers offer these advantages:

- Faster cleaning of parts and equipment
- Reduced human labor
- Less space, water and cleaning agents

A disadvantage of machine washers is that they often require very special racks and correct loading

procedures to assure reliable cleaning results on parts or equipment with complex geometries.

Historically, "lab style" washers have been modified to conform to cGMP requirements. More recently, washers have become available that meet cGMP requirements with design features including:

- A chamber that allows for minimal water retention and provides good drainage from cycle to cycle, with a minimum of solution carried over in any inlet or outlet piping.
- Corners that carry a minimum of a 1" radius, with all surfaces sloped to the drain.
- Internal chamber structures with rounded edges and no threads or fluid entrapment areas.
- No mechanical attachment required for the accessory racks used to mate inventory systems to the hydraulic circuit.
- Spray headers positioned on the top and bottom of the racks to provide the most efficient cleaning.
- A documentation package to qualify and complete the validation of the cleaning system.

The goal of a good loading pattern is to allow good spray and cascading solution contact and good drainage of the parts and equipment.

A well designed machine washer requires cGMP compliant procedures for best use. In this regard, a complete inventory needs to be taken of size, weight, and specific cleaning requirements for each part and piece of equipment to be cleaned. Additionally, parts and equipment which need to be cleaned together must be noted. Using this information, appropriate loading and unloading patterns can be established.

The goal of a good loading pattern is to allow good spray and cascading solution contact and good drainage of the parts and equipment. Optimized multilevel loading patterns can achieve efficient use of water, detergent and utilities. Any opportunity for pockets of solution to fail to drain from parts or equipment in between wash or rinse cycles must be eliminated. Since loads for cGMP cleaning can range from glass to plastic to stainless parts, the design of a loading surface should allow for varying weights. If horizontal drop-down doors are used in the washer, they can both serve as an integrated loading platform when open and allow for better seals than vertical doors when closed. Vertical doors typically require the use of separate loading carts. For these reasons, horizontal doors are often preferred.

Once good loading patterns with proper racking have been established, pre-rinsing, washing, rinsing, and drying cycles must be established. This involves selecting the correct cleaning agents, temperatures, and time for each cycle. The correct cleaning agent can typically be determined by taking into account the substrates and residues to be cleaned. Typically a high alkaline cleaner followed by an acid rinse is used. Other important washer design features to be considered at this point include that the delivery systems allow for precise application of additives, and that drying systems are in place to provide complete coverage of every part in a load. Once the appropriate parameters have been established, cleaning programs using the machine's programmable logic controller (PLC) can be set.

Pharmaceutical Cleaning Validation Method Guidelines

Pharmaceutical device manufacturing must conform to cGMP guidelines, or what's also referred to as Quality Systems (QS). Additional regulations established by agencies such as the US FDA, EU (European Union), and the International Conference on Harmonization (ICH) must also be followed. Cleaning validation requires documented compliance with specific criteria for pharmaceutical manufacturing, and involves testing for acceptable residues on each device's surface. The protocol includes:

- Identifying residues
- Selecting a residue detection method
- Choosing a sampling method
- Setting residue acceptance criteria
- Validating residue defection methods
- Conducting recovery studies
- Writing procedures and training operators

This procedure is used to document acceptable residues three or more times, after which a rational monitoring program to maintain a validated state can be instituted. If any part of the cleaning procedure is changed, including the cleaner to be used, revalidation is required. This is accomplished by first cleaning with the new method, collecting data,

and then cleaning the old way before using any equipment. These steps are to be followed until the new procedure is fully validated.

Case Study: Validation of Aqueous Critical Cleaning in Pharmaceutical Product Manufacturing

Alconox, Inc. frequently provides technical support to help the product manufacturing facilities of pharmaceutical companies establish their critical cleaning validation process. In this case, one of the world's largest producers of generic pharmaceuticals needed to find a new critical cleaning detergent that could meet new local environmental regulations. The company needed a product that could be validated quickly. The Alconox, Inc. technical support team suggested Alconox, Inc. SOLUJET® brand as the pharmaceutical company's ideal cleaner.

