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WHITE PAPER

Stainless-Steel Preservation: Mitigating Rouge

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It is essential for pharmaceutical manufacturers to mitigate risk by evaluating factors that could impact product quality and manufacturing equipment performance. Due to its potential effect on product quality and facility equipment, stainless-steel equipment rouge is a significant risk concern.

This white paper examines the best practices for establishing and evaluating a stainless-steel preservation and rouge mitigation process in pharmaceutical manufacturing.

Figure 1. Elements of stainless-steel preservation control and evaluation.

Control Methods

Reduction of Risk

Due to personnel, validation, disposal and other constraints, establishing a suitable stainless-steel preservation process for your facility is key. Figure 2 compares three methods to control rouge formation in stainless-steel equipment through routine, predictive or corrective measures.

Figure 2. Comparison of three control methods for rouge mitigation and stainless-steel preservation.

Routine Measures	**Rouge mitigation is built into routine cleaning with the use of an acid detergent.**	
	Advantages	Prevents stainless-steel deteriation. Prevents unscheduled downtime.
	Disadvantage	Switching to a routine acid in your cleaning cycle may require revalidation of your cleaning process.
Predictive Measures	**Rouge mitigation is performed periodically using in-house or third-party services.**	
	Advantages	Extends time between maintenance events. Sets data markers to trigger mitigation events.
	Disadvantage	Predictive modeling is required to build data to increase intervals between derouging events.
Corrective Meaures	**Rouge mitigation is performed reactively after rouge buildup has occured.**	
	Advantages	Minimal resource management required.
	Disadvantage	Damage to passive layer and potential damage to surface. Rouge formation leading to unscheduled downtime of equipment to address non-conformances.

Acceptance of Risk

Rouge mitigation measures should be selected based on equipment type and risk level. Table 1 compares the three control methods outlined in Figure 2 with associated risk levels and applications. It is common to utilize a combination of control methods across manufacturing sites.

Table 1. Comparison of three control methods for rouge mitigation for stainless-steel preservation.

Control Method	Description	Risk Level	Applications
Routine Measures	Rouge mitigation is built into routine cleaning with the use of an acid detergent.	Low	Routine measures are ideal for direct product contact surfaces.
Predictive Measures	Rouge mitigation is performed periodically using in-house or third-party services.	Low/Medium	Preventative measures are ideal for utility systems or indirect product contact surfaces.
Corrective Measures	Rouge mitigation is performed reactively after rouge buildup has occurred.	High	Corrective measures are often reserved for non-direct product contact surfaces.

Evaluating Your Process

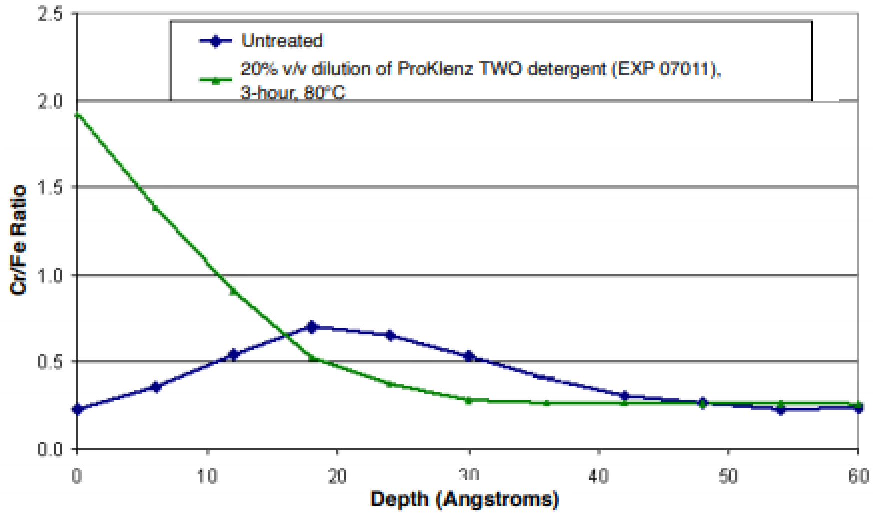
Results

After a stainless-steel preservation and rouge mitigation process is established, it is important to periodically review the process to ensure continuous improvement for derouging and passivating stainless-steel systems.

Evaluating the surface of stainless steel is one method to determine the condition of the passive layer. An X-ray Photoelectron Spectroscopy (XPS) device analyzes stainless-steel surfaces to determine the elemental composition of the material.

In 316L stainless steel, the chromium to iron ratio (Cr/Fe) is typically 0.25 (STERIS, 2009). A higher ratio of chromium, which is less reactive to iron and a more reactive base metal, reduces the likelihood of corrosion on the stainless-steel surface. Figure 3 illustrates the results from an XPS to review the Cr/Fe ratio after passivating stainless-steel equipment.

Figure 3. XPS analysis of 316L stainless-steel panels (STERIS, 2009).



The XPS analysis reveals that a 316L stainless-steel surface has a higher surface Cr/Fe ratio with treatment using STERIS's ProKlenz® TWO Acid Cleaner when compared with an untreated surface (STERIS, 2009). Additional methods to determine the quality of a passivated surface include the Electrical Pen, Copper Sulfate and Salt Spray Cabinet methods (Rivera, Hadziselimovic, & Lopolito, 2017).

Events

Predictive models utilize data to develop and understand cleaning and maintenance processes. Markers are used to trigger cleaning events with an acid detergent. Preventative maintenance events are designed to proactively prevent rouge and deterioration of the passive layer, which may lead to quality or cleaning issues.

Additionally, predictive models use lab or in-line testing to evaluate the risk of the passive surface that is negatively impacted by the manufacturing process. This information can be used to develop routine or preventive cleaning measures with an acid detergent to ensure stainless-steel preservation. Time, temperature and concentration are key conditions that impact derouging and passivation frequency (STERIS, 2015).

STERIS's Process and Cleaner Evaluation (PACE) program utilizes predictive modeling tools to assist with routine cleaning and preventative maintenance programs.

Conclusion

STERIS's Technical Services Team collaborates with facilities to design a proactive, risk-based stainless-steel preservation process. A cleaning process that includes the use of an acid detergent helps maintain the passive layer of stainless steel, reduce waste neutralization chemicals and clean and disinfect equipment to ensure product quality. STERIS helps facilities harmonize cleaning processes to maximize operational efficiency and minimize risk.

To learn more about STERIS's services for predictive modeling and pharmaceutical detergents portfolio, please contact your local STERIS account representative or visit our website.

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FIVE KEY TAKEAWAYS

When developing a stainless-steel preservation and rouge mitigation process, keep the following considerations in mind.

1. Due to personnel, validation, disposal and other constraints, establishing a suitable stainless-steel preservation process for your facility is key.
2. Rouge mitigation measures should be selected based on the equipment type and consequent risk level.
3. After your stainless-steel preservation and rouge mitigation process is established, it is important to periodically review your process to ensure continuous improvement.
4. Predictive modeling uses lab or in-line testing to evaluate the risk of a passive surface that is negatively impacted by the manufacturing process. This information can be used to develop routine or preventive cleaning with an acid detergent to ensure stainless-steel preservation.
5. For indirect or non-product contact surfaces, stainless-steel preservation remains necessary to reduce the risk associated with reactive cleaning.