

AQUEOUS CRITICAL CLEANING: A WHITE PAPER

Aqueous Critical Cleaning in Pharmaceutical Manufacturing

The Benefits of Aqueous Critical Cleaning

The benefits of employing aqueous cleaning in pharmaceutical manufacturing are numerous. Virtually any pharmaceutical manufacturing equipment from tablet press to a stainless steel mixing tank can achieve their defined critically clean criteria using aqueous cleaning. Typically aqueous cleaners are formulated to ensure maximal cleaning performance by using key ingredients such as surface active agents (surfactants) that are 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 effectively removes even worst case substances off 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. Often even multi-product facilities can find a single aqueous cleaner that cleans all residues on all surfaces. This means less cost for the manufacturer because only one cleaner has to be validated.

Aqueous cleaners are suitable for a variety of cleaning methods such as manual, soak, machine, and automated clean-in-place (CIP). The range in formulation from acidic to basic, high emulsifying to low foaming, and availability of liquid concentrates to powder blends ensures that a cleaner can be found to clean whatever residues are encountered using whatever the cleaning method is being used. 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 also readily disposable after use requiring no 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 concerns and are harsher to the environment.



The Aqueous Critical Cleaning Process

The aqueous critical cleaning process involves using aqueous cleaners to remove residues from surfaces where the surface cannot function properly without successful cleaning. This is distinguished from simple cleaning for appearance. Aqueous critical cleaning is often used on high value surfaces or surfaces that are used to manufacture high value products. In the case of pharmaceutical manufacturing, the glass, ceramic, plastic, and metal surfaces that make up the tools and equipment used to manufacture pharmaceuticals must be free of any interfering cross contamination. If there is any interfering cross contamination, then the resulting high value pharmaceutical being made can be rendered unusable. There is also the risk that the cross contamination is not detected and contaminated pharmaceuticals can be released for use by humans or animals, thereby putting their health at risk, while exposing the manufacturer to liability. Surely, the aqueous cleaning processes in pharmaceutical manufacturing are some of 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 very difficult-to-clean residues. Because of the broad range of formulations available with aqueous cleaners, it is possible to find a cleaner that will work even on the most difficult structures and residues by whatever cleaning method is desired. Not only can you find an effective cleaner, but aqueous cleaners are economical and are relatively safe for the environment and workers.

Aqueous Cleaners in Pharmaceutical Manufacturing

Typically, surfaces to be cleaned are constructed 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 scrupulous cleaning necessary for processing healthcare products, including:

- Capsules and tablets: can contain ingredients which resist going into solution, making tablet presses and dies difficult to clean. Even stubborn sustained-release product releases come clean quickly with the appropriate aqueous cleaners.
- Suspensions: aqueous cleaners eliminate intensive scrubbing as well as human contact in cleaning large stainless steel tanks of up to 2000 gallons capacity that are 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.

For Additional Help with Your Critical Cleaning Challenge

Alconox, Inc has 60 + years in developing aqueous cleaning solutions for pharmaceutical manufacturing and is able to help solve critical cleaning challenges.

Please contact the Critical Cleaning Experts at Alconox Validation Support or Alconox Cleaning Verification Lab for assistance.

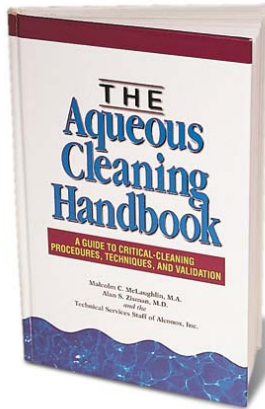
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