ROUGE AND DEROUGING

This Technical Tip covers rouge and its removal from stainless-steel process vessels. Topics covered include:

- The nature of rouge
- The chemistry of derouging
- Practical aspects of derouging

Rouge

Rouge (from the French word for red) is the red blush that sometimes appears on stainless-steel surfaces after prolonged (albeit intermittent) exposure to aqueous solutions. The rouge is an iron-oxide species which forms due to the oxidation of the metallic iron in the stainless steel.

While stainless steel is named stain*less*, it is really stain-*resistant*. Particularly if the passive layer (a chromium-oxide-rich layer) on the stainless is destroyed or interrupted, the iron may begin to oxidize.

A second source of this rouge may be iron oxides which are generated elsewhere, but which deposit on the stainless surface. Rouge deposited in this way may be easier to remove than rouge generated *in situ*.

While rouge is usually identified as a red deposit, the iron oxide may also exist as a black species, such as iron (II/III) oxide (or magnetite). These contaminants are undesirable in pharmaceutical manufacturing vessels, because their presence is clearly an indication that the process vessel is not visibly clean. These deposits may affect the safety and/or efficacy of the manufactured product.

Iron oxide deposits may form in manufacturing vessels, in transfer lines, in steam systems – any place where aqueous water contacts stainless steel. The most severe environments for forming rouge are the extremes of ultrapure water and salt water (tap water has less of a tendency to form rouge than either of these extremes).

The best way to minimize rouge formation is to minimize contact with:

- water solutions (to the extent practical), and
- chemicals that may affect the passive film on the stainless steel.

The Chemistry of Derouging

Since the rouge is an iron oxide, anything that will solubilize iron oxides will remove the rouge. The two items most widely touted for this purpose are acids and chelants. However, much of the published literature on use of acids and chelants involves removal of iron oxides from cold rolled steel, and not from stainless steel. Because of this, STERIS has begun extensive laboratory work on derouging on stainless-steel surfaces (see Laboratory Report #3217 for the results of these studies). This work was done to characterize the boundaries of derouging. The main conclusions were:

1. Different acids have different capacities for iron oxide removal.
2. The rates at which iron oxide dissolves are a function of concentration and temperature.
3. CIP 200® was the preferred derouging product among those studied, with proposed starting concentrations of 10 percent at 60°C (140°F).

Practical Aspects of Derouging

Lab studies on simulated rouge can provide valuable information, but will probably not allow prediction of results in the field. This is because, under field conditions, the nature and amount of iron oxide deposit may be variable and unknown.

Lab derouging studies of samples rouged in the field can produce a more accurate prediction of conditions (time, concentration, and temperature) needed to effectively derouge in the field. The key is to know when derouging is complete without removing the derouging solution and examining the surface (assuming the surface is accessible to be visibly inspected).

Because of these concerns, STERIS has developed a model operating procedure for derouging with CIP 200. This method involves monitoring the derouging process with a portable colorimeter.

The derouging solution is analyzed using the colorimeter for iron concentration as a function of time. Once the iron concentration levels off, then one of two things is true:

- all of the iron oxide has been dissolved from the surface and derouging is complete, or
- the capacity of the derouging solution for iron oxides has been exceeded, and more derouging solution must be added to remove the undissolved iron oxides.

This can be tested by adding additional CIP 200 to the derouging solution, continuing the recirculation for a fixed time, and then analyzing the derouging solution for iron concentration.

If the iron concentration has not changed, then derouging is complete. If the iron concentraton has increased, then derouging should proceed until the iron concentraton has leveled off. At that point, this decision process should be repeated.

By monitoring the progress of derouging in this way, you can be more assured of derouging in a minimum amount of time without using excessive amounts of derouging chemicals. Details of the derouging procedure are available in Technical Tip #3017.

For further information, please contact:

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