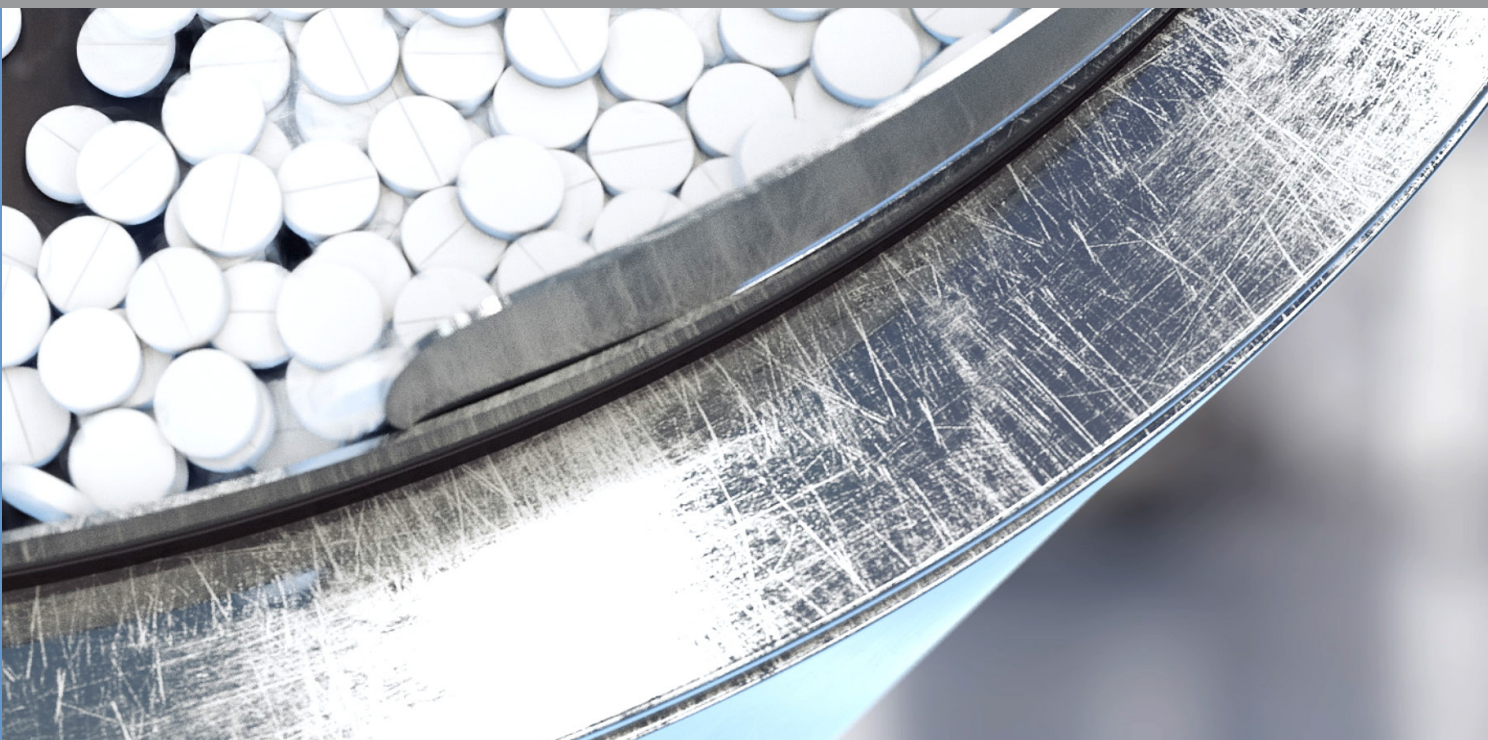


Consistent process cleaning and microbial control are required for pharmaceutical manufacturers to produce safe products and meet current Good Manufacturing Practices (cGMPs). STERIS helps pharmaceutical manufacturers increase productivity and ensure product quality by solving their most difficult process cleaning and validation challenges.