This recommendation allowed the manufacturer to use SOLUJET brand cleaner at more dilute concentrations than their current cleaner and meet the local environmental regulations. Changing to SOLUJET brand cleaner also helped the manufacturer complete their validation with Alconox, Inc. support, including an HPLC method for residue detection.

An Aqueous Cleaner for Every Pharmaceutical Manufacturing Application

Alconox, Inc. has been a pioneer for over 60 years in formulating aqueous cleaners to meet and solve the specific critical cleaning challenges faced by scientists and engineers responsible for cleaning

If any part of the cleaning procedure is changed, including the cleaner to be used, revalidation is required.

TABLE 4: DETERGENT SELECTION GUIDE FOR PHARMACEUTICAL MANUFACTURING EQUIPMENT CLEANING

Application/ Key Concern	Articles Cleaned/ Soil Removed	Cleaning Method	Recommended Cleaner
Passing cleaning validation for FDA good manufacturing practices. For stainless steel, glass, plastic, elastomer cleaning.	Titanium dioxide, oils, petrolatum, emulsions, ointments, carbopols, lacquers, zinc oxides, proteins, steroids, alcohols, sugars, and Eudragit* (L/S/L30/ D55/ NE30D) polymers.	Manual, ultrasonic, soak	DETONOX (mild alkaline)
		Machine washer, power wash, CIP	KEYLAJET (alkaline surfactant low-foam)
	Inorganic residues, salts, metallics, pigments, Eudragit* (E/RL/RS/ E100) polymers, amphoterics, coatings, amines, ethers, starches, alkaloids.	Manual, ultrasonic, soak	CITRANOX (mild acid)
		Machine washer, power wash, CIP	CITRAJET (mild acid)
	Protein/ferment residues, R/O, U/F membranes	Manual, ultrasonic, soak	TERGAZYME (mild alkaline or enzymatic)

*Eudragit is a ® registered trademark of Roehm GmbH & Co.

high value surfaces. Alconox, Inc. cleaners are biodegradable, readily disposable after use, and well suited for critical cleaning of all pharmaceutical production machinery that comes in contact with difficult-to-clean substances and must be free of interfering residues.

Alconox, Inc. aqueous cleaners have been proven in critical cleaning applications for virtually any glass, metal, plastic, or porcelain surface in a pharmaceutical manufacturing facility, including these types of equipment:

- Capsule fillers
- Centrifuges
- Conveyors
- Filters
- Filling lines
- Granulators
- Kettles
- Mixture reactors

No matter what the method, Alconox, Inc. has an aqueous cleaner to critically clean the high value pharmaceutical cleaner.

No matter what the method, Alconox, Inc. has an aqueous cleaner to critically clean your high value product manufacturing equipment and surfaces (See **Table 4**).

Alconox, Inc. cleaners with consistent cGMP-compliant formulations are available worldwide. Certificates of analysis (COA), technical bulletins, SDS, trace analysis, and inhibitory residue testing are available at www.alconox.com.

For biocompatibility and toxicity data, ingredient disclosure, shelf life information, residue sampling techniques and validation information, please contact cleaning@alconox.com.

For cleaning verification, cleaning chemistry identification and initial process condition recommendations, or to be included in a study, please contact cleaning@alconox.com.

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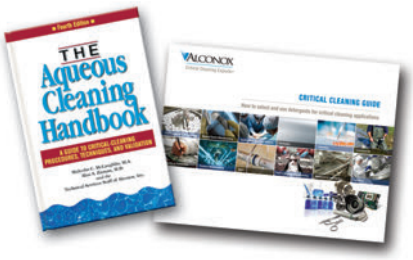

Get Validation Support or Help With Your Critical Cleaning Challenge

Alconox, Inc. has more than 70 years' experience developing aqueous cleaning solutions for pharmaceutical manufacturing. Let us help solve your next critical cleaning challenge.

Please contact Alconox, Inc. for expert validation support or verification laboratory services:

cleaning@alconox.com

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