STERIS
Life Sciences

Critical Process Parameters

Optimizing the Cleaning Process

Critical Process Parameters

When developing a cleaning process, it is important to consider various factors related to the surface, process cleaner, and cleaner. Critical Process Parameters (CPPs) are key factors to evaluate during each step of the cleaning cycle. Commonly abbreviated to the acronym TACT, the critical process parameters of a cleaning cycle include cleaning time, cleaning action, cleaning agent concentration, and temperature.

Time

The total cleaning time is primarily divided into the pre-rinse time, wash time, and rinse time. Other important time considerations include the dirty hold time (DHT) of equipment. The DHT is the amount of time equipment can remain soiled prior to cleaning. In general, a longer DHT results in greater difficulty to clean. The clean hold time is how long the equipment remains clean before reuse.

Action

Action is the physical force acting on the surface to remove soils. Mechanical action from manual cleaning, impingement force from a spray ball, or cascading flow from gravity moving a liquid down a tank wall are examples of cleaning actions. Clean-in-place systems often use spray balls or spray heads internal to the tank to provide physical removal of surface residues. Spray devices must provide complete tank coverage at a minimum for an adequate cleaning result.

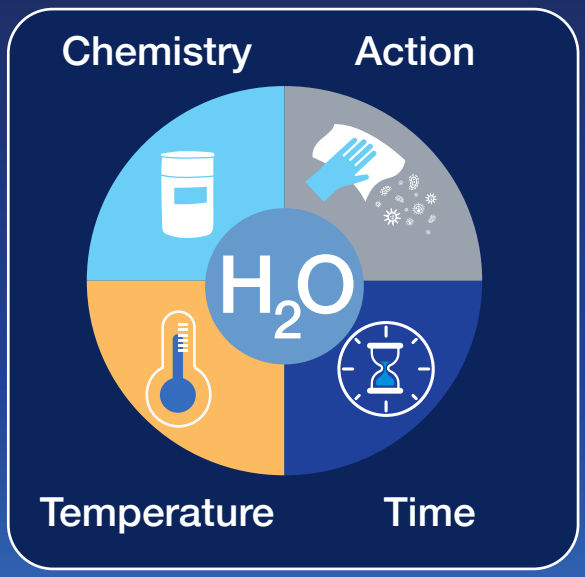
Cleaning Agent Concentration

When selecting a cleaning agent and its concentration, it is important to consider personnel safety, soil properties, and substrate compatibility. Factors such as application method and equipment design impact the concentration of cleaning agent required. The type of cleaner, such as an acidic, alkaline, or neutral, and the components, like surfactants and chelants, contribute to cleaning agent effectiveness. Compared to alternative cleaners, pharmaceutical detergents are engineered to have an increased number of cleaning mechanisms to clean more efficiently and effectively, while maintaining the condition of the surfaces.

Temperature

The final parameter in the TACT acronym is temperature. Temperature impacts solubility and surfactancy of the soil and detergent, respectively. Generally, higher temperatures increase solubility and reaction rates for a faster clean. However, certain process cleaners, like inorganic salts and polymers, and specific classes of surfactants exhibit better cleaning at lower temperatures.

CPPs are factors to consider during each phase when developing a cleaning cycle. The dynamic between time, action, chemistry, and concentration are often referred to as,“Sinner Circle”. When one aspect of the Sinner’s Circle is altered, it impacts the other parameters of the cleaning process. STERIS detergents are engineered for effectiveness on biotechnology and pharmaceutical process cleaners to improve overall process efficiency by reducing the temperature, time, and mechanical action required to clean. A cleaning process that uses a pharmaceutical detergent results in an effective, efficient, and sustainable cleaning cycle.



Why STERIS?

It is important to consider your unique system when developing a cleaning process. STERIS helps evaluate your process with unmatched technical support. STERIS offers:

An Extensive Documentation Package

To help you develop an efficient and effective cleaning process, STERIS offers an extensive documentation package for its pharmaceutical detergents such as anylitical methods, toxicity studies, stability, substrate compatibility, and conductivity studies. An extensive technical library is available to support your validation objectives.

PACE® Program

The STERIS Process and Cleaner Evaluation® (PACE) program helps you target critical performance parameters suited for your manufacturing process, objectives, and constraints. Your process cleaner is coated on a coupon of representative material of construction. Different cleaning agents and cleaning methods are used to determine a fast and efficient cleaning recommendation.

Technical Services Team

By understanding the chemistry of cleaning, utilizing prior experience, and participating in lab evaluations, the STERIS Technical Services team has the expertise to assist you in developing and validating a cleaning process.The STERIS Technical Services team participates in global industry events, presenting on innovative topics and trends.

Technical Sales Team

STERIS has a global direct sales team with the technical experience to assist you on-site. The STERIS sales representatives are available for cleaning trials and product support.

Resources

Verghese G . & Lopolito P., “Cleaning Engineering and Equipment Design ”, in Pluta, P. (Ed) Cleaning and Cleaning Validation, Vol 1 , PDA & DHI publishing (2009).

STERIS Life Sciences Technical Tip, “Derouging Stainless-Steel Process Systems with CIP 200® Acid-Based Process and Research Cleaner” Literature number 410 - 500 – 3608.

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