

DEROUGING STAINLESS STEEL PROCESS SYSTEMS WITH CIP 200

BACKGROUND

Rouging of stainless steel appears to be an industry-wide problem in the pharmaceutical, medical devices, and related industries. Rouge is seen as a mild reddish-brown film deposited with time on the interior surfaces of high purity water generation, storage, and distribution systems, and also in process systems using high purity water or other corrosive products. Rouge is seen in systems made of 304, 316 and 316L stainless steel, and can also occur on electropolished surfaces.

A large pharmaceutical company encountered frequent rouge problems in their manufacturing vessels and piping. The process consists of several vessels of capacities ranging from 300 liters to 5000 gallons with associated piping of several hundred feet. The material of construction is electropolished 316L stainless steel.

STERIS CORPORATION INVOLVEMENT

The rouge was being cleaned by contracting the derouging operation to an outside contractor. A proprietary citric acid based derouging agent was being used. The interest in STERIS Corporation's CIP 200® emerged due to several factors including easy availability, cost of derouging, surfactancy (contributing to simultaneous cleaning along with derouging), and potential passivating ability of CIP 200.

DEROUGING PROCESS

Piping

The derouging of process piping was done by using a 600 liter portable vessel with a centrifugal pump. A 5% bv solution of CIP 200 was made in hot WFI (water for injection). The pipes, which were typically 1½ inches in diameter, were hooked up to this portable system, and the cleaning solution was recirculated through the pipe under turbulent flow conditions.

The temperature at the start of the process was about 158°F (70°C) and fell during the derouging process due to heat losses. The derouging was done for about 45 minutes. The spent solution was then neutralized and discharged. This was followed by three water rinses, each recirculated for 15 minutes before disposal. The rinse water samples were analyzed for residual CIP 200 by titration and pH.

Vessels

The process vessels have dedicated spray devices in place. Unlike derouging of piping, here the process vessel to be derouged is used for preparing the CIP 200 solution at a 5% concentration in WFI. The solution is then recirculated through the process piping and the spray device, using a portable centrifugal pump, if necessary. The derouging process is continued for about 1½ hours. This is followed by three water rinses. Each rinse consists of a 15 minute recirculation through the spray device. The residual CIP 200 concentration in the final rinse water is ensured to be below limits by pH measurement and by titration.

RESULTS

Derouging using this procedure resulted in visually clean and derouged surfaces. As a result of this successful trial, a decision was made to undertake routine derouging using CIP 200 every year considering the corrosive saline solutions manufactured in the plant.

For further information, please contact:

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