Oral Solid Dose Manufacturing

Product Quality | Efficiency | Efficacy | Patient Safety





A Difficult Cleaning Challenge

Oral solid dosage forms (powders and granules, capsules, and tablets) are engineered blends of active pharmaceutical ingredients (APIs) and excipients (e.g. fillers, binders, colorants, lubricants, coatings, etc.) formed using wet and dry granulation, direct compression, or capsulation processes. These processes use complex equipment for operations including milling, blending, granulating, drying, forming and coating. The interaction of ingredients, equipment and materials create difficult cleaning challenges.

STERIS Can Help

Our Pharmaceutical Detergents, application experience and technical support can help your company:

- Develop and optimize your cleaning and microbial control program
- Meet process and cleaning validation requirements
- Maximize production uptime

Our Process And Cleaner Evaluation (PACE[®]) program is used by Customers worldwide to determine the optimum cleaning chemistry and parameters (time, action, concentration, and temperature) for their specific residues. Through our extensive experience, we've developed a vast knowledge of how to clean APIs, excipients, and difficult tablet coatings on both complex equipment and sensitive surfaces.

Application Support

STERIS's Technical Services Team of chemists, microbiologists and engineers is available to offer product and process consultation for your cleaning, microbial control and validation needs. They provide remote and on-site support including process development, trouble shooting and training with an extensive library of technical tips, laboratory reports, analytical methods and other support documentation.

STERIS Formulated Chemistries are designed for your most difficult cleaning challenges. Each product is supported by our industry-leading technical support staff, as well as an extensive documentation package to help facilitate cleaning validation.

Pharmaceutical Detergents

Alkaline Detergents

Used for the majority of cleaning applications due to their ability to penetrate and efficiently remove a wide range of organic residues

CIP 100™ Alkaline Process and Research Cleaner

Formulated for a broad range of residues and applications

ProKlenz® ONE

Formulated using a multiple-surfactant system

Registered disinfectant and virucide

ProKlenz® 120 Mild Alkaline Detergent

Formulated for enhanced substrate compatibility

Neutral Detergents

Commonly used in manual cleaning applications or with sensitive substrates due to their mild pH and enhanced compatibility

ProKlenz® ALIGN Neutral Pharmaceutical Detergent

Engineered for OSD residues at a neutral pH

ProKlenz® Booster High Performance Detergent Additive

Surfactant-based formulation with oxidizing agent

Effective against many tablet coatings

Acid Detergents

Commonly used for the removal of inorganic residues and salts. Additionally, they are widely used for rouge removal and passivation of stainless steel equipment

CIP 200™ Acid-Based Cleaner and Disinfectant

Phosphoric acid formulation

Registered disinfectant and virucide

ProKlenz® TWO Acid Cleaner and Disinfectant

Registered disinfectant

Organic acid formulation

ProKlenz® RESTORE High Performance Acid-Based Cleaner

Effective derouging formulation

Foaming Products

Commonly used for the removal of inorganic residues and salts. Additionally, they are widely used for rouge removal and passivation of stainless steel equipment

ProKlenz® FOAM High Performance Alkaline Cleaner

Globally available high foaming alkaline product

FOAM 140® Alkaline Process and research Cleaner

Effective derouging formulation

FOAM 240® Acid Based Process and Research Cleaner

Produces heavy foam with spray applicator



Surface Disinfectants and Alcohols

The main product in any bioburden control program should be a quality formulated disinfectant. This allows for good surface cleaning and broad spectrum efficacy while having superior material compatibility suitable for routine use.

Disinfectants

Quaternary Ammonium Disinfectants

Formulated to provide excellent fungicidal efficacy and available globally. Offered in a variety of formats including concentrates, ready-to-use, sterile and non-sterile. Includes:

- Vesta-Syde® SQ Disinfectant
- Vesta-Syde SQ 128 Ready-To-Use Disinfectant

Phenolic Disinfectants

Broad spectrum disinfectants with TB efficacy. Offered in a variety of formats including sterile and non-sterile. Includes:

- LpH® III se Phenolic Disinfectant
- Vesphene® III se Phenolic Disinfectant

Alcohols

Ideally suited for the removal of process residues from surfaces or glove decontamination.

- Septihol® Ready-To-Use Alcohol Solution

Sporicides

Fast acting chemistry to eliminate challenging spore forming microbes with excellent material compatibility.

- Spor-Klenz® Ready-To-Use Cold Sterilant